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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a Regulation on the European Health Data Space - 4-column table

Delegations will find enclosed the four column table on the above mentioned proposal. This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, changes to the proposal approved by the Coreper on 6 December 2023, the amendments voted by the European Parliament on 13 December 2023.

ANNEX A

Explanation of the table layout

	Commission proposal	EP amendments voted on 13 December 2023	Text approved by Coreper on 6 December 2023	Tentatively agreed text, compromise proposals and comments
		Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in blue underlined bold italics in this column is text that the EP proposes to add to the Commission proposal.*** *Text in red italics ~~strikethrough~~ in this column is text that the EP proposes to delete.* When an empty cell in this column is on the same row as a Commission proposal, it means that that text was not changed by the EP.	Plain text in this column is text from the Commission proposal that Council wishes to maintain. **Text in bold** in this column is text that Council has agreed to add. Text in ~~strikethrough~~ in this column is text that Council has agreed to delete.	*This column will contain comments, compromise proposals and tentatively agreed text.*

ANNEX B

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space (Text with EEA relevance)

2022/0140(COD)

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Formula				
1	2022/0140 (COD)		2022/0140 (COD)	2022/0140 (COD)	
	Proposal Title				
2	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL		Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	on the European Health Data Space (Text with EEA relevance)		on the European Health Data Space (Text with EEA relevance)	on the European Health Data Space (Text with EEA relevance)	
	Formula				
3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
	Citation 1				
4	Having regard to the Treaty on the Functioning of the		having regard to the Treaty on the Functioning of the	Having regard to the Treaty on the Functioning of the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	European Union, and in particular Articles 16 and 114 thereof,		European Union, and in particular Articles 16 and 114 thereof,	European Union, and in particular Articles 16 and 114 thereof,	
	Citation 2				
5	Having regard to the proposal from the European Commission,		Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	
	Citation 3				
6	After transmission of the draft legislative act to the		After transmission of the draft legislative act to the	After transmission of the draft legislative act to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	national parliaments,		national parliaments,	national parliaments,	
		Citation 4			
7	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .		Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	
		Citation 5			
8	Having regard to the		Having regard to the	Having regard to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .		opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	
		Citation 6			
9	Acting in accordance with the ordinary legislative procedure,		Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	
		Formula			
10					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Whereas:		Whereas:	Whereas:	
	Recital 1				
11	(1) The aim of this Regulation is to establish the European Health Data Space ('EHDS') in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation,		(1) The aim of this Regulation is to establish the European Health Data Space ('EHDS') in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for ***better achieving*** other purposes ***in the health sector*** that would benefit	(1) The aim of this Regulation is to establish the European Health Data Space ('EHDS') in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data). In addition, the goal is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of electronic health record systems ('EHR systems') in conformity with Union values.		~~*the*~~ society such as research~~,~~ ***such as*** innovation, policy-making, ***health threats preparedness and response,*** patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data). In addition, the goal is to improve the functioning of the internal market by laying down a uniform legal ***and technical*** framework in particular for the development, marketing and use of electronic health record systems ('EHR systems') in conformity with Union values.	policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data). In addition, the goal is to improve the functioning of the internal market by laying down a uniform legal framework in particular for the development, marketing and use of electronic health record systems ('EHR systems') in conformity with Union values.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 1a				
11a			***(1a) The EHDS is intended to constitute a key component in the creation of a strong and resilient European Health Union to better protect the health of Union citizens, prevent and address future pandemics and improve the resilience of Union healthcare systems.***		
	Recital 1b				
11b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(1b) This Regulation should complement Union programmes such as the EU4Health Programme, Digital Europe Programme, Connecting Europe Facility and Horizon Europe. The Commission should ensure that Union programmes complement and facilitate the implementation of the European Health Data Space.		
	Recital 2				
12	(2) The COVID-19		(2) The COVID-19	(2) The COVID-19	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	pandemic has highlighted the imperative of having timely access to electronic health data for health threats preparedness and response, as well as for diagnosis and treatment and secondary use of health data. Such timely access would have contributed, through efficient public health surveillance and monitoring, to a more effective management of the pandemic, and ultimately would have helped to save lives. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by		pandemic has highlighted the imperative of having timely access to ***quality*** electronic health data for health threats preparedness and response, as well as for ***prevention,*** diagnosis and treatment ~~*and*~~***through the*** secondary use of health data. Such timely access ~~*would have contributed*~~***can potentially contribute***, through efficient public health surveillance and monitoring, to a more effective management of the pandemic, ***to a reduction of costs and to improving the response to health threats and ultimately can help***~~*and ultimately would have*~~	pandemic has highlighted the imperative of having timely access to electronic health data for health threats preparedness and response, as well as for diagnosis and treatment and secondary use of health data. Such timely access would have contributed, through efficient public health surveillance and monitoring, to a more effective management of the pandemic, and ultimately would have helped to save lives. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by Commission	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Commission Implementing Decision (EU) 2019/1269[1], to allow Member States to share electronic health data of COVID-19 patients moving between healthcare providers and Member States during the peak of the pandemic, but this was only an emergency solution, showing the need for a structural approach at Member States and Union level. _____ 1. Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating		~~*helped*~~ to save ***more*** lives ***in the future***. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by Commission Implementing Decision (EU) 2019/1269[1], ~~,~~ to allow Member States to share electronic health data of COVID-19 patients moving between healthcare providers and Member States during the peak of the pandemic, but this was only an emergency solution, showing the need for a structural ***and consistent*** approach at Member States and Union level ***on access to electronic health data in***	Implementing Decision (EU) 2019/1269[1], to allow Member States to share electronic health data of COVID-19 patients moving between healthcare providers and Member States during the peak of the pandemic, but this was only an emergency solution, showing the need for a structural approach at Member States and Union level. _____ 1. Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).		***order to steer effective policy responses and contribute to high standards of human health***. _____ 1. Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).	European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).	
	Recital 3				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
13	(3) The COVID-19 crisis strongly anchored the work of the eHealth Network, a voluntary network of digital health authorities, as the main pillar for the development of mobile contact tracing and warning applications and the technical aspects of the EU Digital COVID Certificates. It also highlighted the need for sharing electronic health data that are findable, accessible, interoperable and reusable ('FAIR principles'), and ensuring that electronic health data are as open as possible and		(3) The COVID-19 crisis strongly anchored the work of the eHealth Network, a voluntary network of digital health authorities, as the main pillar for the development of mobile contact tracing and warning applications and the technical aspects of the EU Digital COVID Certificates. It also highlighted the need for sharing electronic health data that are findable, accessible, interoperable and reusable ('FAIR principles'), and ensuring that ***the necessary*** electronic health data are ~~as~~	(3) The COVID-19 crisis strongly anchored the work of the eHealth Network, a voluntary network of digital health authorities, as the main pillar for the development of mobile contact tracing and warning applications and the technical aspects of the EU Digital COVID Certificates. It also highlighted the need for sharing electronic health data that are findable, accessible, interoperable and reusable ('FAIR principles'), and ensuring that electronic health data are as open as possible and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	as closed as necessary. Synergies between the EHDS, the European Open Science Cloud[1] and the European Research Infrastructures should be ensured, as well as lessons learned from data sharing solutions developed under the European COVID-19 Data Platform. _____ 1. EOSC Portal (eosc-portal.eu).		~~*open as possible and as closed as necessary*~~***available while respecting the principle of data minimisation***. Synergies between the EHDS, the European Open Science Cloud[1] and the European Research Infrastructures should be ensured, as well as lessons learned from data sharing solutions developed under the European COVID-19 Data Platform. _____ 1. EOSC Portal (eosc-portal.eu).	as closed as necessary. Synergies between the EHDS, the European Open Science Cloud[1] and the European Research Infrastructures should be ensured, as well as lessons learned from data sharing solutions developed under the European COVID-19 Data Platform. _____ 1. EOSC Portal (eosc-portal.eu).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 3a				
13a			***(3a) Given the sensitivity of personal health data, this Regulation seeks to provide sufficient safeguards at both Union and national level to ensure a high degree of data protection, security, confidentiality and ethical use. Such safeguards are necessary to promote trust in safe handling of the health data of natural persons for primary and secondary uses. To achieve those objectives, pursuant to Article 9(4) of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation (EU) 2016/679, Member States can impose further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.		
	Recital 4				
14	(4) The processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council[1] and, for Union institutions and bodies,		(4) The processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council[1]***, Regulation (EU) 2018/1725 of the***	(4) The processing of personal electronic health data is subject to the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council[1] and, for Union institutions and bodies,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation (EU) 2018/1725 of the European Parliament and of the Council[2]. References to the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant. _____ 1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection		***European Parliament and of the Council[2], as regards*** ~~*and, for*~~ Union institutions, ***bodies, offices and agencies*** ~~*and bodies*~~, ***and*** Regulation (EU) ~~*2018/1725*~~***2022/868[3]*** of the European Parliament and of the Council[2]. References to the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions, ***bodies, offices and agencies*** ~~*and bodies*~~, where relevant. ***In relation to mixed datasets, where personal and non-personal***	Regulation (EU) 2018/1725 of the European Parliament and of the Council[2]. References to the provisions of Regulation (EU) 2016/679 should be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant. _____ 1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation) (OJ L 119, 4.5.2016, p. 1). 2. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).		***data are inextricably linked, and where it is difficult to distinguish between those categories thereby resulting in the possibility of inferring personal data from non-personal data, the provisions of Regulation (EU) 2016/679 and of this Regulation concerning personal electronic health data should apply.*** _____ 1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and	Regulation) (OJ L 119, 4.5.2016, p. 1). 2. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1). 2. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39). ***3. Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (OJ L 152, 3.6.2022, p. 1).***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 4a				
14a			***(4a) The implementation of the EHDS should take into consideration the European ethical principles for digital health adopted by the eHealth network[1] on 26 January 2022. Monitoring the application of those ethical principles should be one of the tasks of the EHDS Board.*** _____ ***1. Established following Article***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			14 of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.		
	Recital 5				
15	(5) More and more Europeans cross national borders to work, study, visit relatives or to travel. To facilitate the exchange of health data, and in line with the need for empowering citizens, they should be able to access their health data in an electronic format that can be recognised and accepted across the Union. Such personal electronic		(5) More and more Europeans cross national borders to work, study, visit relatives or to travel. To facilitate the exchange of health data, and in line with the need for empowering citizens, they should be able to access their health data in an electronic format that can be recognised and accepted across the Union. Such personal electronic	(5) More and more Europeans cross national borders to work, study, visit relatives or to travel. To facilitate the exchange of health data, and in line with the need for empowering citizens, they should be able to access their health data in an electronic format that can be recognised and accepted across the Union. Such personal electronic	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data could include personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about their health status, personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question, as well as data determinants of health, such as		health data could include personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about their health status, personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question, as well as data determinants of health, such as	health data could include personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about their health status, personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question, as well as data determinants of health, such as	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	behaviour, environmental, physical influences, medical care, social or educational factors. Electronic health data also includes data that has been initially collected for research, statistics, policy making or regulatory purposes and may be made available according to the rules in Chapter IV. The electronic health data concern all categories of those data, irrespective to the fact that such data is provided by the data subject or other natural or legal persons, such as health professionals, or is processed in relation to a		behaviour, environmental, physical influences, medical care, social or educational factors. Electronic health data also includes data that has been initially collected for research, statistics, ***health threat assessment,*** policy making or regulatory purposes and may be made available according to the rules in Chapter IV. The electronic health data concern all categories of those data, irrespective to the fact that such data is provided by the data subject or other natural or legal persons, such as health professionals, or is processed in relation to a	behaviour, environmental, physical influences, medical care, social or educational factors. Electronic health data also includes data that has been initially collected for research, statistics, policy making or regulatory purposes and may be made available according to the rules in Chapter IV. The electronic health data concern all categories of those data, irrespective to the fact that such data is provided by the data subject or other natural or legal persons, such as health professionals, or is processed in relation to a natural person's health or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	natural person's health or well-being and should also include inferred and derived data, such as diagnostics, tests and medical examinations, as well as data observed and recorded by automatic means.		natural person's health or well-being and should also include inferred and derived data, such as diagnostics, tests and medical examinations, as well as data observed and recorded by automatic means.	well-being and should also include inferred and derived data, such as diagnostics, tests and medical examinations, as well as data observed and recorded by automatic means.	
	Recital 5a				
15a			***(5a) The scope of this Regulation should not cover natural persons who are not Union citizens, or third-country nationals not legally residing on the territory of the Member***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			States. Therefore, where Member States require electronic registration of health data or where health data holders register health data regarding those natural persons, processors can only process the electronic health data of such persons, in accordance with Articles 6(1) and 9(2) of Regulation (EU) 2016/679 including for any secondary use.		
	Recital 5a				
15b				**(5a) In health systems,**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				personal electronic health data is usually gathered in electronic health records, which typically contain a natural person's medical history, diagnoses and treatment, medications, allergies, immunisations, as well as radiology images and laboratory results, spread between different entities from the health system (general practitioners, hospitals, pharmacies, care services). In order to enable that electronic health data be accessed, shared and changed by the natural persons or health professionals, some	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported or provided health data access services for patients and health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				professionals (for instance through patients or health professional portals). They have also taken measures to ensure the EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented manner. In order to facilitate the free	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved access to their own personal electronic health data and are empowered to share it. [[RECITAL (7) MOVED BEFORE RECITAL (6)]]	
	Recital 6				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
16	(6) Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. EHDS builds upon these rights and further develops some of them. The EHDS should support the coherent implementation of those rights as applied to electronic health data, regardless of the Member State in which the personal electronic health data are processed, type of healthcare provider, sources		(6) Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. EHDS builds upon these rights and further develops some of them. The EHDS should support the coherent implementation of those rights as applied to electronic health data, regardless of the Member State in which the personal electronic health data are processed, type of healthcare provider, sources	(6) Chapter III of Regulation (EU) 2016/679 sets out specific provisions concerning the rights of natural persons in relation to the processing of their personal data. **The** EHDS builds upon these rights and ~~further develops~~ **complements** some of them~~. The EHDS should support the coherent implementation of those rights~~ as applied to **personal** electronic health data~~,~~**. These rights apply** regardless of the Member State in which the personal electronic health data are	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of data or Member State of affiliation of the natural person. The rights and rules related to the primary use of personal electronic health data under Chapter II and III of this Regulation concern all categories of those data, irrespective of how they have been collected or who has provided hem, of the legal ground for the processing under Regulation (EU) 2016/679 or the status of the controller as a public or private organisation of the legal ground for their processing.		of data or Member State of affiliation of the natural person. The rights and rules related to the primary use of personal electronic health data under Chapter II and III of this Regulation concern all categories of those data, irrespective of how they have been collected or who has provided hem, of the legal ground for the processing under Regulation (EU) 2016/679 or the status of the controller as a public or private organisation of the legal ground for their processing.	processed, type of healthcare provider, sources of data or Member State of affiliation of the natural person. The rights and rules related to the primary use of personal electronic health data under Chapter II and III of this Regulation concern all categories of those data, irrespective of how they have been collected or who has provided ~~hem~~**them**, of the legal ground for the processing under Regulation (EU) 2016/679 or the status of the controller as a public or private organisation**. The enhanced rights of access**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and portability of personal electronic health data should be without prejudice to the rights of access and portability as established under Regulation (EU) 2016/679. Natural persons continue to have those rights under the conditions set out in that regulation ~~of the legal ground for their processing~~. {Articles 8A-G}	
	Recital 7				
17					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(7) In health systems, personal electronic health data is usually gathered in electronic health records, which typically contain a natural person's medical history, diagnoses and treatment, medications, allergies, immunisations, as well as radiology images and laboratory results, spread between different entities from the health system (general practitioners, hospitals, pharmacies, care services). In order to enable that electronic health data to be accessed, shared and changed by the natural persons or health		(7) In health systems, personal electronic health data is usually gathered in electronic health records, which typically contain a natural person's medical history, diagnoses and treatment, medications, allergies, immunisations, as well as radiology images and laboratory results, ***and other complementary diagnosis and therapeutics results,*** spread between different entities from the health system (general practitioners, hospitals, pharmacies, care services). In order to enable that electronic health data to be accessed, shared and	(7) In health systems, personal electronic health data is usually gathered in electronic health records, which typically contain a natural person's medical history, diagnoses and treatment, medications, allergies, immunisations, as well as radiology images and laboratory results, spread between different entities from the health system (general practitioners, hospitals, pharmacies, care services). In order to enable that electronic health data to be accessed, shared and changed by the natural persons or health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	professionals, some Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported or provided health data access services for patients		changed by the natural persons or health professionals, some Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported	professionals, some Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported or provided health data access services for patients	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and health professionals (for instance through patients or health professional portals). They have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented manner. In order to facilitate the free movement		or provided health data access services for patients and health professionals (for instance through patients or health professional portals). They have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented manner. In order to	and health professionals (for instance through patients or health professional portals). They have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented manner. In order to facilitate the free movement of personal health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved acess to their own personal electronic health data and are empowered to share it.		facilitate the free movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved ~~*acess*~~***access*** to their own personal electronic health data and are empowered to share it. ***To that end, Member States should ensure a common standard is in place for the exchange of electronic health data to ensure and facilitate its transfer and translation into the Union's official languages. In this respect,***	across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved ~~acess~~**access** to their own personal electronic health data and are empowered to share it.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			appropriate funding and support at Union and national level should be fairly distributed and considered as a means of reducing fragmentation, heterogeneity, and division and to achieve a system that is user-friendly and intuitive in all Member States.		
	Recital 8				
18	(8) The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679,		(8) The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679,	(8) The right of access to data by a natural person, established by Article 15 of Regulation (EU) 2016/679,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	should be further developed in the health sector. Under Regulation (EU) 2016/679, controllers do not have to provide access immediately. While patient portals, mobile applications and other personal health data access services exist in many places, including national solutions in some Member States, the right of access to health data is still commonly implemented in many places through the provision of the requested health data in paper format or as scanned documents, which is time-consuming. This may severely impair timely access to health data		should be further developed in the health sector. Under Regulation (EU) 2016/679, controllers do not have to provide access immediately. While patient portals, mobile applications and other personal health data access services exist in many places, including national solutions in some Member States, the right of access to health data is still commonly implemented in many places through the provision of the requested health data in paper format or as scanned documents, which is time-consuming. This may severely impair timely access to health data	should be further ~~developed~~ **complemented** in the health sector. Under Regulation (EU) 2016/679, controllers do not have to provide access immediately. While patient portals, mobile applications and other personal health data access services exist in many places, including national solutions in some Member States, the right of access to health data is still commonly implemented in many places through the provision of the requested health data in paper format or as scanned documents, which is time-consuming **for the controller, such as**	

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	by natural persons, and may have a negative impact on natural persons who need such access immediately due to urgent circumstances pertaining to their health condition.		by natural persons, and may have a negative impact on natural persons who need such access immediately due to urgent circumstances pertaining to their health condition.	**a hospital or other healthcare provider providing access. This slows down**~~. This may severely impair timely~~ access to health data by natural persons, and may have a negative impact on natural persons ~~who~~**if they** need such access immediately due to urgent circumstances pertaining to their health condition. **For that reason, it is necessary to provide a more efficient way for natural persons to access their own personal electronic health data. They should have the right to have free of charge, immediate access,**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				adhering to technological practicability, to certain defined priority categories of personal electronic health data, such as the patient summary, through an electronic health data access service. The scope of this complementary right established under this Regulation and the conditions for exercising it differ in certain ways from the right of access under Article 15 of Regulation (EU) 2016/679. The latter covers all personal data held by a controller and is exercised against an individual controller, which then has	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				up to a month to reply to a request. The right to access personal electronic health data under this Regulation is limited to the categories of data falling within its scope, is exercised via an electronic health data access service, and provides an immediate answer. {Article 8A}	
	Recital 9				
19	(9) At the same time, it		(9) At the same time, it	(9) At the same time, it	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	should be considered that immediate access to certain types of personal electronic health data may be harmful for the safety of natural persons, unethical or inappropriate. For example, it could be unethical to inform a patient through an electronic channel about a diagnosis with an incurable disease that is likely to lead to their swift passing instead of providing this information in a consultation with the patient first. Therefore, a possibility for limited exceptions in the implementation of this right should be ensured. Such an		should be considered that immediate access ***of natural persons*** to certain types of ***their*** personal electronic health data may be harmful for the safety of natural persons, unethical or inappropriate. For example, it could be unethical to inform a patient through an electronic channel about a diagnosis with an incurable disease that is likely to lead to their swift passing instead of providing this information in a consultation with the patient first. Therefore, a possibility for limited exceptions in the implementation of this right should be ensured. Such an	should be considered that immediate access to certain types of personal electronic health data may be harmful for the safety of natural persons~~,~~ **or** unethical ~~or inappropriate~~. For example, it could be unethical to inform a patient through an electronic channel about a diagnosis with an incurable disease that is likely to lead to their swift passing instead of providing this information in a consultation with the patient first. Therefore, ~~a possibility for limited exceptions in the implementation~~**it should be possible to delay the provision** of this ~~right~~	

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	exception may be imposed by the Member States where this exception constitutes a necessary and proportionate measure in a democratic society, in line with the requirements of Article 23 of Regulation (EU) 2016/679. Such restrictions should be implemented by delaying the display of the concerned personal electronic health data to the natural person for a limited period. Where health data is only available on paper, if the effort to make data available electronically is disproportionate, there should be no obligation that		exception may be imposed by the Member States where this exception constitutes a necessary and proportionate measure in a democratic society, in line with the requirements of Article 23 of Regulation (EU) 2016/679. Such restrictions should be implemented by delaying the display of the concerned personal electronic health data to the natural person for a limited period~~. *Where health data is only available on paper, if the effort to make data available electronically is disproportionate, there*~~***, for instance until the moment***	~~should be ensured. Such an exception may be imposed by the~~**access in such situations for a limited amount of time.** Member States ~~where this~~**should be able to define such an** exception **where it** constitutes a necessary and proportionate measure in a democratic society, in line with the requirements of Article 23 of Regulation (EU) 2016/679.~~ Such restrictions should be implemented by delaying the display of the concerned personal electronic health data to the natural person for a limited period.~~ Where health data is only available	

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	such health data is converted into electronic format by Member States. Any digital transformation in the healthcare sector should aim to be inclusive and benefit also natural persons with limited ability to access and use digital services. Natural persons should be able to provide an authorisation to the natural persons of their choice, such as to their relatives or other close natural persons, enabling them to access or control access to their personal electronic health data or to use digital health services on their behalf. Such authorisations may		***where the patient and the health professional get in contact. Member States*** should be ~~*no obligation that such*~~***encouraged to require that*** health data ~~*is*~~***available prior to the implementation of this Regulation be*** converted into ***an*** electronic format ***through a process facilitated*** by Member States. Any digital transformation in the healthcare sector should aim to be inclusive and benefit also natural persons with limited ability to access and use digital services. Natural persons should be able to provide an authorisation to the natural persons of their	on paper, if the effort to make data available electronically is disproportionate, there should be no obligation that such health data is converted into electronic format by Member States. Any digital transformation in the healthcare sector should aim to be inclusive and benefit also natural persons with limited ability to access and use digital services. ~~Natural persons should be able to provide an authorisation to the natural persons of their choice, such as to their relatives or other close natural persons, enabling them to access or~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	also be useful for convenience reasons in other situations. Proxy services should be established by Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals on patient-facing mobile applications. The proxy services should also enable guardians to act on behalf of their dependent children; in such situations, authorisations could be automatic. In order to take into account cases in which the display of some personal electronic health		choice, such as to their relatives or other close natural persons, enabling them to access or control access to their personal electronic health data or to use digital health services on their behalf. Such authorisations may also be useful for convenience reasons in other situations. Proxy services should be established by Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals on patient-facing mobile applications. The proxy services should also enable	~~control access to their personal electronic health data or to use digital health services on their behalf. Such authorisations may also be useful for convenience reasons in other situations. Proxy services should be established by Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals on patient-facing mobile applications. The proxy services should also enable guardians to act on behalf of their dependent children; in such situations,~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data of minors to their guardians could be contrary to the interests or will of the minor, Member States should be able to provide for such limitations and safeguards in national law, as well as the necessary technical implementation. Personal health data access services, such as patient portals or mobile applications, should make use of such authorisations and thus enable authorised natural persons to access personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect.		guardians to act on behalf of their dependent children; in such situations, authorisations could be automatic. In order to take into account cases in which the display of some personal electronic health data of minors to their guardians could be contrary to the interests or will of the minor, Member States should be able to provide for such limitations and safeguards in national law, as well as the necessary technical implementation. Personal health data access services, such as patient portals or mobile applications, should make	~~authorisations could be automatic. In order to take into account cases in which the display of some personal electronic health data of minors to their guardians could be contrary to the interests or will of the minor, Member States should be able to provide for such limitations and safeguards in national law, as well as the necessary technical implementation. Personal health data access services, such as patient portals or mobile applications, should make use of such authorisations and thus enable authorised natural persons to access~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			use of such authorisations and thus enable authorised natural persons to access personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect.	~~personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect.~~ {Article 8A(3)} [[MOVED TO RECITAL 15B]]	
	Recital 10				
20	(10) Some Member States allow natural persons to add		(10) Some Member States allow natural persons to add	(10) Some Member States allow natural persons to add	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data to their EHRs or to store additional information in their separate personal health record that can be accessed by health professionals. However, this is not a common practice in all Member States and therefore should be established by the EHDS across the EU. Information inserted by natural persons may not be as reliable as electronic health data entered and verified by health professionals, therefore it should be clearly marked to indicate the source of such additional data. Enabling		electronic health data to their EHRs or to store additional information in their separate personal health record that can be accessed by health professionals. However, this is not a common practice in all Member States and therefore should be established by the EHDS across the EU. Information inserted by natural persons may not be as reliable as electronic health data entered and verified by health professionals ***and does not have the same clinical or legal value as information provided by a health professional***,	electronic health data to their EHRs or to store additional information in their separate personal health record that can be accessed by health professionals**, to complement the information available to them**. However, this is not a common practice in all Member States and therefore should be ~~established by the EHDS across the EU~~**left to Member States**. Information inserted by natural persons may not be as reliable as electronic health data entered and verified by health	

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	natural persons to more easily and quickly access their electronic health data also further enables them to notice possible errors such as incorrect information or incorrectly attributed patient records and have them rectified using their rights under Regulation (EU) 2016/679. In such cases, natural person should be enabled to request rectification of the incorrect electronic health data online, immediately and free of charge, for example through the personal health data access service. Data rectification requests should be assessed and, where		therefore it should be clearly marked to indicate the source of such additional data ***and should be validated only by a health professional. More specifically, relevant fields in the EHR should be clearly marked***. Enabling natural persons to more easily and quickly access their electronic health data also further enables them to notice possible errors such as incorrect information or incorrectly attributed patient records and have them rectified using their rights under Regulation (EU) 2016/679. In such cases, natural person should be	professionals~~,~~**.** Therefore**, where Member States provide for this right, it should be clearly distinguishable from data provided by** ~~it should be clearly marked to indicate the source of such additional data. Enabling natural persons to more easily and quickly access their electronic~~ health ~~data also further enables them to notice possible errors such as incorrect information or incorrectly attributed patient records and have them rectified using their rights under Regulation (EU) 2016/679. In such cases,~~**professionals. This**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	relevant, implemented by the data controllers on case by case basis, if necessary involving health professionals.		enabled to request rectification of the incorrect electronic health data online, immediately and free of charge, for example through the personal health data access service. Data rectification requests should be assessed and, where relevant, implemented by the data controllers on case by case basis, if necessary involving health professionals***, with a relevant specialisation, responsible for the natural person's treatment***.	**possibility for** natural ~~person should be enabled to request rectification of the incorrect~~**persons to add and complement personal** electronic health data ~~online, immediately and free of charge, for example through the personals~~**should not entitle them to change personal electronic** health data ~~access service. Data rectification requests should be assessed and, where relevant, implemented by the data controllers on case by case basis, if necessary involving~~ **provided by** health professionals.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				{Article 8B} [[PART OF RECITAL (10) MOVED TO RECITAL (10A)]]	
	Recital 10a				
20a				**(10a) Enabling natural persons to more easily and quickly access their personal electronic health data also further enables them to notice possible errors such as incorrect information or incorrectly**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				attributed patient records. In such cases, natural persons should be enabled to request rectification of the incorrect electronic health data online, immediately and free of charge, for example through a personal health data access service. Such rectification requests should then be treated by the relevant data controllers in line with Regulation (EU) 2016/679. In this situation, the health data access service forwards the request for rectification under Regulation (EU) 2016/679 to the competent	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				controller. This facilitates the exercise of this right for the natural person, who can submit requests through the health data access service instead of contacting controllers individually. It also helps the controller, who will receive assurance that the requester is in fact the data subject, as the requester will be reliably identified and authenticated by the health data access service. To further facilitate the exercise of existing data subject rights under Regulation (EU) 2016/679, Member States may also	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				provide possibilities to submit requests to exercise them through their health data access services, complementing the possibility to contact the controller directly. {Article 8C}	
	Recital 11				
21	(11) Natural persons should be further empowered to exchange and to provide access to personal electronic health		(11) Natural persons should be further empowered to exchange and to provide access to personal electronic health data to the health	(11) Natural persons should be further empowered to exchange and to provide access to personal electronic health data to the health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data to the health professionals of their choice, going beyond the right to data portability as established in Article 20 of Regulation (EU) 2016/679. This is necessary to tackle objective difficulties and obstacles in the current state of play. Under Regulation (EU) 2016/679, portability is limited only to data processed based on consent or contract, which excludes data processed under other legal bases, such as when the processing is based on law, for example when their processing is necessary for the performance of a task carried out in the public		professionals of their choice, going beyond the right to data portability as established in Article 20 of Regulation (EU) 2016/679 ***and to download their health data***. This is necessary to tackle objective difficulties and obstacles in the current state of play. Under Regulation (EU) 2016/679, portability is limited only to data processed based on consent or contract, which excludes data processed under other legal bases, such as when the processing is based on law, for example when their processing is necessary for the performance of a task	professionals of their choice, going beyond **and complementing** the right to data portability as established in Article 20 of Regulation (EU) 2016/679. ~~This is necessary to tackle objective difficulties and obstacles in the current state of play.~~ Under Regulation (EU) 2016/679, portability is limited only to data processed based on consent or contract~~,~~ which ~~excludes data processed under other legal bases, such as when the processing is based on law, for example when their processing is necessary for the performance of a task~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	interest or in the exercise of official authority vested in the controller. It only concerns data provided by the data subject to a controller, excluding many inferred or indirect data, such as diagnoses, or tests. Finally, under Regulation (EU) 2016/679, the natural person has the right to have the personal data transmitted directly from one controller to another only where technically feasible. That Regulation, however, does not impose an obligation to make this direct transmission technically feasible. All these elements limit the		carried out in the public interest or in the exercise of official authority vested in the controller. It only concerns data provided by the data subject to a controller, excluding many inferred or indirect data, such as diagnoses, or tests. Finally, under Regulation (EU) 2016/679, the natural person has the right to have the personal data transmitted directly from one controller to another only where technically feasible. That Regulation, however, does not impose an obligation to make this direct transmission technically feasible. All	~~carried out in the public interest or in the exercise of official authority vested in the controller. It only concerns data~~**were** provided by the data subject to a controller~~, excluding many inferred or indirect data, such as diagnoses, or tests~~. Finally, under Regulation (EU) 2016/679, the natural person has the right to have the personal data transmitted directly from one controller to another only where technically feasible. That Regulation, however, does not impose an obligation to make this direct transmission technically feasible. ~~All~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data portability and may limit its benefits for provision of high-quality, safe and efficient healthcare services to the natural person.		these elements limit the data portability and may limit its benefits for provision of high-quality, safe and efficient healthcare services to the natural person.	~~these elements limit the data portability and may limit its benefits for provision of high-quality, safe and efficient healthcare services to the natural person.~~ {Article 8D} [[RECITAL (11) MERGED WITH RECITAL (12)]]	
	Recital 12				
22	(12) Natural persons		(12) Natural persons should	(12) ~~Natural persons should~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	should be able to exercise control over the transmission of personal electronic health data to other healthcare providers. Healthcare providers and other organisations providing EHRs should facilitate the exercise of this right. Stakeholders such as healthcare providers, digital health service providers, manufacturers of EHR systems or medical devices should not limit or block the exercise of the right of portability because of the use of proprietary standards or other measures taken to limit the portability. For these reasons, the		be able to exercise control over the transmission of personal electronic health data to other healthcare providers. Healthcare providers and other organisations providing EHRs should facilitate the exercise of this right. Stakeholders such as healthcare providers, digital health service providers, manufacturers of EHR systems or medical devices should not limit or block the exercise of the right of portability because of the use of proprietary standards or other measures taken to limit the portability. ***In accordance with***	~~be able to exercise control over the transmission of personal electronic health data to other healthcare providers. Healthcare providers and other organisations providing EHRs should facilitate the exercise of this right. Stakeholders such as healthcare providers, digital health service providers, manufacturers of EHR systems or medical devices should not limit or block the exercise of the right of portability because of the use of proprietary standards or other measures taken to limit the portability.~~ For these reasons, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	framework laid down by this Regulation builds on the right to data portability established in Regulation (EU) 2016/679 by ensuring that natural persons as data subjects can transmit their electronic health data, including inferred data, irrespective of the legal basis for processing the electronic health data. This right should apply to electronic health data processed by public or private controllers, irrespective of the legal basis for processing the data under in accordance with the Regulation (EU) 2016/679. This right should		***Regulation (EU) 2016/679, healthcare providers should follow the data minimisation principle when accessing personal health data, limiting the data accessed to data that are strictly necessary and justified for a given service.*** For these reasons, the framework laid down by this Regulation builds on the right to data portability established in Regulation (EU) 2016/679 by ensuring that natural persons as data subjects can transmit their electronic health data, including inferred data, irrespective of the legal basis for processing the	framework laid down by this Regulation ~~builds on~~ **extends** the right to data portability established in Regulation (EU) 2016/679 by ensuring that natural persons as data subjects can transmit their electronic health data, including inferred data **in the European electronic health record exchange format**, irrespective of the legal basis for processing the electronic health data. **Health professionals** ~~This right~~ should ~~apply to electronic health data processed by public or private controllers, irrespective of the legal~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	apply to all electronic health data.		electronic health data. This right should apply to electronic health data processed by public or private controllers, irrespective of the legal basis for processing the data under in accordance with the Regulation (EU) 2016/679. This right should apply to all electronic health data.	~~basis for processing the data under in accordance with the Regulation (EU) 2016/679. This right should apply to all~~**refrain from hindering the implementation of the rights of natural persons, such as refusing to take into account electronic health data originating from another Member State and provided in the interoperable and reliable European** electronic health ~~data~~**record exchange format**.	
		Recital 12a			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
22a				**(12a) Moreover, the access to personal health records should be transparent to natural persons. The health data access services should provide detailed information on accesses to data, such as when and which healthcare providers or other individuals accessed which data. To ensure uniform implementation, the Commission should be empowered to lay down detailed elements in an implementing act.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				{Article 8E, transparency part}	
	Recital 13				
23	(13) Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, such restrictions may have life threatening		(13) Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, ***natural persons should be informed of the patient safety risks***	(13) Natural persons may not want to allow access to some parts of their personal electronic health data while enabling access to other parts. Such selective sharing of personal electronic health data should be supported. However, such restrictions may have life threatening consequences and,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	consequences and, therefore, access to personal electronic health data should be possible to protect vital interests as an emergency override. According to Regulation (EU) 2016/679, vital interests refer to situations in which it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person. Processing of personal electronic health data based on the vital interest of another natural person should in principle take place only where the processing cannot be		***associated with limiting access to health data. However,*** such restrictions may have life threatening consequences and, therefore, access to personal electronic health data should be possible to protect vital interests as an emergency override. According to Regulation (EU) 2016/679, vital interests refer to situations in which it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person. Processing of personal electronic health data based on the vital interest of	therefore, access to personal electronic health data should be possible to protect vital interests as an emergency override. According to Regulation (EU) 2016/679, vital interests refer to situations in which it is necessary to protect an interest which is essential for the life of the data subject or that of another natural person. Processing of personal electronic health data based on the vital interest of another natural person should in principle take place only where the processing cannot be manifestly based on another	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	manifestly based on another legal basis. More specific legal provisions on the mechanisms of restrictions placed by the natural person on parts of their personal electronic health data should be provided by Member States in national law. Because the unavailability of the restricted personal electronic health data may impact the provision or quality of health services provided to the natural person, he/she should assume responsibility for the fact that the healthcare provider cannot take the data into account when		another natural person should in principle take place only where the processing cannot be manifestly based on another legal basis. More specific legal provisions on the mechanisms of restrictions placed by the natural person on parts of their personal electronic health data should be provided by Member States in national law~~.~~ ***, in particular as regards medical liability in the event that restrictions have been placed by the natural person,*** Because the unavailability of the restricted personal electronic health data may	legal basis. More specific legal provisions on the mechanisms of restrictions placed by the natural person on parts of their personal electronic health data ~~should~~**may** be provided by Member States in national law. **In particular, this right may be restricted in a justified and proportionate manner, for purposes such as the preservation of public health in the case of highly contagious and hazardous diseases.** Because the unavailability of the restricted personal electronic health data may impact the provision or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	providing health services.		impact the provision or quality of health services provided to the natural person, he/she should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services.	quality of health services provided to the natural person, ~~he/she~~ **they** should assume responsibility for the fact that the healthcare provider cannot take the data into account when providing health services. Article 8E, restriction part + Article 7A(3)}	
	Recital 13a				
23a				**(13a) In addition, due to the different sensitivities**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				in the Member States on the degree of patients' control over their health data, Member States should be able to provide for an absolute right to object without an emergency override, both for cross-border access and for access internal to that Member State. If they choose to do so, they should establish the rules and specific safeguards regarding such mechanisms. Such rules and specific safeguards may also relate to specific categories of personal electronic health data, for example genetic data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Such a right to object means that personal electronic health data relating to the persons who made use of it would not be made available through the services set up under the EHDS beyond the healthcare provider that provided the treatment. If a natural person has exercised this right to object healthcare providers will still document treatment provided in accordance with the applicable rules, and will be able to access the data registered by them. Natural persons who made use of such a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				right to object should be able to reverse their decision. Should they do so, personal electronic health data generated during the period of the objection might not be available via the access services and MyHealth@EU. {8F}	
	Recital 14				
24	(14) In the context of the EHDS, natural persons		(14) In the context of the EHDS, natural persons	~~(14) In the context of the EHDS, natural persons~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	should be able to exercise their rights as they are enshrined in Regulation (EU) 2016/679. The supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679 should remain competent, in particular to monitor the processing of personal electronic health data and to address any complaints lodged by the natural persons. In order to carry out their tasks in the health sector and uphold the natural persons' rights, digital health authorities should cooperate with the supervisory authorities		should be able to exercise their rights ~~as they are enshrined in~~***under this Regulation without prejudice to*** Regulation (EU) 2016/679. The supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679 should remain competent, in particular to monitor the processing of personal electronic health data and to address any complaints lodged by the natural persons. In order to carry out their tasks in the health sector and uphold the natural persons' rights, digital health authorities	~~should be able to exercise their rights as they are enshrined in Regulation (EU) 2016/679. The supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679 should remain competent, in particular to monitor the processing of personal electronic health data and to address any complaints lodged by the natural persons. In order to carry out their tasks in the health sector and uphold the natural persons' rights, digital health authorities should cooperate with the supervisory authorities~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	under Regulation (EU) 2016/679.		should cooperate with the supervisory authorities under Regulation (EU) 2016/679.	~~under Regulation (EU) 2016/679.~~ [[MOVED TO RECITAL (16A)]]	
		Recital 15			
25	(15) Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of senstitive data is necessary for the purposes of preventive or occupational medicine, for		(15) Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of ~~*senstitive*~~***sensitive*** data is necessary for the purposes of preventive or	(15) ~~Article 9(2), point (h), of Regulation (EU) 2016/679 provides for exceptions where the processing of senstitive data is necessary for the purposes of preventive or occupational medicine, for~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the assessment of the working capacity of the employee, medical diagnosis, the provision of health care or treatment or the management of health care systems and services on the basis of Union or Member State law. This Regulation should provide conditions and safeguards for the processing of electronic health data by healthcare providers and health professionals in line with Article 9(2), point (h), of Regulation (EU) 2016/679 with the purpose of accessing personal electronic health data provided by the natural		occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health care or treatment or the management of health care systems and services on the basis of Union or Member State law. This Regulation should provide conditions and safeguards for the processing of electronic health data by healthcare providers and health professionals in line with Article 9(2), point (h), of Regulation (EU) 2016/679 with the purpose of accessing personal electronic health data	~~the assessment of the working capacity of the employee,~~**Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications and errors. However, due to a lack of interoperability, in many cases, health professionals cannot access the complete medical records of their patients and cannot make optimal** medical **decisions for their** diagnosis **and treatment, which adds considerable costs for both**~~, the provision of~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	person or transmitted from other healthcare providers. However, this Regulation should be without prejudice to the national laws concerning the processing of health data, including the legislation establishing categories of health professionals that can process different categories of electronic health data.		provided by the natural person or transmitted from other healthcare providers. However, this Regulation should be without prejudice to the national laws concerning the processing of health data ***outside the scope of this Regulation, including for other secondary use purposes established by this Regulation***, including the legislation establishing categories of health professionals that can process different categories of electronic health data.	health ~~care or treatment or the management of~~ **systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, which can be transmitted between healthcare providers can also reduce the administrative burden on health professionals of manually entering or copying** health ~~care~~**data between electronic** systems**. Therefore, health professionals should be provided with appropriate electronic means, such as health professional portals**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				or other health professional access ~~and~~ services**, to use personal electronic health data for the exercise of their duties. Providing this service to health professionals is a task in the public interest assigned by** ~~on the basis of Union or Member State law.~~ this Regulation ~~should provide~~**whose performance requires the processing of personal data in the sense of Article 6(1)(e) of Regulation (EU) 2016/679. This Regulation provides** conditions and safeguards for the processing of electronic health data ~~by healthcare providers and~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				~~health professionals~~**in the health professional access service** in line with Article 9(2), point (h)~~,~~ of Regulation (EU) 2016/679 ~~with the purpose of accessing personal electronic health data provided by the natural person or transmitted from other healthcare providers~~**, such as detailed provisions on logging to provide transparency towards data subjects**. However, this Regulation should be without prejudice to the national laws concerning the processing of health data **for the delivery of healthcare**, including the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				legislation establishing categories of health professionals that can process different categories of electronic health data. {Article 7B}	
	Recital 15a				
25a				**(15aa) In accordance with the general principles of European Union law, which include the fundamental rights guaranteed by Articles 7 and 8 of the Charter, a**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				particular high level of protection and security should be ensured when processing personal electronic health data for primary use, by means of appropriate technical and organisational measures. In this respect, this Regulation is without prejudice to a requirement under national law, with regards to the national context, according to which, where personal electronic health data are processed by healthcare providers for the provision of healthcare or by the national contact point for	

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				digital health connected to MyHealth@EU, the storage of personal electronic health data referred to in Article 5 for the purpose of primary use is located within the European Union in line with Union law and international commitments”	
	Recital 15b				
25b				**(15a) In order to facilitate the exercise of the complementary access and portability rights**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				established under this Regulation, Member States should establish one or more electronic health data access services. These services may be provided as an online patient portal, via a mobile application or other means. They should be designed in an accessible way, including for persons with disabilities. Proving such a service to enable natural persons with easy access to their personal electronic health data is a substantial public interest. The processing of personal electronic health data in these services is	

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				necessary for the performance of that task assigned by this Regulation in the sense of Articles 6(1)(e) and 9(2) of Regulation (EU) 2016/679. {Article 8G(1)}	
	Recital 15c				
25c				**(15b) Natural persons should be able to provide an authorisation to the natural persons of their choice, such as to their relatives or other close**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				natural persons, enabling them to access or control access to their personal electronic health data or to use digital health services on their behalf. Such authorisations may also be useful for convenience reasons in other situations. Proxy services for enabling such authorisations should be established by Member States to implement these authorisations, and they should be linked to personal health data access services, such as patient portals or patient-facing mobile applications. The proxy	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				services should also enable guardians to act on behalf of their dependent children; in such situations, authorisations could be automatic. In order to take into account cases in which the display of some personal electronic health data of minors to their guardians could be contrary to the interests or the will of the minor, Member States should be able to provide for such limitations and safeguards in national law, as well as the necessary technical implementation. Personal health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				services, such as patient portals or mobile applications, should make use of such authorisations and thus enable authorised natural persons to access personal electronic health data falling within the remit of the authorisation, in order for them to produce the desired effect. Digital proxy solutions should be aligned with Regulation […] [eID regulation COM/2021/281 final] and the technical specifications of the European Digital Identity Wallet to ensure a horizontal solution with increased user-	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				friendliness. This should contribute to reduce both administrative and financial burdens for Member States by lowering the risk of developing parallel systems that are not interoperable across the Union. {Article 8G(2) and (3)} [[MOVED FROM RECITAL (9) AND AMMENDED]]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 15d				
25d				**(15c) In some Member States, health care is provided by primary care management teams, defined as groups of healthcare professionals centred on primary care (general practitioners), who carry out their primary care activities based on a healthcare plan drawn up by them. Also, other types of healthcare teams exist in several Member States for other care purposes. In the context of primary use of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				health data in the European Health Data Space, access should be provided to the healthcare professional of such teams. {Article 7A}	
	Recital 16				
26	(16) Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications		(16) Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care ~~and~~, avoiding duplications	~~(16) Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and errors. However, due to a lack of interoperability, in many cases, health professionals cannot access the complete medical records of their patients and cannot make optimal medical decisions for their diagnosis and treatment, which adds considerable costs for both health systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, which can be transmitted between healthcare providers can also reduce the administrative burden on		and errors ***and reducing costs***. However, due to a lack of interoperability, in many cases, health professionals cannot access the complete medical records of their patients and cannot make optimal medical decisions for their diagnosis and treatment, which adds considerable costs for both health systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, which can be transmitted between healthcare providers can also reduce the	~~and errors. However, due to a lack of interoperability, in many cases, health professionals cannot access the complete medical records of their patients and cannot make optimal medical decisions for their diagnosis and treatment, which adds considerable costs for both health systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, which can be transmitted between healthcare providers can also reduce the administrative burden on~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health professionals of manually entering or copying health data between electronic systems. Therefore, health professionals should be provided with appropriate electronic means, such as health professional portals, to use personal electronic health data for the exercise of their duties. Moreover, the access to personal health records should be transparent to the natural persons and natural persons should be able to exercise full control over such access, including by limiting access to all or part of the personal electronic		administrative burden on health professionals of manually entering or copying health data between electronic systems. Therefore, health professionals should be provided with appropriate electronic means, such as ***appropriate electronic and digital devices and*** health professional portals, to use personal electronic health data for the exercise of their duties ***on a need-to-know basis***. Moreover, the access to personal health records should be transparent to the natural persons and natural persons should be able to exercise full control over	~~health professionals of manually entering or copying health data between electronic systems. Therefore, health professionals should be provided with appropriate electronic means, such as health professional portals, to use personal electronic health data for the exercise of their duties. Moreover, the access to personal health records should be transparent to the natural persons and natural persons should be able to exercise full control over such access, including by limiting access to all or part of the personal electronic~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data in their records. Health professionals should refrain from hindering the implementation of the rights of natural persons, such as refusing to take into account electronic health data originating from another Member State and provided in the interoperable and reliable European electronic health record exchange format.		such access, including by limiting access to all or part of the personal electronic health data in their records. Health professionals should refrain from hindering the implementation of the rights of natural persons, such as refusing to take into account electronic health data originating from another Member State and provided in the interoperable and reliable European electronic health record exchange format. ***This Regulation should not be construed or interpreted as limiting the obligation of health professionals to comply with the applicable law,***	~~health data in their records. Health professionals should refrain from hindering the implementation of the rights of natural persons, such as refusing to take into account electronic health data originating from another Member State and provided in the interoperable and reliable European electronic health record exchange format.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			codes of conduct, deontological guidelines or other provisions governing ethical conduct with respect to sharing or accessing information, particularly in life-threatening or extreme situations. For that purpose, providers of electronic health records should keep a record of who has accessed data in the previous 36 months and which data they accessed.		
	Recital 16a				
26a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(16a) Health professionals are faced with a profound change in the context of digitalisation and implementation of the EHDS. Health professionals need to develop their digital health literacy and digital skills. Therefore, health professionals who qualify as micro enterprises, as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[1], should be temporarily exempted from the obligations laid down in this Regulation, in order to avoid a disproportionate administrative burden for		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			micro enterprises. During the period of exemption, Member States should enable health professionals working as micro enterprises to take digital literacy courses to be able to prepare to work in EHR systems. _____ ***1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium sized enterprises (OJ L 124, 20.5.2003, p. 36)***		
	Recital 16a				
26b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(16a) The supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679 are competent for the monitoring and enforcement of that Regulation, in particular to monitor the processing of personal electronic health data and to address any complaints lodged by the natural persons. This notably includes the forwarding of complaints that falls within the other authorities' competences. The EHDS establishes additional rights for natural persons in primary use, going beyond	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the access and portability rights enshrined in Regulation (EU) 2016/679, complementing those rights. These additional rights should also be enforced by the supervisory authorities established pursuant to Article 51 of Regulation (EU) 2016/679. Digital health authorities should cooperate with the supervisory authorities established pursuant to Regulation (EU) 2016/679. The supervisory authority or authorities responsible for monitoring and enforcement of the processing of personal	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronic health data for primary use in compliance with the regulation should be competent to impose administrative fines. The legal system of Denmark and Ireland does not allow for administrative fines as set out in this Regulation. The rules on administrative fines may be applied in such a manner that in Denmark and Ireland the fines are imposed by the competent national courts as a criminal penalty, provided that such an application of the rules has an equivalent effect to administrative fines imposed by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				supervisory authorities. In any event, the fines imposed shall be effective, proportionate and dissuasive. MOVED FROM RECITAL (14) AND AMENDED]] {Article 11A}	
	Recital 16b				
26c				**(16b) Recognising the importance of ethical**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				principles and the principle of doctor-patient confidentiality, Member States should strive to adhere to ethical principles and to respect the principle of doctor-patient confidentiality in the application of this Regulation. In particular, the European ethical principles for digital health provide guidance to practitioners, researchers, innovators, policy-makers and regulators at Union and Member State level for the application of the Regulation. The possibilities offered by the Regulation in terms of,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				inter alia, the promotion of better diagnosis, treatment and well-being of natural persons, should be attained without prejudice to the observance of ethical imperatives and the principle of doctor-patient confidentiality.	
	Recital 16c				
26d				**(16c) The processing of health data for the purpose of law enforcement should not fall within the scope of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				primary or secondary use of electronic health data in the meaning of this Regulation.	
	Recital 17				
27	(17) The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity in standardisation, and therefore the implementation of mechanisms for their		(17) The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity in standardisation, and therefore the implementation of mechanisms for their	(17) The relevance of different categories of electronic health data for different healthcare scenarios varies. Different categories have also achieved different levels of maturity in standardisation, and therefore the implementation of mechanisms for their	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	exchange may be more or less complex depending on the category. Therefore, the improvement of interoperability and data sharing should be gradual and prioritisation of categories of electronic health data is needed. Categories of electronic health data such as patient summary, electronic prescription and dispensation, laboratory results and reports, hospital discharge reports, medical images and reports have been selected by the eHealth Network as most relevant for the majority of healthcare situations and		exchange may be more or less complex depending on the category. Therefore, the improvement of interoperability and data sharing should be gradual and prioritisation of categories of electronic health data is needed. Categories of electronic health data such as patient summary, electronic prescription and dispensation, laboratory results and reports, hospital discharge reports, medical images and reports have been selected by the eHealth Network as most relevant for the majority of healthcare situations and	exchange may be more or less complex depending on the category. Therefore, the improvement of interoperability and data sharing should be gradual and prioritisation of categories of electronic health data is needed. Categories of electronic health data such as patient summary, electronic prescription and dispensation, laboratory results and reports, hospital discharge reports, medical images and reports have been selected by the eHealth Network as most relevant for the majority of healthcare situations and	

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	should be considered as priority categories for Member States to implement access to them and their transmission. When further needs for the exchange of more categories of electronic health data are identified for healthcare purposes, the list of priority categories should be expanded. The Commission should be empowered to extend the list of priority categories, after analysing relevant aspects related to the necessity and possibility for the exchange of new datasets, such as their support by systems		should be considered as priority categories for Member States to implement access to them and their transmission. When further needs for the exchange of more categories of electronic health data are identified for healthcare purposes, the list of priority categories should be expanded~~. *The Commission should be empowered to extend the list of priority categories*~~, after analysing relevant aspects related to the necessity and possibility for the exchange of new datasets, such as their support by systems	should be considered as priority categories for Member States to implement access to them and their transmission. When further needs for the exchange of more categories of electronic health data are identified for healthcare purposes, the list of priority categories should be expanded. The Commission should be empowered to extend the list of priority categories, after analysing relevant aspects related to the necessity and possibility for the exchange of new datasets, such as their support by systems	

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	established nationally or regionally by the Member States. Particular attention should be given to the data exchange in border regions of neighbouring Member States where the provision of cross-border health services is more frequent and needs even quicker procedures than across the Union in general.		established nationally or regionally by the Member States. Particular attention should be given to the data exchange in border regions of neighbouring Member States where the provision of cross-border health services is more frequent and needs even quicker procedures than across the Union in general.	established nationally or regionally by the Member States. Particular attention should be given to the data exchange in border regions of neighbouring Member States where the provision of cross-border health services is more frequent and needs even quicker procedures than across the Union in general.	
	Recital 18				
28	(18) Access and sharing of electronic health data should be enabled for all		(18) Access and sharing of electronic health data should be enabled for all the	(18) Access and sharing of electronic health data should be enabled for all the	

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	the data that exist in the EHR of a natural person, when technically feasible. However, some electronic health data may not be structured or coded, and the transmission between healthcare providers may be limited or only possible in formats that do not allow for translation (when data is shared cross-borders). In order to provide enough time to prepare for implementation, dates of deferred application should be determined to allow for achieving legal, organisational, semantic and technical readiness for the transmission of different		data that exist in the EHR of a natural person, when technically feasible. However, some electronic health data may not be structured or coded, and the transmission between healthcare providers may be limited or only possible in formats that do not allow for translation (when data is shared cross-borders). In order to provide enough time to prepare for implementation, dates of deferred application should be determined to allow for achieving legal, organisational, semantic and technical readiness for the transmission of different	data that exist in the EHR of a natural person, when technically feasible. However, some electronic health data may not be structured or coded, and the transmission between healthcare providers may be limited or only possible in formats that do not allow for translation (when data is shared cross-borders). In order to provide enough time to prepare for implementation, dates of deferred application should be determined to allow for achieving legal, organisational, semantic and technical readiness for the transmission of different	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	categories of electronic health data. When need for the exchange of new categories of electronic health data is identified, related dates of application should be determined in order to allow for the implementation of this exchange.		categories of electronic health data. When need for the exchange of new categories of electronic health data is identified, related dates of application should be determined in order to allow for the implementation of this exchange.	categories of electronic health data. When need for the exchange of new categories of electronic health data is identified, related dates of application should be determined in order to allow for the implementation of this exchange.	
	Recital 19				
29	(19) The level of availability of personal health and genetic data in an electronic format varies between Member States.		(19) The level of availability of personal health and genetic data in an electronic format varies between Member States.	(19) The level of availability of personal health and genetic data in an electronic format varies between Member States.	

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	The EHDS should make it easier for natural persons to have those data available in electronic format. This would also contribute to the achievement of the target of 100% of Union citizens having access to their electronic health records by 2030, as referred to in the Policy Programme "Path to the Digital Decade". In order to make electronic health data accesible and transmissible, such data should be accessed and transmitted in an interoperable common European electronic health record exchange format, at least for certain categories		The EHDS should make it easier for natural persons to have those data available in electronic format ***as well as for them to have better control over accessing and sharing their personal electronic health data***. This would also contribute to the achievement of the target of 100% of Union citizens having access to their electronic health records by 2030, as referred to in the Policy Programme "Path to the Digital Decade". In order to make electronic health data ~~accesible~~***accessible*** and transmissible, such data should be accessed and	The EHDS should make it easier for natural persons to have those data available in electronic format. This would also contribute to the achievement of the target of 100% of Union citizens having access to their electronic health records by 2030, as referred to in the Policy Programme "Path to the Digital Decade". In order to make electronic health data ~~accesible~~**accessible** and transmissible, such data should be accessed and transmitted in an interoperable common European electronic health record exchange format, at	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of electronic health data, such as patient summaries, electronic prescriptions and dispensations, medical images and image reports, laboratory results and discharge reports, subject to transition periods. Where personal electronic health data is made available to a healthcare provider or a pharmacy by a natural person, or is transmitted by another data controller in the European electronic health record exchange format, the electronic health data should be read and accepted for the provision of healthcare or for dispensation of a medicinal		transmitted in an interoperable common European electronic health record exchange format, at least for certain categories of electronic health data, such as patient summaries, electronic prescriptions and dispensations, medical images and image reports, laboratory results and discharge reports, subject to transition periods. Where personal electronic health data is made available to a healthcare provider or a pharmacy by a natural person, or is transmitted by another data controller in the European electronic health record exchange	least for certain categories of electronic health data, such as patient summaries, electronic prescriptions and dispensations, medical images and image reports, laboratory results and discharge reports, subject to transition periods. Where personal electronic health data is made available to a healthcare provider or a pharmacy by a natural person, or is transmitted by another data controller in the European electronic health record exchange format, the electronic health data should be read and accepted for the provision of healthcare or for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	product, thus supporting the provision of the health care services or the dispensation of the electronic prescription. Commission Recommendation (EU) 2019/243[1] provides the foundations for such a common European electronic health record exchange format. The use of European electronic health record exchange format should become more generalised at EU and national level. While the eHealth Network under Article 14 of Directive 2011/24/EU of the European Parliament and of the Council[2] recommended		format, the electronic health data should be read and accepted for the provision of healthcare or for dispensation of a medicinal product, thus supporting the provision of the health care services or the dispensation of the electronic prescription. Commission Recommendation (EU) 2019/243[1] provides the foundations for such a common European electronic health record exchange format. ***The interoperability of the EHDS should contribute to a high quality of European health data sets***. The use of European electronic health	dispensation of a medicinal product, thus supporting the provision of the health care services or the dispensation of the electronic prescription. Commission Recommendation (EU) 2019/243[1] provides the foundations for such a common European electronic health record exchange format. The use of European electronic health record exchange format should become more generalised at EU and national level. While the eHealth Network under Article 14 of Directive 2011/24/EU of the European Parliament and of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Member States to use the European electronic health record exchange format in procurements, in order to improve interoperability, uptake was limited in practice, resulting in fragmented landscape and uneven access to and portability of electronic health data. _____ 1. Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (OJ L 39, 11.2.2019, p. 18). 2. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in		record exchange format should become more generalised at EU and national level. While the eHealth Network under Article 14 of Directive 2011/24/EU of the European Parliament and of the Council[2] recommended Member States to use the European electronic health record exchange format in procurements, in order to improve interoperability, uptake was limited in practice, resulting in fragmented landscape and uneven access to and portability of electronic health data.	the Council[2] recommended Member States to use the European electronic health record exchange format in procurements, in order to improve interoperability, uptake was limited in practice, resulting in fragmented landscape and uneven access to and portability of electronic health data. _____ 1. Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (OJ L 39, 11.2.2019, p. 18). 2. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	cross-border healthcare (OJ L 88, 4.4.2011, p. 45).		——————— 1. Commission Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format (OJ L 39, 11.2.2019, p. 18). 2. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).	application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).	
		Recital 20			
30	(20) While EHR systems are widely spread, the level of digitalisation of health		(20) While EHR systems are widely spread, the level of digitalisation of health	(20) While EHR systems are widely spread, the level of digitalisation of health	

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	data varies in Member States depending on data categories and on the coverage of healthcare providers that register health data in electronic format. In order to support the implementation of data subjects' rights of access to and exchange of electronic health data, Union action is needed to avoid further fragmentation. In order to contribute to a high quality and continuity of healthcare, certain categories of health data should be registered in electronic format systematically and according to specific data		data varies in Member States depending on data categories and on the coverage of healthcare providers that register health data in electronic format. In order to support the implementation of data subjects' rights of access to and exchange of electronic health data, Union action is needed to avoid further fragmentation. In order to contribute to a high quality and continuity of healthcare, certain categories of health data should be registered in electronic format systematically and according to specific data	data varies in Member States depending on data categories and on the coverage of healthcare providers that register health data in electronic format. In order to support the implementation of data subjects' rights of access to and exchange of electronic health data, Union action is needed to avoid further fragmentation. In order to contribute to a high quality and continuity of healthcare, certain categories of health data should be registered in electronic format systematically and according to specific data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	quality requirements. The European electronic health record exchange format should form the basis for specifications related to the registration and exchange of electronic health data. The Commission should be empowered to adopt implementing acts for determining additional aspects related to the registration of electronic health data, such as categories of healthcare providers that are to register health data electronically, categories of data to be registered electronically, or data quality requirements.		quality requirements. The European electronic health record exchange format should form the basis for specifications related to the registration and exchange of electronic health data. The Commission should be empowered to adopt ~~*implementing*~~***delegated*** acts for determining~~ *additional aspects related to the registration of electronic health data, such as categories of healthcare providers that are to register health data electronically, categories of data to be registered electronically, or*~~ data quality requirements.	quality requirements. The European electronic health record exchange format should form the basis for specifications related to the registration and exchange of electronic health data. The Commission should be empowered to adopt implementing acts for determining additional aspects related to the registration of electronic health data, such as categories of healthcare providers that are to register health data electronically, categories of data to be registered electronically, or data quality requirements. **The European electronic**	

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				health record exchange format may have two profiles: a simple technical specification for use applicable to EHR systems and a detailed technical specification for cross-border use, which should only apply to the national contact points for MyHealth@EU. At the national level, the European electronic health record exchange format should include the technical specifications for the 'European interoperability component for EHR systems'. Also, harmonised technical	

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				specifications for the 'European logging component for EHR systems' should be defined by means of implementing acts. These two components are mainly focused on data transformation, although they may imply indirect requirements for data registry and data presentation in EHR systems at the national level. Given the purposes of these components and the wide scope of the definition of EHR systems in this Regulation, conformance assessment of the harmonised	

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				components should be by means of self-certification. The Commission should establish a testing environment to facilitate such self-certification. Member States should retain the competence to define requirements relating to any other components of EHR systems and the terms and conditions for connection of healthcare providers to their respective national infrastructures, which may be subject to third-party assessment at the national level. The cross-border specifications of the European electronic	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				health record exchange format should be complemented by further cybersecurity, technical and semantic interoperability, operations and service management specifications for cross-border use in the MyHealth@EU infrastructure, defined by means of implementing acts.	
	Recital 20a				
30a			***(20a) In order to support***		

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			the successful implementation of the EHDS and the creation of effective conditions for European health data cooperation, the Commission and Member States should agree on time-based targets to implement conditions for improved health data interoperability across the Union with a range of objectives and milestones, including in respect of disease-specific registry interoperability, which should be reviewed and assessed in an annual report.		

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	Recital 21				
31	(21) Under Article 168 of the Treaty Member States are responsible for their health policy, in particular for decisions on the services (including telemedicine) that they provide and reimburse. Different reimbursement policies should, however, not constitute barriers to the free movement of digital health services such as telemedicine, including online pharmacy services.		(21) Under Article 168 of the Treaty ***on the Functioning of the European Union (TFEU),*** Member States are responsible for their health policy, in particular for decisions on the services ~~*(including telemedicine)*~~ that they provide and reimburse. Different reimbursement policies should, however, not constitute barriers to the free movement of digital	(21) Under Article 168 of the Treaty Member States are responsible for their health policy, in particular for decisions on the services (including telemedicine) that they provide and reimburse. Different reimbursement policies should, however, not constitute barriers to the free movement of digital health services such as telemedicine, including online pharmacy services.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	When digital services accompany the physical provision of a healthcare service, the digital service should be included in the overall care provision.		health services such as telemedicine, including online pharmacy services. When digital services accompany the physical provision of a healthcare service, the digital service should be included in the overall care provision. ***Telemedicine is becoming an increasingly important tool that can provide patients with access to care and tackle inequities and has the potential to reduce health inequalities and reinforce the free movement of Union citizens across borders. Digital and other technological tools can***	When digital services accompany the physical provision of a healthcare service, the digital service should be included in the overall care provision.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			facilitate the provision of care in remote regions. However, telemedicine should not be viewed as a replacement for in-person medicine, as there are certain conditions and procedures that require in-person physical examination and intervention.		
	Recital 22				
32	(22) Regulation (EU) No 910/2014 of the European Parliament and of the Council[1] lays down the		(22) Regulation (EU) No 910/2014 of the European Parliament and of the Council[1] lays down the	(22) Regulation (EU) No 910/2014 of the European Parliament and of the Council[1] lays down the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conditions under which Members States perform identification of natural persons in cross-border situations using identification means issued by another Member State, establishing rules for the mutual recognition of such electronic identification means. The EHDS requires a secure access to electronic health data, including in cross-border scenarios where the health professional and the natural person are from different Member States, to avoid cases of unauthorised access. At the same time, the existence of different		conditions under which Members States perform identification of natural persons in cross-border situations using identification means issued by another Member State, establishing rules for the mutual recognition of such electronic identification means. The EHDS requires a secure access to electronic health data, including in cross-border scenarios where the health professional and the natural person are from different Member States, to avoid cases of unauthorised access. At the same time, the existence of different	conditions under which Members States perform identification of natural persons in cross-border situations using identification means issued by another Member State, establishing rules for the mutual recognition of such electronic identification means. The EHDS requires a secure access to electronic health data, including in cross-border scenarios where the health professional and the natural person are from different Member States, to avoid cases of unauthorised access. At the same time, the existence of different	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	means of electronic identification should not be a barrier for exercising the rights of natural persons and health professionals. The rollout of interoperable, cross-border identification and authentication mechanisms for natural persons and health professionals across the EHDS requires strengthening cooperation at Union level in the European Health Data Space Board ('EHDS Board').As the rights of the natural persons in relation to the access and transmission of personal electronic health data		means of electronic identification should not be a barrier for exercising the rights of natural persons and health professionals. ***Therefore, natural persons and health professionals should have the right to electronic identification using any recognised electronic identification, including eID schemes where such are offered.*** The rollout of interoperable, cross-border identification and authentication mechanisms for natural persons and health professionals across the EHDS requires strengthening cooperation at	means of electronic identification should not be a barrier for exercising the rights of natural persons and health professionals. The rollout of interoperable, cross-border identification and authentication mechanisms for natural persons and health professionals across the EHDS requires strengthening cooperation at Union level in the European Health Data Space Board ('EHDS Board').~~As the rights of the natural persons in relation to the access and transmission of personal electronic health data should be implemented~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	should be implemented uniformly across the Union, a strong governance and coordination is necessary at both Union and Member State level. Member States should establish relevant digital health authorities for the planning and implementation of standards for electronic health data access, transmission and enforcement of rights of natural persons and health professionals. In addition, governance elements are needed in Member States to facilitate the participation of national actors in the cooperation at Union level,		Union level in the European Health Data Space Board ('EHDS Board'). As the rights of the natural persons in relation to the access and transmission of personal electronic health data should be implemented uniformly across the Union, a strong governance and coordination is necessary at both Union and Member State level. ~~*Member States should establish relevant digital health authorities for the planning and implementation of standards for electronic health data access, transmission and enforcement of rights of*~~	~~uniformly across the Union, a strong governance and coordination is necessary at both Union and Member State level. Member States should establish relevant digital health authorities for the planning and implementation of standards for electronic health data access, transmission and enforcement of rights of natural persons and health professionals. In addition, governance elements are needed in Member States to facilitate the participation of national actors in the cooperation at Union level, channelling expertise and advising the design of~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	channelling expertise and advising the design of solutions necessary to achieve the goals of the EHDS. Digital health authorities exist in most of the Member States and they deal with EHRs, interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of the currently existing authorities. _____ 1. Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust		~~*natural persons and health professionals. In addition, governance elements are needed in Member States to facilitate the participation of national actors in the cooperation at Union level, channelling expertise and advising the design of solutions necessary to achieve the goals of the EHDS. Digital health authorities exist in most of the Member States and they deal with EHRs, interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of*~~	~~solutions necessary to achieve the goals of the EHDS. Digital health authorities exist in most of the Member States and they deal with EHRs, interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of the currently existing authorities.~~ _____ 1. Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).		~~*the currently existing authorities.*~~ _____ 1. Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73).	repealing Directive 1999/93/EC (OJ L 257, 28.8.2014, p. 73). THE REST OF THE RECITAL MOVED TO (22B)	
	Recital 22a				
32a			***(22a) Member States should establish relevant digital health authorities for the planning and***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			implementation of standards for electronic health data access and transmission and the enforcement of the rights of natural persons and health professionals. In addition, governance elements are needed in Member States to facilitate the participation of national actors in the cooperation at Union level, channelling expertise and advising on the design of solutions necessary to achieve the goals of the EHDS. Digital health authorities exist in most of the Member States and they deal with EHRs,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of currently existing authorities.		
	Recital 22a				
32b				**(22a) Natural persons should be provided with sufficient tools for exercising their rights related to the personal electronic health data. Member States should**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				therefore ensure that electronic health data access services are made available for natural persons and their representatives. Such services may be implemented for instance through online portals or mobile applications, at national or regional level, or by healthcare providers. Electronic health data access services should implement the rights of natural persons regardless of their Member State of affiliation, and should therefore support the identification of natural	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				persons using any electronic identification means recognised pursuant to Article 6 of Regulation (EU) No 910/2014. Considering the possibility of identity matching challenges in cross-border situations, supplementary access tokens or codes may need to be issued by Member States to natural persons who arrive from other Member States and receive healthcare. The Commission should be empowered to adopt implementing acts for the interoperable, cross-border identification and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				authentication of natural persons and health professionals, including any supplementary mechanisms that are necessary for ensuring the possibility for natural persons to exercise their rights to personal electronic health data in cross-border situations.	
	Recital 22b				
32c				**(22b) As the rights of the natural persons in relation to the access and transmission of personal**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronic health data should be implemented uniformly across the Union, a strong governance and coordination is necessary at both Union and Member State level. Member States should establish relevant digital health authorities for the planning and implementation of standards for electronic health data access, transmission and enforcement of rights of natural persons and health professionals. In addition, governance elements are needed in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Member States to facilitate the participation of national actors in the cooperation at Union level, channelling expertise and advising the design of solutions necessary to achieve the goals of the EHDS. Digital health authorities exist in most of the Member States and they deal with EHRs, interoperability, security or standardisation. Digital health authorities should be established in all Member States, as separate organisations or as part of the currently existing authorities.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 23				
33	(23) Digital health authorities should have sufficient technical skills, possibly bringing together experts from different organisations. The activities of digital health authorities should be well-planned and monitored in order to ensure their efficiency. Digital health authorities should take necessary measures to ensuring rights of natural persons by setting up national, regional, and		(23) Digital health authorities should have sufficient technical skills, possibly bringing together experts from different organisations. The activities of digital health authorities should be well-planned and monitored in order to ensure their efficiency. Digital health authorities should take necessary measures to ensuring rights of natural persons by setting up national, regional, and local	(23) Digital health authorities should have sufficient technical skills, possibly bringing together experts from different organisations. The activities of digital health authorities should be well-planned and monitored in order to ensure their efficiency. Digital health authorities should take necessary measures to ensuring rights of natural persons by setting up national, regional, and local	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	local technical solutions such as national EHR, patient portals, data intermediation systems. When doing so, they should apply common standards and specifications in such solutions, promote the application of the standards and specifications in procurements and use other innovative means including reimbursement of solutions that are compliant with interoperability and security requirements of the EHDS. To carry out their tasks, the digital health authorities should cooperate at national and Union level with other entities, including with		technical solutions such as national EHR, patient portals, data intermediation systems. When doing so, they should apply common standards and specifications in such solutions, promote the application of the standards and specifications in procurements and use other innovative means including reimbursement of solutions that are compliant with interoperability and security requirements of the EHDS. ***Member States should ensure that appropriate training initiatives are undertaken. In particular, health professionals should be***	technical solutions such as national EHR, patient portals, data intermediation systems. When doing so, they should apply common standards and specifications in such solutions, promote the application of the standards and specifications in procurements and use other innovative means including reimbursement of solutions that are compliant with interoperability and security requirements of the EHDS. To carry out their tasks, the digital health authorities should cooperate at national and Union level with other entities, including with insurance	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	insurance bodies, healthcare providers, manufacturers of EHR systems and wellness applications, as well as stakeholders from health or information technology sector, entities handling reimbursement schemes, health technology assessment bodies, medicinal products regulatory authorities and agencies, medical devices authorities, procurers and cybersecurity or e-ID authorities.		***informed and trained with respect to their rights and obligations under this Regulation.*** To carry out their tasks, the digital health authorities should cooperate at national and Union level with other entities, including with insurance bodies, healthcare providers, ***health professionals,*** manufacturers of EHR systems and wellness applications, as well as ***other*** stakeholders from health or information technology sector, entities handling reimbursement schemes, health technology assessment bodies,	bodies, healthcare providers, manufacturers of EHR systems and wellness applications, as well as stakeholders from health or information technology sector, entities handling reimbursement schemes, health technology assessment bodies, medicinal products regulatory authorities and agencies, medical devices authorities, procurers and cybersecurity or e-ID authorities.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			medicinal products regulatory authorities and agencies, medical devices authorities, procurers and cybersecurity or e-ID authorities.		
	Recital 24				
34	(24) Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of		(24) Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of	(24) Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	residence. Continuity of care and rapid access to personal electronic health data is even more important for residents in border regions, crossing the border frequently to get health care. In many border regions, some specialised health care services may be available closer across the border rather than in the same Member State. An infrastructure is needed for the transmission of personal electronic health data across borders, in situations where a natural person is using services of a healthcare provider established in another Member State. A		residence. Continuity of care and rapid access to personal electronic health data is even more important for residents in border regions, crossing the border frequently to get health care. In many border regions, some specialised health care services may be available closer across the border rather than in the same Member State. An infrastructure is needed for the transmission of personal electronic health data across borders, in situations where a natural person is using services of a healthcare provider established in another Member State. A	residence. Continuity of care and rapid access to personal electronic health data is even more important for residents in border regions, crossing the border frequently to get health care. In many border regions, some specialised health care services may be available closer across the border rather than in the same Member State. An infrastructure is needed for the transmission of personal electronic health data across borders, in situations where a natural person is using services of a healthcare provider established in another Member State. A	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	voluntary infrastructure for that purpose, MyHealth@EU, has been established as part of the actions provided for in Article 14 of Directive 2011/24/EU. Through MyHealth@EU, Member States started to provide natural persons with the possibility to share their personal electronic health data with healthcare providers when travelling abroad. To further support such possibilities, the participation of Member States in the digital infrastructure MyHealth@EU should become mandatory. All		voluntary infrastructure for that purpose, MyHealth@EU, has been established as part of the actions provided for in Article 14 of Directive 2011/24/EU. Through MyHealth@EU, Member States started to provide natural persons with the possibility to share their personal electronic health data with healthcare providers when travelling abroad. To further support such possibilities, the participation of Member States in the digital infrastructure MyHealth@EU should become mandatory. All	voluntary infrastructure for that purpose, MyHealth@EU, has been established as part of the actions provided for in Article 14 of Directive 2011/24/EU. Through MyHealth@EU, Member States started to provide natural persons with the possibility to share their personal electronic health data with healthcare providers when travelling abroad. To further support such possibilities, the participation of Member States in the digital infrastructure MyHealth@EU should become mandatory. All	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Member States should join the infrastructure and connect healthcare providers and pharmacies to it, as this is necessary for the implementation of the rights of natural persons to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually expanded to support further categories of electronic health data.		Member States should join the infrastructure and connect healthcare providers and pharmacies to it, as this is necessary for the implementation of the rights of natural persons to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually expanded to support further categories of electronic health data***, and funding as well as other means of support at Union level should be considered***.	Member States should join the infrastructure and connect healthcare providers ~~and~~**including** pharmacies to it, as this is necessary for the implementation of the rights of natural persons **established under this Regulation** to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually expanded to support further categories of electronic health data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 25				
35	(25) In the context of MyHealth@EU, a central platform should provide a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way. In order to guarantee compliance with data protection rules and to provide a risk management framework for the transmission of personal electronic health data, the Commission should, by means of implementing		(25) In the context of MyHealth@EU, a central platform should provide a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way. In order to guarantee compliance with data protection rules and to provide a risk management framework for the transmission of personal electronic health data, the Commission should, by means of implementing	(25) ~~In the context of~~ MyHealth@EU~~, a central platform should provide~~ **provides** a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way **to support cross-border healthcare. The Commission should, as a processor on behalf of the Member States, provide this infrastructure**. In order to guarantee compliance with data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	acts, allocate specific responsibilities among the Member States, as joint controllers, and prescribe its own obligations, as processor.		acts, allocate specific responsibilities ***with time-based targets*** among the Member States, as joint controllers, and prescribe its own obligations, as processor.	protection rules and to provide a risk management framework for the transmission of personal electronic health data, **specific responsibilities of the Member States, as controllers, and the** ~~the~~ Commission**'s obligations** should~~, by means of~~ **be laid down in detail in** implementing acts~~, allocate specific responsibilities among the Member States, as joint controllers, and prescribe its own obligations, as processor~~**. This Regulation provides the legal basis for the processing of personal electronic health data in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this infrastructure as a task carried out in the public interest assigned by Union law in the sense of Article 6(1)(e) of Regulation (EU) 2016/679. This processing is necessary for the provision of healthcare, as mentioned in Article 9(2)(h) of that Regulation, in cross-border situations.	
	Recital 26				
36	(26) In addition to services in MyHealth@EU for the exchange of personal		(26) In addition to services in MyHealth@EU for the exchange of personal	(26) In addition to services in MyHealth@EU for the exchange of personal	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data based on the European electronic health record exchange format, other services or supplementary infrastructures may be needed for example in cases of public health emergencies or where the architecture of MyHealth@EU is not suitable for the implementation of some use cases. Examples of such use cases include support for vaccination card functionalities, including the exchange of information on vaccination plans, or verification of vaccination certificates or other health-		electronic health data based on the European electronic health record exchange format, other services or supplementary infrastructures may be needed for example in cases of public health emergencies or where the architecture of MyHealth@EU is not suitable for the implementation of some use cases. Examples of such use cases include support for vaccination card functionalities, including the exchange of information on vaccination plans, or verification of vaccination certificates or other health-	electronic health data based on the European electronic health record exchange format, other services or supplementary infrastructures may be needed for example in cases of public health emergencies or where the architecture of MyHealth@EU is not suitable for the implementation of some use cases. Examples of such use cases include support for vaccination card functionalities, including the exchange of information on vaccination plans, or verification of vaccination certificates or other health-	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	related certificates. This would be also important for introducing additional functionality for handling public health crises, such as support for contact tracing for the purposes of containing infectious diseases. Connection of national contact points for digital health of third countries or interoperability with digital systems established at international level should be subject to a check ensuring the compliance of the national contact point with the technical specifications, data protection rules and other requirements of		related certificates. This would be also important for introducing additional functionality for handling public health crises, such as support for contact tracing for the purposes of containing infectious diseases. ~~*Connection of national contact points for digital health of third countries or interoperability with digital systems established at international level should be subject to a check ensuring the compliance of the national contact point with the technical specifications, data protection rules and other requirements of*~~	related certificates. This would be also important for introducing additional functionality for handling public health crises, such as support for contact tracing for the purposes of containing infectious diseases. Connection of national contact points for digital health of third countries or interoperability with digital systems established at international level should be subject to a check ensuring the compliance of the national contact point with the technical specifications, data protection rules and other requirements of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU.		~~*MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU.*~~	MyHealth@EU. A decision to connect a national contact point of a third country should be taken by data controllers in the joint controllership group for MyHealth@EU.	
		Recital 27			
37	(27) In order to ensure respect for the rights of natural persons and health professionals, EHR systems marketed in the internal market of the Union should be able to store and transmit, in a secure way,		(27) In order to ensure respect for the rights of natural persons and health professionals, EHR systems marketed in the internal market of the Union should be able to store and transmit, in a secure way,	(27) In order to ~~ensure~~**enable seamless exchange of electronic health and contribute to ensuring** respect for the rights of natural persons and health professionals, EHR systems marketed in the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	high quality electronic health data. This is a key principle of the EHDS to ensure the secure and free movement of electronic health data across the Union. To that end, a mandatory self-certification scheme for EHR systems processing one or more priority categories of electronic health data should be established to overcome market fragmentation while ensuring a proportionate approach. Through this self-certification, EHR systems should prove compliance with essential requirements on interoperability and		high quality electronic health data. This is a key principle of the EHDS to ensure the secure and free movement of electronic health data across the Union. To that end, a mandatory self-certification scheme for EHR systems processing one or more priority categories of electronic health data should be established to overcome market fragmentation while ensuring a proportionate approach. Through this self-certification, EHR systems should prove compliance with essential requirements on interoperability and	~~internal~~**Single** Market of the Union should be able to store and transmit, in a secure way, high quality electronic health data. ~~This~~**It** is a key ~~principle~~**objective** of the EHDS to ensure the secure and free movement of electronic health data across the Union. To that end, a mandatory ~~self-certification scheme~~**scheme of self-conformity assessment** for EHR systems processing one or more priority categories of electronic health data should be established to overcome market fragmentation while ensuring a proportionate	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	security, set at Union level. In relation to security, essential requirements should cover elements specific to EHR systems, as more general security properties should be supported by other mechanisms such as cybersecurity schemes under Regulation (EU) 2019/881 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications		security, set at Union level. In relation to security, essential requirements should cover elements specific to EHR systems, as more general security properties should be supported by other mechanisms such as cybersecurity schemes under Regulation (EU) 2019/881 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications	approach. Through this ~~self-certification~~**self-assessment**, EHR systems ~~should~~**will** prove compliance with ~~essential~~**the** requirements on interoperability**, security and logging for communication of personal electronic health data established by the two mandatory EHR components harmonised by this Regulation, namely the 'European EHR systems exchange interoperability component' and the 'European logging component for EHR systems'** ~~and security, set at~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).		technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).	~~Union level~~. In relation to security **of those components, these**~~,~~ ~~essential~~ requirements should cover elements specific to EHR systems, as more general security properties should be supported by other mechanisms such as ~~cybersecurity schemes under~~ Regulation ~~(EU) 2019/881 of the European Parliament and of the Council~~[1]**[…]… [Cyber-Resilience Act COM/2022/454 final]**. _____ ~~1. Regulation (EU) 2019/881 of the European Parliament and of~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				~~the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).~~	
	Recital 28				
38	(28) While EHR systems specifically intended by the manufacturer to be used for processing one or more specific categories of electronic health data should be subject to mandatory self-		(28) While EHR systems specifically intended by the manufacturer to be used for processing one or more specific categories of electronic health data should be subject to mandatory self-certification,	(28) While EHR systems specifically intended by the manufacturer to be used for processing one or more specific categories of electronic health data should be subject to mandatory self-certification,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	certification, software for general purposes should not be considered as EHR systems, even when used in a healthcare setting, and should therefore not be required to comply with the provisions of Chapter III.		software for general purposes should not be considered as EHR systems, even when used in a healthcare setting, and should therefore not be required to comply with the provisions of Chapter III.	software for general purposes should not be considered as EHR systems, even when used in a healthcare setting, and should therefore not be required to comply with the provisions of Chapter III.	
	Recital 28a				
38a				**(28a) This Regulation imposes a mandatory self-conformity assessment scheme for the two mandatory harmonised EHR components of EHR systems, to ensure that**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				EHR systems placed on the Union market are able to exchange data in the European electronic health record exchange format and that they have the required logging capabilities. The declaration of conformity by the manufacturer is justified by ensuring that these requirements are guaranteed in a proportionate way, without imposing an undue burden on Member States and manufacturers.	
	Recital 28b				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
38b				**(28b) In order to promote the smooth functioning of the internal market for electronic health data, digital health products and services, as much transparency as possible should be ensured as regards national regulations establishing requirements for EHR systems and provisions on their conformity assessment in relation to aspects other than the harmonised components of EHR systems under the regulation. It is essential for the Commission to**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				have the necessary information regarding those national requirements in order to ensure that they do not impede or adversely interact with the harmonised components of EHR systems.	
	Recital 29				
39	(29) Software or module(s) of software which falls within the definition of a medical device or high-risk artificial intelligence (AI) system should be certified		(29) Software or module(s) of software which falls within the definition of a medical device or high-risk artificial intelligence (AI) system should be certified	(29) Software or module(s) of software which falls within the definition of a medical device**, in vitro diagnostic medical devices** or high-risk artificial	

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	in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council[1] and Regulation […] of the European Parliament and of the Council [AI Act COM/2021/206 final], as applicable. The essential requirements on interoperability of this Regulation should only apply to the extent that the manufacturer of a medical device or high-risk AI system, which is providing electronic health data to be processed as part of the EHR system, claims interoperability with such EHR system. In such case,		in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council[1] and Regulation […] of the European Parliament and of the Council [AI Act COM/2021/206 final], as applicable. The essential requirements on interoperability of this Regulation should only apply to the extent that the manufacturer of a medical device or high-risk AI system, which is providing electronic health data to be processed as part of the EHR system, claims interoperability with such EHR system. In such case,	intelligence (AI) system should be certified in accordance with Regulation (EU) 2017/745**, Regulation (EU) 2017/746** of the European Parliament and of the Council[1] and Regulation […] of the European Parliament and of the Council [AI Act COM/2021/206 final], as applicable. The essential requirements on interoperability of this Regulation should only apply to the extent that the manufacturer of a medical device**, in vitro diagnostic medical devices,** or high-risk AI system, which is providing electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the provisions on common specifications for EHR systems should be applicable to those medical devices and high-risk AI systems. _____ 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).		the provisions on common specifications for EHR systems should be applicable to those medical devices and high-risk AI systems. _____ 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	data to be processed as part of the EHR system, claims interoperability with such EHR system. In such case, the provisions on common specifications for EHR systems should be applicable to those medical devices**, in vitro diagnostic medical devices,** and high-risk AI systems. _____ 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117,	

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				5.5.2017, p. 1).	
	Recital 30				
40	(30) To further support interoperability and security, Member States may maintain or define specific rules for the procurement, reimbursement, financing or use of EHR systems at national level in the context of the organisation, delivery or financing of health services. Such specific rules should not impede the free movement of EHR systems		(30) To further support interoperability and security, Member States may maintain or define specific rules for the procurement, reimbursement, financing or use of EHR systems at national level in the context of the organisation, delivery or financing of health services. Such specific rules should not impede the free movement of EHR systems	(30) To further support interoperability and security, Member States may maintain or define specific rules for the procurement, reimbursement, financing or use of EHR systems at national level in the context of the organisation, delivery or financing of health services. Such specific rules should not impede the free movement of EHR systems	

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	in the Union. Some Member States have introduced mandatory certification of EHR systems or mandatory interoperability testing for their connection to national digital health services. Such requirements are commonly reflected in procurements organised by healthcare providers, national or regional authorities. Mandatory certification of EHR systems at Union level should establish a baseline that can be used in procurements at national level.		in the Union. Some Member States have introduced mandatory certification of EHR systems or mandatory interoperability testing for their connection to national digital health services. Such requirements are commonly reflected in procurements organised by healthcare providers, national or regional authorities. Mandatory certification of EHR systems at Union level should establish a baseline that can be used in procurements at national level.	in the Union. Some Member States have introduced mandatory certification of EHR systems or mandatory interoperability testing for their connection to national digital health services. Such requirements are commonly reflected in procurements organised by healthcare providers, national or regional authorities. Mandatory certification of EHR systems at Union level should establish a baseline that can be used in procurements at national level.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 31				
41	(31) In order to guarantee effective exercise by patients of their rights under this Regulation, where healthcare providers develop and use an EHR system 'in house' to carry out internal activities without placing it on the market in return of payment or remuneration, they should also comply with this Regulation. In that context, such healthcare providers should comply with all requirements applicable to the		(31) In order to guarantee effective exercise by patients of their rights under this Regulation, where healthcare providers develop and use an EHR system 'in house' to carry out internal activities without placing it on the market in return of payment or remuneration, they should also comply with this Regulation. In that context, such healthcare providers should comply with all requirements applicable to the	(31) In order to guarantee effective exercise by patients of their rights under this Regulation, where healthcare providers develop and use an EHR system 'in house' to carry out internal activities without placing it on the market in return of payment or remuneration, they should also comply with this Regulation. In that context, such healthcare providers should comply with all requirements applicable to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	manufacturers.		manufacturers.	manufacturers **for such 'in house'-developed system that they put into service. However, such healthcare providers may need additional time to prepare. For that reason, these requirements should only apply to such systems after an extended transition period**.	
	Recital 32				
42	(32) It is necessary to provide for a clear and proportionate division of obligations corresponding		(32) It is necessary to provide for a clear and proportionate division of obligations corresponding	(32) It is necessary to provide for a clear and proportionate division of obligations corresponding	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to the role of each operator in the supply and distribution process of EHR systems. Economic operators should be responsible for compliance in relation to their respective roles in such process and should ensure that they make available on the market only EHR systems which comply with relevant requirements.		to the role of each operator in the supply and distribution process of EHR systems. Economic operators should be responsible for compliance in relation to their respective roles in such process and should ensure that they make available on the market only EHR systems which comply with relevant requirements.	to the role of each operator in the supply and distribution process of EHR systems. Economic operators should be responsible for compliance in relation to their respective roles in such process and should ensure that they make available on the market only EHR systems which comply with relevant requirements.	
	Recital 33				
43	(33) Compliance with essential requirements on		(33) Compliance with essential requirements on	(33) Compliance with essential requirements on	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	interoperability and security should be demonstrated by the manufacturers of EHR systems through the implementation of common specifications. To that end, implementing powers should be conferred on the Commission to determine such common specifications regarding datasets, coding systems, technical specifications, including standards, specifications and profiles for data exchange, as well as requirements and principles related to security, confidentiality, integrity, patient safety and protection of personal data		interoperability and security should be demonstrated by the manufacturers of EHR systems through the implementation of common specifications. To that end, implementing powers should be conferred on the Commission to determine such common specifications regarding datasets, coding systems, technical specifications, including standards, specifications and profiles for data exchange, as well as requirements and principles related to security, confidentiality, integrity, patient safety and protection of personal data as well as	interoperability and security should be demonstrated by the manufacturers of EHR systems through the implementation of common specifications. To that end, implementing powers should be conferred on the Commission to determine such common specifications regarding datasets, coding systems, technical specifications, including standards, specifications and profiles for data exchange, as well as requirements and principles related to security, confidentiality, integrity, patient safety and protection of personal data as well as	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	as well as specifications and requirements related to identification management and the use of electronic identification. Digital health authorities should contribute to the development of such common specifications.		specifications and requirements related to identification management and the use of electronic identification. Digital health authorities should contribute to the development of such common specifications.	specifications and requirements related to identification management and the use of electronic identification. Digital health authorities should contribute to the development of such common specifications.	
	Recital 34				
44	(34) In order to ensure an appropriate and effective enforcement of the requirements and obligations laid down in Chapter III of this		(34) In order to ensure an appropriate and effective enforcement of the requirements and obligations laid down in Chapter III of this	(34) In order to ensure an appropriate and effective enforcement of the requirements and obligations laid down in Chapter III of this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply. Depending on the organisation defined at national level, such market surveillance activities could be carried out by the digital health authorities ensuring the proper implementation of Chapter II or a separate market surveillance authority responsible for EHR systems. While designating digital health authorities as market surveillance authorities could have important practical advantages for the		Regulation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply. Depending on the organisation defined at national level, such market surveillance activities could be carried out by the digital health authorities ensuring the proper implementation of Chapter II or a separate market surveillance authority responsible for EHR systems. While designating digital health authorities as market surveillance authorities could have important practical advantages for the	Regulation, the system of market surveillance and compliance of products established by Regulation (EU) 2019/1020 should apply. Depending on the organisation defined at national level, such market surveillance activities could be carried out by the digital health authorities ensuring the proper implementation of Chapter II or a separate market surveillance authority responsible for EHR systems. While designating digital health authorities as market surveillance authorities could have important practical advantages for the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.		implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.	implementation of health and care, any conflicts of interest should be avoided, for instance by separating different tasks.	
		Recital 34a			
44a			***(34a) EHR systems could qualify as medical devices under Regulation (EU) 2017/745 or in-vitro diagnostic devices under Regulation (EU) 2017/746 of the European Parliament and of the Council[l]. While those EHR systems need to fulfil the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			requirements under each applicable regulation, Member States should take appropriate measures to ensure that the respective conformity assessment is carried out as a joint or coordinated procedure, as appropriate, inter alia by encouraging the same notified bodies to become responsible for the conformity assessment under each applicable regulation. _____ ***1. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).		
	Recital 35				
45	(35) Users of wellness applications, such as mobile applications, should be informed about the capacity of such applications to be connected and to supply data to EHR systems or to national electronic health solutions, in cases where data produced by wellness applications is useful for healthcare purposes. The capability of those		(35) Users of wellness applications, such as mobile applications, should be informed about the capacity of such applications to be connected and to supply data to EHR systems or to national electronic health solutions, in cases where data produced by wellness applications is useful for healthcare purposes. The capability of those	(35) Users of wellness applications, such as mobile applications, should be informed about the capacity of such applications to be connected and to supply data to EHR systems or to national electronic health solutions, in cases where data produced by wellness applications is useful for healthcare purposes. The capability of those	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	applications to export data in an interoperable format is also relevant for data portability purposes. Where applicable, users should be informed about the compliance of such applications with interoperability and security requirements. However, given the large number of wellness applications and the limited relevance for healthcare purposes of the data produced by many of them, a certification scheme for these applications would not be proportionate. A voluntary labelling scheme should therefore be established as an		applications to export data in an interoperable format is also relevant for data portability purposes. Where applicable, users should be informed about the compliance of such applications with interoperability and security requirements. However, given the large number of wellness applications and the limited relevance for healthcare purposes of the data produced by many of them, a certification scheme for these applications would not be proportionate. A ~~*voluntary*~~***mandatory*** labelling scheme ***for wellness applications***	applications to export data in an interoperable format is also relevant for data portability purposes. Where applicable, users should be informed about the compliance of such applications with interoperability and security requirements. However, given the large number of wellness applications and the limited relevance for healthcare purposes of the data produced by many of them, a certification scheme for these applications would not be proportionate. A voluntary labelling scheme should therefore be established as an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	appropriate mechanism for enabling the transparency for the users of wellness applications regarding compliance with the requirements, thereby supporting users in their choice of appropriate wellness applications with high standards of interoperability and security. The Commission may set out in implementing acts the details regarding the format and content of such label.		***claiming interoperability with EHR systems*** should therefore be established as an appropriate mechanism for enabling the transparency for the users of wellness applications regarding compliance with the requirements, thereby supporting users in their choice of appropriate wellness applications with high standards of interoperability and security. The Commission ~~*may*~~***should*** set out in implementing acts the details regarding the format and content of such label.	appropriate mechanism for enabling the transparency for the users of wellness applications regarding compliance with the requirements, thereby supporting users in their choice of appropriate wellness applications with high standards of interoperability and security. The Commission may set out in implementing acts the details regarding the format and content of such label.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 35a				
45a				**(35a) Member States should remain free to regulate the use of wellness applications as referred to in Article 31 in the context of the provision of healthcare, provided that such rules are in compliance with Union law.**	
	Recital 36				
46	(36) The distribution of		(36) The distribution of	(36) The distribution of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	information on certified EHR systems and labelled wellness applications is necessary to enable procurers and users of such products to find interoperable solutions for their specific needs. A database of interoperable EHR systems and wellness applications, which are not falling within the scope of Regulations (EU) 2017/745 and […] [AI act COM/2021/206 final] should therefore be established at Union level, similar to the European database on medical devices (Eudamed) established by Regulation		information on certified EHR systems and labelled wellness applications is necessary to enable procurers and users of such products to find interoperable solutions for their specific needs. A database of interoperable EHR systems and wellness applications, which are not falling within the scope of Regulations (EU) 2017/745 and […] [AI act COM/2021/206 final] should therefore be established at Union level, similar to the European database on medical devices (Eudamed) established by Regulation (EU) 2017/745.	information on certified EHR systems and labelled wellness applications is necessary to enable procurers and users of such products to find interoperable solutions for their specific needs. A database of interoperable EHR systems and wellness applications, which are not falling within the scope of Regulations (EU) 2017/745 and […] [AI act COM/2021/206 final] should therefore be established at Union level, similar to the European database on medical devices (Eudamed) established by Regulation (EU) 2017/745.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(EU) 2017/745. The objectives of the EU database of interoperable EHR systems and wellness applications should be to enhance overall transparency, to avoid multiple reporting requirements and to streamline and facilitate the flow of information. For medical devices and AI systems, the registration should be maintained under the existing databases established respectively under Regulations (EU) 2017/745 and […] [AI act COM/2021/206 final], but the compliance with interoperability		The objectives of the EU database of interoperable EHR systems and wellness applications should be to enhance overall transparency, to avoid multiple reporting requirements and to streamline and facilitate the flow of information. For medical devices and AI systems, the registration should be maintained under the existing databases established respectively under Regulations (EU) 2017/745 and […] [AI act COM/2021/206 final], but the compliance with interoperability requirements should be	The objectives of the EU database of interoperable EHR systems and wellness applications should be to enhance overall transparency, to avoid multiple reporting requirements and to streamline and facilitate the flow of information. For medical devices and AI systems, the registration should be maintained under the existing databases established respectively under Regulations (EU) 2017/745 and […] [AI act COM/2021/206 final], but the compliance with interoperability requirements should be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	requirements should be indicated when claimed by manufacturers, to provide information to procurers.		indicated when claimed by manufacturers, to provide information to procurers.	indicated when claimed by manufacturers, to provide information to procurers.	
	Recital 36a				
46a			***(36a) The uptake of real-world data and real-world evidence, including patient-reported outcomes, for evidence-based regulatory and policy purposes as well as for research, health technology assessment and clinical objectives should be encouraged. Real-world***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data and real-world evidence have the potential to complement health data currently made available.		
	Recital 37				
47	(37) For the secondary use of the clinical data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by Regulation (EU) 2016/679 for a Union law should be used as a basis and rules		(37) For the secondary use of ~~*the clinical*~~***personal electronic health*** data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by Regulation (EU) 2016/679 for a Union law should be	(37) **Without hindering or replacing contractual or other voluntary mechanisms in place, this Regulation is aimed at establishing a common mechanism to access electronic health data for secondary use, which makes it mandatory for data holders to make the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and mechanisms and providing suitable and specific measures to safeguard the rights and freedoms of the natural persons. This Regulation provides the legal basis in accordance with Articles 9(2) (g), (h), (i) and (j) of Regulation (EU) 2016/679 for the secondary use of health data, establishing the safeguards for processing, in terms of lawful purposes, trusted governance for providing access to health data (through health data access bodies) and processing in a secure environment, as well as modalities for data		used as a basis ~~and~~*for* rules and mechanisms~~ *and*~~ providing suitable and specific measures to safeguard the rights and freedoms of the natural persons. ***For the purpose of processing electronic health data for secondary use, one of the legal bases set out in Article 6(1), points (a), (c), (e) or (f), of Regulation (EU) 2016/679 combined with Article 9(2) of that Regulation should be required. The most relevant processing condition listed in Article 9(2) of Regulation (EU) 2016/679 in this context is that of substantial public***	**data they hold available on the basis of a data permit or a data request.** For the secondary use of **electronic health** ~~the clinical~~ data for research, innovation, policy making, regulatory purposes, patient safety or the treatment of other natural persons, the possibilities offered by ~~Regulation~~**Regulations** (EU) 2016/679 ~~for a~~ **and (EU) 2018/1725 for** Union ~~law~~**laws** should be used as a basis ~~and rules and mechanisms and providing~~**for the processing as well as** suitable and specific measures to safeguard the	

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	processing, set out in the data permit. At the same time, the data applicant should demonstrate a legal basis pursuant to Article 6 of Regulation (EU) 2016/679, based on which they could request access to data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV. More specifically: for processing of electronic health data held by the data holder pursuant to this Regulation, this Regulation creates the legal obligation in the sense of Article 6(1) point (c) of Regulation (EU) 2016/679 for disclosing the data by		***interest, the provision of health or social care, public interest in the area of public health and research. Hence,*** this Regulation provides the legal basis in accordance with ***Article 6 and*** Articles 9(2) (g), (h), (i) and (j) of Regulation (EU) 2016/679 for the secondary use of health data, establishing the safeguards for processing, in terms of lawful purposes, trusted governance for providing access to health data (through health data access bodies) and processing in a secure environment, as well as modalities for data	rights and freedoms of ~~the~~ natural persons. This Regulation provides ~~the~~**a** legal basis in accordance with **Regulation (EU) 2016/679 and (EU) 2018/1725 for the secondary use of personal electronic health data including the safeguards to permit the processing of special categories of data, in accordance with** Articles 9(2) (g), (h), (i) and (j) of Regulation (EU) 2016/679 ~~for the secondary use of health data, establishing the safeguards for processing~~**and Articles 10(2) (g), (h), (i) and (j) of (EU) 2018/1725**, in terms	

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	the data holder to health data access bodies, while the legal basis for the purpose of the initial processing (e.g. delivery of care) is unaffected. This Regulation also meets the conditions for such processing pursuant to Articles 9(2) (h),(i),(j) of the Regulation (EU) 2016/679. This Regulation assigns tasks in the public interest to the health data access bodies (running the secure processing environment, processing data before they are used, etc.) in the sense of Article 6(1)(e) of Regulation (EU) 2016/679 to the health data		processing, set out in the data permit. ~~*At the same time, the data applicant should demonstrate a legal basis pursuant to Article 6 of Regulation (EU) 2016/679, based on which they could request access to data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV.*~~ More specifically~~:~~**,** for processing of electronic health data held by the ***health*** data holder pursuant to this Regulation, this Regulation creates the legal obligation in the sense of Article 6(1)**,** point (c)**,** of Regulation (EU) 2016/679 for	of lawful purposes, trusted governance for providing access to health data (through health data access bodies) and processing in a secure environment, as well as modalities for data processing, set out in the data permit. ~~At the same time, the data applicant~~**Consequently, Member States may no longer maintain or introduce under Article 9(4) of Regulation (EU) 2016/679 further conditions, including limitations and specific provisions requesting the consent of natural persons, with regard to**	

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	access bodies, and meets the requirements of Article 9(2)(h),(i),(j) of the Regulation (EU) 2016/679. Therefore, in this case, this Regulation provides the legal basis under Article 6 and meets the requirements of Article 9 of that Regulation on the conditions under which electronic health data can be processed. In the case where the user has access to electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or		disclosing the data by the ***health*** data holder to health data access bodies, while the legal basis for the purpose of the initial processing (e.g. delivery of care) is unaffected. This Regulation ~~*also meets the conditions for such processing pursuant to Articles 9(2) (h),(i),(j) of the Regulation (EU) 2016/679. This Regulation*~~ assigns tasks in the public interest to the health data access bodies (running the secure processing environment, processing data before they are used, etc.) in the sense of Article ~~*6(1)(e) of Regulation (EU) 2016/679*~~	**the processing for secondary use of personal electronic health data under this Regulation. At the same time data applicants** should demonstrate a legal basis pursuant to Article 6 of Regulation (EU) 2016/679 **or Article 5 of Regulation (EU) 2018/1725, where applicable**, based on which they could request access to **electronic health** data pursuant to this Regulation and should fulfil the conditions set out in Chapter IV. More specifically~~:~~**,** for processing of electronic health data held by the ~~data holder~~	

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	(f), of Regulation (EU) 2016/679 and explain the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation: on the basis of the applicable legislation, where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on Article 6(1), point (f), of Regulation (EU) 2016/679. If the user relies upon a legal basis offered by Article 6(1), point (e), it should make reference to another EU or national law, different from this Regulation, mandating the		~~to the health data access bodies, and meets the requirements of Article 9(2)(h),(i)~~**6(1), point (e)**~~,(j) of the~~ **of** Regulation (EU) 2016/679~~. Therefore, in this case, this Regulation provides the legal basis under Article 6~~ and meets the requirements of Article ~~9 of that Regulation on the conditions under which electronic health data can be processed. In the case where the user has access to electronic health data (for secondary use of data for one~~**9(2), points (g) to (j),** of the ~~purposes defined in this Regulation), the data user should demonstrate its~~	~~pursuant to this Regulation,~~**health data holders** this Regulation creates the legal obligation in the sense of Article 6(1) point (c) of Regulation (EU) 2016/679**, in accordance with Article 9(2)(i) and (j) of the same Regulation for making available the personal electronic health** ~~for disclosing the~~ data by the **health** data holder to health data access bodies, while the legal basis for the purpose of the initial processing (e.g. **providing** delivery of ~~care~~**healthcare**) is unaffected. This Regulation also ~~meets the conditions for such~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	user to process personal health data for the compliance of its tasks. If the lawful ground for processing by the user is Article 6(1), point (f), of Regulation (EU) 2016/679, in this case it is this Regulation that provides the safeguards. In this context, the data permits issued by the health data access bodies are an administrative decision defining the conditions for the access to the data.		~~*legal basis pursuant to Articles 6(1), points (e) or (f), of*~~ Regulation (EU) 2016/679***. At the same time, the*** ~~*and explain the specific legal basis on which it relies as part of the application for access to electronic*~~ health data ~~*pursuant to this Regulation: on the basis of the applicable legislation, where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or on*~~***access body should verify the compliance with*** Article ~~*6(1), point (f),*~~***6*** of Regulation (EU) 2016/679~~.~~ ~~*If the user relies upon a legal basis offered by*~~	~~processing pursuant to Articles 9(2) (h),(i),(j) of the Regulation (EU) 2016/679. This Regulation~~ assigns tasks in the public interest ~~to the health data access bodies (running the secure processing environment, processing data before they are used, etc.)~~ in the sense of Article 6(1)(e) of Regulation (EU) 2016/679 to the health data access bodies, and meets the requirements of Article 9(2)(h),(i),(j) of the Regulation (EU) 2016/679~~. Therefore, in this case, this Regulation provides the legal basis under Article 6 and meets the requirements~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			~~*Article 6(1), point (e), it should make reference to another EU or national law, different from this Regulation, mandating the user to process personal health data*~~ ***, combined with Article 9(2) thereof, based on which they should be able to issue a data permit*** for the ~~*compliance of its tasks. If the lawful ground for*~~ processing ~~*by the user is Article 6(1), point (f), of Regulation (EU) 2016/679, in this case it is*~~***of personal electronic health data pursuant to*** this Regulation that ~~*provides the safeguards. In this context, the data permits issued by*~~	~~of Article 9 of that Regulation~~ **for the health data access body's processing of personal electronic health data when the body is fulfilling its tasks of gathering, combining, preparing, including pseudonymisation and anonymisation of the data, and makes those data available to the health data user for secondary use** on the ~~conditions under which electronic health data can be processed~~**basis of a data permit or a data request**. In the case where the **health data** user has access to **personal**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			~~*the health data access bodies are an administrative decision defining the conditions for the access to the data*~~***should fulfil the requirements and conditions set out in Chapter IV of this Regulation***.	electronic health data (for secondary use of data for one of the purposes defined in this Regulation), the **health** data user should demonstrate its legal basis pursuant to Articles 6(1), points (e) or (f), of Regulation (EU) 2016/679 **or pursuant to Article 5(1), point (a) of Regulation (EU) 2018/1725** and explain the specific legal basis on which it relies as part of the application for access to electronic health data pursuant to this Regulation~~:~~ ~~on the basis of the applicable legislation, where the~~**. If the health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data user relies upon a legal basis ~~under Regulation (EU) 2016/679 is~~**offered by** Article 6(1), point (e)~~, or on Article 6(1), point (f),~~ of Regulation (EU) 2016/679~~.~~ ~~If the user relies upon a legal basis offered by Article 6(1), point (e)~~ **or Article 5(1), point (a) of Regulation (EU) 2018/1725**, it should make reference to another ~~EU~~**Union** or national law, different from this Regulation, mandating the **health data** user to process personal health data for the compliance of its tasks. If the lawful ground for processing by the **health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data user is Article 6(1), point (f), of Regulation (EU) 2016/679, in this case it is this Regulation that provides the safeguards. In this context, the data permits issued by the health data access bodies are an administrative decision defining the conditions for the access to the data.	
	Recital 37a				
47a			***(37a) In the case where the health data user has access to electronic health data for secondary use of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data for one of the purposes defined in this Regulation, the health data user should demonstrate the specific legal ground on which it relies as part of the application for access to electronic health data pursuant to this Regulation, namely, on the basis of the applicable law, where the legal basis under Regulation (EU) 2016/679 is Article 6(1), point (e), or Article 6(1), point (f), thereof. If the health data user relies upon the ground provided for in Article 6(1), point (e), it should make reference to another Union or national law, requiring		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the user to process personal health data for the compliance of its tasks. If the ground for processing by the health data user is Article 6(1), point (f), of Regulation (EU) 2016/679, appropriate and necessary safeguards should be determined in accordance with this Regulation. In this context, the data permits issued by the health data access bodies should be an administrative decision defining the conditions for the access to the data.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 37a				
47b				**(37a) The secondary use of electronic health data can bring great societal benefits. To achieve this goal, it is important that data sets made available for secondary use by the present Regulation are as complete as possible. This Regulation provides the necessary safeguards to mitigate certain risks involved in the realisation of those benefits. The secondary use of electronic health data is based on pseudonymised**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				or anonymised data, in order to preclude the identification of the data subjects. However, to balance the need of data users to have exhaustive and representative datasets with the autonomy of natural persons over data that are considered particularly sensitive, Member State should be able to allow natural persons to indicate that they do not wish for their personal electronic health data to be made available for secondary use pursuant to this Regulation. To do so, Member States may	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				introduce a specific right to object from the processing of personal electronic health data for secondary use which complements the right to object set out by article 21 of Regulation (EU) 2016/679. It is appropriate to leave Member States free to decide to introduce and modulate such a right as it involves a balance between individual autonomy and the availability of health data for secondary use purposes, which is best made at national level, taking into account Member States' specific	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				situations and historical experiences. Should a Member State choose to provide for such a right, it should also define how and where to exercise it and facilitate its exercise. This right can be implemented at the level of the health data holder that is subject to a legal obligation to make data available to the health data access body, at the level of the health data intermediary entity, or at the level of the health data access body, or at several levels. As such a right can affect the representativity of datasets, statistics	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				providing sufficient information for data users shall be available at Member State level to assess the impact of the exercise of this right on the utility of the dataset. Where a Member State does not introduce a specific right to object in accordance with article 35F of this regulation, solely Article 21 of Regulation (EU) 2016/679 will apply.	
	Recital 38				
48					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(38) In the context of the EHDS, the electronic health data already exists and is being collected by healthcare providers, professional associations, public institutions, regulators, researchers, insurers etc. in the course of their activities. Some categories of data are collected primarily for the provisions of healthcare (e.g. electronic health records, genetic data, claims data, etc.), others are collected also for other purposes such as research, statistics, patient safety, regulatory activities or policy making (e.g. disease		(38) In the context of the EHDS, the electronic health data already exists and is being collected by healthcare providers, professional associations, public institutions, regulators, researchers, insurers etc. in the course of their activities. Some categories of data are collected primarily for the provisions of healthcare (e.g. electronic health records, genetic data, claims data, etc.), others are collected also for other purposes such as research, statistics, patient safety, regulatory activities or policy making (e.g. disease	(38) In the context of the EHDS, the electronic health data already exists and is being collected by healthcare providers, professional associations, public institutions, regulators, researchers, insurers etc. in the course of their activities. Some categories of data are collected primarily for the provisions of healthcare (e.g. electronic health records, genetic data, claims data, etc.), others are collected also for other purposes such as research, statistics, patient safety, regulatory activities or policy making (e.g. disease	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	registries, policy making registries, registries concerning the side effects of medicinal products or medical devices, etc.). For instance, European databases that facilitate data (re)use are available in some areas, such as cancer (European Cancer Information System) or rare diseases (European Platform on Rare Disease Registration, ERN registries, etc.). These data should also be made available for secondary use. However, much of the existing health-related data is not made available for purposes other than that for		registries, policy making registries, registries concerning the side effects of medicinal products or medical devices, etc.). For instance, European databases that facilitate data (re)use are available in some areas, such as cancer (European Cancer Information System) or rare diseases (European Platform on Rare Disease Registration, ERN registries, etc.). These data should also be made available for secondary use. However, much of the existing health-related data is not made available for purposes other than that for	registries, policy making registries, registries concerning the side effects of medicinal products or medical devices, etc.). For instance, European databases that facilitate data (re)use are available in some areas, such as cancer (European Cancer Information System) or rare diseases (European Platform on Rare Disease Registration, ERN registries, etc.). These data should also be made available for secondary use. However, much of the existing health-related data is not made available for purposes other than that for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	which they were collected. This limits the ability of researchers, innovators, policy-makers, regulators and doctors to use those data for different purposes, including research, innovation, policy-making, regulatory purposes, patient safety or personalised medicine. In order to fully unleash the benefits of the secondary use of electronic health data, all data holders should contribute to this effort in making different categories of electronic health data they are holding available for secondary use.		which they were collected. This limits the ability of researchers, innovators, policy-makers, regulators and doctors to use those data for different purposes, including research, innovation, policy-making, regulatory purposes, patient safety or personalised medicine. In order to fully unleash the benefits of the secondary use of electronic health data, all ***health*** data holders should contribute to this effort in making different categories of electronic health data they are holding available for secondary use ***provided that such effort is always made***	which they were collected. This limits the ability of researchers, innovators, policy-makers, regulators and doctors to use those data for different purposes, including research, innovation, policy-making, regulatory purposes, patient safety or personalised medicine. In order to fully unleash the benefits of the secondary use of electronic health data, all data holders should contribute to this effort in making different categories of electronic health data they are holding available for secondary use.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			through effective and secured processes, such as aggregation and randomisation, and with due respect for professional duties, such as confidentiality duties.		
	Recital 39				
49	(39) The categories of electronic health data that can be processed for secondary use should be broad and flexible enough to accommodate the evolving needs of data users, while remaining		(39) The categories of electronic health data that can be processed for secondary use should be broad and flexible enough to accommodate the evolving needs of ***health*** data users, while remaining	(39) The categories of electronic health data that can be processed for secondary use should be broad and flexible enough to accommodate the evolving needs of data users, while remaining	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	limited to data related to health or known to influence health. It can also include relevant data from the health system (electronic health records, claims data, disease registries, genomic data etc.), as well as data with an impact on health (for example consumption of different substances, homelessness, health insurance, minimum income, professional status, behaviour, including environmental factors (for example, pollution, radiation, use of certain chemical substances). They can also include person-		limited to data related to health or known to influence health. It can also include relevant data from the health system (electronic health records, claims data, disease registries, genomic data etc.), as well as data with an impact on health (for example consumption of different substances, ~~homelessness, health insurance, minimum income, professional~~***socio-economic*** status, behaviour, including environmental factors (for example, pollution, radiation, use of certain chemical substances). They can also	limited to data related to health or known to influence health. It can also include relevant data from the health system (electronic health records, claims data, disease registries, genomic data etc.), as well as data with an impact on health (for example consumption of different substances, homelessness, health insurance, minimum income, professional status, behaviour, including environmental factors (for example, pollution, radiation, use of certain chemical substances). They can also include person-	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	generated data, such as data from medical devices, wellness applications or other wearables and digital health applications. The data user who benefits from access to datasets provided under this Regulation could enrich the data with various corrections, annotations and other improvements, for instance by supplementing missing or incomplete data, thus improving the accuracy, completeness or quality of data in the dataset. To support the improvement of the original database and further use of the enriched dataset, the dataset with such		include ~~*person-generated data, such as*~~***automatically generated*** data from medical devices~~*, wellness applications or other wearables and digital health*~~ ***and person-generated data, such as wellness*** applications. The ***health*** data user who benefits from access to datasets provided under this Regulation could enrich the data with various corrections, annotations and other improvements, for instance by supplementing missing or incomplete data, thus improving the accuracy, completeness or quality of data in the	generated data, such as data from medical devices, wellness applications or other wearables and digital health applications. The data user who benefits from access to datasets provided under this Regulation could enrich the data with various corrections, annotations and other improvements, for instance by supplementing missing or incomplete data, thus improving the accuracy, completeness or quality of data in the dataset. To support the improvement of the original database and further use of the enriched dataset, the dataset with such	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	improvements and a description of the changes should be made available free of charge to the original data holder. The data holder should make available the new dataset, unless it provides a justified notification against it to the health data access body, for instance in cases of low quality of the enrichment. Secondary use of non-personal electronic data should also be ensured. In particular, pathogen genomic data hold significant value for human health, as proven during the COVID-19 pandemic. Timely access to and		dataset. ***Health data users should be encouraged to report critical errors in datasets to health data access bodies***. To support the improvement of the original database and further use of the enriched dataset, the dataset with such improvements and a description of the changes should be made available free of charge to the original data holder. The data holder should make available the new dataset, unless it provides a justified notification against it to the health data access body, for instance in cases of low quality of the enrichment.	improvements and a description of the changes should be made available free of charge to the original data holder. The data holder should make available the new dataset, unless it provides a justified notification against it to the health data access body, for instance in cases of low quality of the enrichment. Secondary use of non-personal electronic data should also be ensured. In particular, pathogen genomic data hold significant value for human health, as proven during the COVID-19 pandemic. Timely access to and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	sharing of such data has proven to be essential for the rapid development of detection tools, medical countermeasures and responses to public health threats. The greatest benefit from pathogen genomics effort will be achieved when public health and research processes share datasets and work mutually to inform and improve each other.		Secondary use of non-personal electronic data should also be ensured. In particular, pathogen genomic data hold significant value for human health, as proven during the COVID-19 pandemic. Timely access to and sharing of such data has proven to be essential for the rapid development of detection tools, medical countermeasures and responses to public health threats. The greatest benefit from pathogen genomics effort will be achieved when public health and research processes share datasets and work mutually	sharing of such data has proven to be essential for the rapid development of detection tools, medical countermeasures and responses to public health threats. The greatest benefit from pathogen genomics effort will be achieved when public health and research processes share datasets and work mutually to inform and improve each other.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to inform and improve each other.		
	Recital 39a				
49a			***(39a) In order to guarantee trust in the patient-physician relationship, the principle of professional secrecy and the patient's right to confidentiality should be safeguarded when digitalising healthcare services. A relationship of trust between patients and health professionals and healthcare providers and***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			other holders of personal health data is a paramount element of the provision of health or social care or treatment. It is within that context that the patient or the legal representative of the patient should have a say in the processing of their health data for secondary use in the form of a right to opt-out of the processing of all or parts of their health data for secondary use for some or all purposes. An easily understandable and accessible opt-out mechanism in a user-friendly format should be provided for in this regard.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			However, due to the sensitive nature of human genetic, genomic and proteomic data, data from biobanks and to the nature of the use of data from wellness applications, it is appropriate to provide that the secondary use of such data can only occur following the consent of the natural person concerned in accordance with Article 4(11) of the Regulation (EU) 2016/679. An opt-in mechanism whereby data subjects explicitly consent or give their permission to the processing of part or all of such data for some or all		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			secondary use purposes should be envisaged. Where data subjects explicitly consent to the use of parts or all of this data for some or all secondary use purposes, they should be made aware of the sensitive nature of the data they are sharing. Moreover, it is imperative to provide natural persons with sufficient information regarding their right to opt-out, including on the possibility of reconsidering their choice of opting-out and agreeing to some or all of their health data being processed for secondary use at a later point.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 39a				
49b				**(39a) In order to increase the effectiveness of the secondary use of personal electronic health data, and to fully benefit from the possibilities offered by this Regulation in terms of, among others, health research, innovation, policy-making, and regulatory purposes, personal electronic health data for secondary use should be made available prioritising the datasets**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				according to their usefulness, quality and readiness. This Regulation aims to ensure the availability in the EHDS of electronic health data described in Chapter IV that are accessible, ready and suitable for the purpose of creating scientific, innovative and societal value and quality.	
	Recital 40				
50	(40) The data holders can be public, non for profit or private health or care		(40) The ***health*** data holders ***in the context of secondary use of electronic***	(40) The data holders can be public, non for profit or private health or care	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the health sector that process the categories of health and health related data mentioned above. In order to avoid a disproportionate burden on small entities, micro-enterprises are excluded from the obligation to make their data available for secondary use in the framework of EHDS. The public or private entities often receive public funding, from national or		***health data*** can be public, non for profit or private health or care providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the health sector that process the categories of health and health related data mentioned above ***To the extent that they process personal electronic health data, health data holders are controllers within the meaning of Regulation (EU) 2016/679 in the health or care sector***. In order to avoid a	providers, public, non for profit and private organisations, associations or other entities, public and private entities that carry out research with regards to the ~~health sector~~**healthcare or care sectors, entities developing products and services intended for the healthcare or care sectors and Union institutions, bodies, offices or agencies** that process the categories of health and ~~health~~**healthcare data mentioned above, as well as mortality registries. Also included in the category of data holders are entities in the care**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union funds to collect and process electronic health data for research, statistics (official or not) or other similar purposes, including in area where the collection of such data is fragmented of difficult, such as rare diseases, cancer etc. Such data, collected and processed by data holders with the support of Union or national public funding, should be made available by data holders to health data access bodies, in order to maximise the impact of the public investment and support research, innovation, patient safety or policy making benefitting		disproportionate burden on small entities, micro-enterprises are excluded from the obligation to make their data available for secondary use in the framework of EHDS. ***Health data access bodies should provide specific support to small enterprises, in particular medical practioners and pharmacies, in complying with their obligation to make data available for secondary use.*** The public or private entities often receive public funding, from national or Union funds to collect and process electronic health data for	**sector such as nursing homes, day-care centres, entities providing services for people with disabilities, business and technological activities** related **to care such as orthopaedics and companies providing care services. Legal persons developing products and services intended for the healthcare or care sectors, and wellness applications should also be data holders. This consideration applies both if these entities or bodies are developing new products or services, or if they already have**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the society. In some Member States, private entities, including private healthcare providers and professional associations, play a pivotal role in the health sector. The health data held by such providers should also be made available for secondary use. At the same time, data benefiting from specific legal protection such as intellectual property from medical device companies or pharmaceutical companies often enjoy copyright protection or similar types of protection. However, public authorities and regulators should have		research, statistics (official or not) or other similar purposes, including in area where the collection of such data is fragmented of difficult, such as rare diseases, cancer etc. Such data, collected and processed by ***health*** data holders with the support of Union or national public funding, should be made available by ***health*** data holders to health data access bodies, in order to maximise the impact of the public investment and support research, innovation, patient safety or policy making benefitting the society. In some	**products on the market**~~data mentioned above~~. In order to avoid a disproportionate burden**, natural persons and** ~~on small entities,~~ micro-enterprises are**, as a general rule,** excluded from the ~~obligation to make their data available~~**obligations as data holders** for secondary use in the framework of EHDS. **Member States should, however, be able to extend the obligations of data holders to natural persons and micro-enterprises in their national legislation. Due to the diversity in the structure of healthcare**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access to such data, for instance in the event of pandemics, to verify defective devices and protect human health. In times of severe public health concerns (for example, PIP breast implants fraud) it appeared very difficult for public authorities to get access to such data to understand the causes and knowledge of manufacturer concerning the defects of some devices. The COVID-19 pandemic also revealed the difficulty for policy makers to have access to health data and other data related to health. Such data should be made		Member States, private entities, including private healthcare providers and professional associations, play a pivotal role in the health sector. The health data held by such providers should also be made available for secondary use. At the same time, data benefiting from specific legal protection such as intellectual property from medical device companies or pharmaceutical companies often enjoy copyright protection or similar types of protection ***and should be made available while taking all necessary measures to***	**systems of the Member States and the administrative burden the inclusion of the care sector may entail at the national level, it should be possible to exclude the care sector from the obligations of data holders by way of national legislation. In order to reduce the administrative burden, and in the light of the effectiveness and efficiency principles, Member States should be able to decide, by way of national legislation that for certain categories of data holders their duties as data holders are to be**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	available for public and regulatory activities, supporting public bodies to carry out their legal mandate, while complying with, where relevant and possible, the protection enjoyed by commercial data. Specific rules in relation to the secondary use of health data should be provided. Data altruism activities may be carried out by different entities, in the context of Regulation […] [Data Governance Act COM/2020/767 final] and taking into account the specificities of the health sector.		***protect such rights***. However, public authorities and regulators should have access to such data, for instance in the event of pandemics, to verify defective devices and protect human health. In times of severe public health concerns (for example, PIP breast implants fraud) it appeared very difficult for public authorities to get access to such data to understand the causes and knowledge of manufacturer concerning the defects of some devices. The COVID-19 pandemic also revealed the difficulty for policy makers to have	**carried out by health data intermediation entities.** The public or private entities often receive public funding, from national or Union funds to collect and process electronic health data for research, statistics (official or not) or other similar purposes, including in ~~area~~**areas** where the collection of such data is fragmented of difficult, such as rare diseases, cancer etc. Such data, collected and processed by data holders with the support of Union or national public funding, should be made available by data holders to health data access bodies, in order to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			access to health data and other data related to health. Such data should be made available for public and regulatory activities, supporting public bodies to carry out their legal mandate, while complying with, where relevant and possible, the protection enjoyed by commercial data. Specific rules in relation to the secondary use of health data should be provided. Data altruism activities may be carried out by different entities, in the context of Regulation […] [Data Governance Act COM/2020/767 final] and taking into account the	maximise the impact of the public investment and support research, innovation, patient safety or policy making benefitting the society. In some Member States, private entities, including private healthcare providers and professional associations, play a pivotal role in the health sector. The health data held by such providers should also be made available for secondary use. At the same time, data benefiting from specific legal protection such as intellectual property from medical device companies or pharmaceutical	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			specificities of the health sector.	companies often enjoy copyright protection or similar types of protection. However, public authorities and regulators should have access to such data, for instance in the event of pandemics, to verify defective devices and protect human health. In times of severe public health concerns (for example, PIP breast implants fraud) it appeared very difficult for public authorities to get access to such data to understand the causes and knowledge of ~~manufacturer~~**manufacturers** concerning the defects of some devices. The COVID-	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				19 pandemic also revealed the difficulty for policy makers to have access to health data and other data related to health. Such data should be made available for public and regulatory activities, supporting public bodies to carry out their legal mandate, while complying with, where relevant and possible, the protection enjoyed by commercial data. Specific rules in relation to the secondary use of health data should be provided. Data altruism activities may be carried out by different entities, in the context of Regulation […] [Data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Governance Act COM/2020/767 final] and taking into account the specificities of the health sector.	
	Recital 40a				
50a			***(40a) Different demographic groups have varying degrees of digital literacy, which can affect natural persons' ability to exercise their rights to control their electronic health data. In addition to the right for natural persons to authorise***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			another natural person of their choice to access or control their electronic health data on their behalf, Member States should create targeted national digital literacy programmes, including programmes to maximise social inclusion and to ensure all natural persons can effectively exercise their rights under this Regulation. Member States should also provide patient-centric guidance to natural persons in relation to the use of electronic health records and primary use of their personal electronic health data.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Guidance should be tailored to the patient's level of digital health literacy, with specific attention to be given to the needs of vulnerable groups.		
	Recital 40b				
50b			***(40b) Clinical trials and studies are of utmost importance in fostering innovation within the Union for the benefit of Union patients. In order to incentivise continuous Union leadership in this domain, the sharing of the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			clinical trials data through the EHDS for secondary use should be consistent with the relevant transparency provisions laid down in Union law including Regulation (EU) .../... [proposal for a Regulation on blood, tissue, cells and organs (SoHO) COM(2022)338 final], Regulations (EC) No 726/2004[1] and (EU) 2019/6[2] of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council[3] regarding veterinary and human medicines and establishing		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the EMA, Regulation (EC) No 141/2000 of the European Parliament and of the Council[4] related to medicinal products for rare diseases ('orphan medicines'), Regulation (EC) No 1901/2006 of the European Parliament and of the Council[5] on medicinal products for children, Regulation (EC) No 1394/2007 of the European Parliament and of the Council[6] on advanced therapy medicinal products, Regulation (EU) No 536/2014 of the European Parliament and of the Council[7] on clinical trials,		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation (EU) No 2017/745 and Regulation (EU) No 2017/746. _____ ***1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).*** ***2. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).*** ***3. Directive 2001/83/EC of the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67). ***4. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).*** ***5. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).*** ***6. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121). ***7. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).***		
	Recital 40a				
50c				**(40a) Electronic health data protected by intellectual property rights or trade secrets can**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				be very useful for secondary use. While they should be made available to the extent possible, however, this Regulation should not be used to reduce or circumvent such protection. It is for the Health Data Access Body to assess how to preserve this protection while also enabling access to such data for health data users to the extent possible. If it is unable to do so, it should inform the health data user and explain why it is not possible to provide access to such data. Legal, organisational and technical measures to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				preserve intellectual property rights or trade secrets could include common electronic health data access contractual arrangements, specific obligations in relation to such rights within the data permit, pre-processing the data to generate derived data that protects a trade secret but still has utility for the user or configuration of the secure processing environment so that such data is not accessible by the health data user.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 40b				
50d				**(40b) Taking into account the specific purposes of the processing, data should be anonymised or pseudonymised as early as possible in the chain of making data available for secondary use. Pseudonymisation and anonymisation can be carried out by the health data access bodies or by the health data holders. As data controllers, health data access bodies and health data holders may delegate these tasks to**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data processors.	
	Recital 41				
51	(41) The secondary use of health data under EHDS should enable the public, private, not for profit entities, as well as individual researchers to have access to health data for research, innovation, policy making, educational activities, patient safety, regulatory activities or personalised medicine, in line with the purposes set out in this Regulation.		(41) The secondary use of health data under EHDS should enable the public, private, not for profit entities, as well as individual researchers***, with a demonstrated link to the field of public health,*** to have access to health data for research, innovation, policy making, educational activities, patient safety, regulatory activities or personalised medicine, in	(41) The secondary use of health data under EHDS should enable the public, private, not for profit entities, as well as individual researchers to have access to health data for research, innovation, policy making, educational activities, patient safety, regulatory activities or personalised medicine, in line with the purposes set out in this Regulation.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Access to data for secondary use should contribute to the general interest of the society. Activities for which access in the context of this Regulation is lawful may include using the electronic health data for tasks carried out by public bodies, such as exercise of public duty, including public health surveillance, planning and reporting duties, health policy making, ensuring patient safety, quality of care, and the sustainability of health care systems. Public bodies and Union institutions, bodies, offices and agencies may require to		line with the purposes set out in this Regulation. Access to data for secondary use should contribute to the general interest of the society. ***In particular, the secondary use of health data for research and development purposes should contribute to a benefit to society in the form of new medicines, medical devices, health care products and services at affordable and fair prices for Union citizens, as well as to enhancing access to and the availability of such products and services in all Member States.*** Activities	Access to data for secondary use should contribute to the general interest of the society. Activities for which access in the context of this Regulation is lawful may include using the electronic health data for tasks carried out by public bodies, such as exercise of public duty, including public health surveillance, planning and reporting duties, health policy making, ensuring patient safety, quality of care, and the sustainability of health care systems. Public bodies and Union institutions, bodies, offices and agencies may require to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	have regular access to electronic health data for an extended period of time, including in order to fulfil their mandate, which is provided by this Regulation. Public sector bodies may carry out such research activities by using third parties, including sub-contractors, as long as the public sector body remain at all time the supervisor of these activities. The provision of the data should also support activities related to scientific research (including private research), development and innovation, producing goods and services for the		for which access in the context of this Regulation is lawful may include using the electronic health data for tasks carried out by public bodies, such as exercise of public duty, including public health surveillance, planning and reporting duties, health policy making, ensuring patient safety, quality of care, and the sustainability of health care systems. Public bodies and Union institutions, bodies, offices and agencies may require to have regular access to electronic health data for an extended period of time, including in order to fulfil	have regular access to electronic health data for an extended period of time, including in order to fulfil their mandate, which is provided by this Regulation. Public sector bodies may carry out such research activities by using third parties, including sub-contractors, as long as the public sector body remain at all ~~time~~**times** the supervisor of these activities. The provision of the data should also support activities related to scientific research (including private research), development and innovation, producing goods and services for the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health or care sectors, such as innovation activities or training of AI algorithms that could protect the health or care of natural persons. In some cases, the information of some natural persons (such as genomic information of natural persons with a certain disease) could support the diagnosis or treatment of other natural persons. There is a need for public bodies to go beyond the emergency scope of Chapter V of Regulation […] [Data Act COM/2022/68 final]. However, the public sector bodies may request the support of health data		their mandate, which is provided by this Regulation. Public sector bodies may carry out such research activities by using third parties, including sub-contractors, as long as the public sector body remain at all time the supervisor of these activities. The provision of the data should also support activities related to scientific research (including private research~~)~~, development and innovation, producing goods and services for the health or care sectors, such as innovation activities or training of ~~AI~~***artificial intelligence*** algorithms that	health or care sectors, such as innovation activities or training of AI algorithms that could protect the health or care of natural persons. In some cases, the information of some natural persons (such as genomic information of natural persons with a certain disease) could support the diagnosis or treatment of other natural persons. There is a need for public bodies to go beyond the emergency scope of Chapter V of Regulation […] [Data Act COM/2022/68 final]. However, the public sector bodies may request the support of health data	

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	access bodies for processing or linking data. This Regulation provides a channel for public sector bodies to obtain access to information that they require for fulfilling their tasks assigned to them by law, but does not extend the mandate of such public sector bodies. Any attempt to use the data for any measures detrimental to the natural person, to increase insurance premiums, to advertise products or treatments, or develop harmful products should be prohibited.		could protect the health or care of natural persons). In some cases, the information of some natural persons (such as genomic information of natural persons with a certain disease) could support the diagnosis or treatment of other natural persons. There is a need for public bodies to go beyond the emergency scope of Chapter V of Regulation […] [Data Act COM/2022/68 final]. However, the public sector bodies may request the support of health data access bodies for processing or linking data. This Regulation provides a	access bodies for processing or linking data. This Regulation provides a channel for public sector bodies to obtain access to information that they require for fulfilling their tasks assigned to them by law, but does not extend the mandate of such public sector bodies. Any attempt to use the data for any measures detrimental to the natural person, to increase insurance premiums, to **engage in activities potentially detrimental to the natural persons related to employment, pension and banking, including mortgaging of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			channel for public sector bodies to obtain access to information that they require for fulfilling their tasks assigned to them by law, but does not extend the mandate of such public sector bodies. Any attempt to use the data for any measures detrimental to the natural person, to increase insurance premiums, to advertise products or treatments***, to automate individual decision-making, to re-identify natural persons***, or develop harmful products should be prohibited.	**properties, to** advertise products or treatments, or develop harmful products should be prohibited. **This prohibition applies to the activities contrary to ethical provisions according to national law, with the exception of ethical provisions related to consent the right to object to the processing of personal data and the right to object, which in application of the general principle of primacy of Union law, this Regulation takes precedence over national law.**	

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	Recital 41a				
51a				**(41a) This Regulation does not create an empowerment for the secondary use of health data for the purpose of law enforcement. The prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties by competent authorities is not among the secondary use purposes covered under this Regulation. Therefore, courts and other entities of the justice**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				system cannot be considered data users in the secondary use of health data under this Regulation. In addition, courts and other entities of the justice system are not covered under the definition of data holders, and are therefore not addressees of obligations on data holders under this Regulation.	
	Recital 42				
52	(42) The establishment of one or more health data		(42) The establishment of one or more health data	(42) The establishment of one or more health data	

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	access bodies, supporting access to electronic health data in Member States, is an essential component for promoting the secondary use of health-related data. Member States should therefore establish one or more health data access body, for instance to reflect their constitutional, organisational and administrative structure. However, one of these health data access bodies should be designated as a coordinator in case there are more than one data access body. Where a Member State establishes several bodies, it should lay down		access bodies, supporting access to electronic health data in Member States, is an essential component for promoting the secondary use of health-related data. Member States should therefore establish one or more health data access body, for instance to reflect their constitutional, organisational and administrative structure. However, one of these health data access bodies should be designated as a coordinator in case there are more than one data access body. Where a Member State establishes several bodies, it should lay down	access bodies, supporting access to electronic health data in Member States, is an essential component for promoting the secondary use of health-related data. Member States should therefore establish one or more health data access body, for instance to reflect their constitutional, organisational and administrative structure. However, one of these health data access bodies should be designated as a coordinator in case there are more than one data access body. Where a Member State establishes several bodies, it should lay down	

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	rules at national level to ensure the coordinated participation of those bodies in the EHDS Board. That Member State should in particular designate one health data access body to function as a single contact point for the effective participation of those bodies, and ensure swift and smooth cooperation with other health data access bodies, the EHDS Board and the Commission. Health data access bodies may vary in terms of organisation and size (spanning from a dedicated full-fledged organization to a unit or department in an		rules at national level to ensure the coordinated participation of those bodies in the EHDS Board. That Member State should in particular designate one health data access body to function as a single contact point for the effective participation of those bodies, and ensure swift and smooth cooperation with other health data access bodies, the EHDS Board and the Commission. Health data access bodies may vary in terms of organisation and size (spanning from a dedicated full-fledged organization to a unit or department in an existing	rules at national level to ensure the coordinated participation of those bodies in the EHDS Board. That Member State should in particular designate one health data access body to function as a single contact point for the effective participation of those bodies, and ensure swift and smooth cooperation with other health data access bodies, the EHDS Board and the Commission. Health data access bodies may vary in terms of organisation and size (spanning from a dedicated full-fledged organization to a unit or department in an existing	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	existing organization) but should have the same functions, responsibilities and capabilities. Health data access bodies should not be influenced in their decisions on access to electronic data for secondary use. However, their independence should not mean that the health data access body cannot be subject to control or monitoring mechanisms regarding its financial expenditure or to judicial review. Each health data access body should be provided with the financial and human resources, premises and infrastructure		organization) but should have the same functions, responsibilities and capabilities. Health data access bodies should not be influenced in their decisions on access to electronic data for secondary use***, Members of the governance and decision-making bodies and staff of each health data access body should therefore refrain from any action that is incompatible with their duties and should not engage in any incompatible occupation***. However, their independence should not mean that the health data access body cannot be	organization) but should have the same functions, responsibilities and capabilities. Health data access bodies should not be influenced in their decisions on access to electronic data for secondary use. However, their independence should not mean that the health data access body cannot be subject to control or monitoring mechanisms regarding its financial expenditure or to judicial review. Each health data access body should be provided with the financial and human resources, premises and infrastructure	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	necessary for the effective performance of its tasks, including those related to cooperation with other health data access bodies throughout the Union. Each health data access body should have a separate, public annual budget, which may be part of the overall state or national budget. In order to enable better access to health data and complementing Article 7(3) of Regulation […] of the European Parliament and of the Council [Data Governance Act COM/2020/767 final], Member States should entrust health data access		subject to control or monitoring mechanisms regarding its financial expenditure or to judicial review. Each health data access body should be provided with the financial, ***technical*** and human resources, ***ethics bodies,*** premises and infrastructure necessary for the effective performance of its tasks, including those related to cooperation with other health data access bodies throughout the Union ***and have separate structures for application processing on the one hand, and anonymisation, pseudonymisation and re-***	necessary for the effective performance of its tasks, including those related to cooperation with other health data access bodies throughout the Union. Each health data access body should have a separate, public annual budget, which may be part of the overall state or national budget. In order to enable better access to health data and complementing Article 7(3) of Regulation […] of the European Parliament and of the Council [Data Governance Act COM/2020/767 final], Member States should entrust health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies with powers to take decisions on access to and secondary use of health data. This could consist in allocating new tasks to the competent bodies designated by Member States under Article 7(1) of Regulation […] [Data Governance Act COM/2020/767 final] or in designating existing or new sectoral bodies responsible for such tasks in relation to access to health data.		***identification on the other hand***. Each health data access body should have a separate, public annual budget, which may be part of the overall state or national budget. In order to enable better access to health data and complementing Article 7(3) of Regulation […] of the European Parliament and of the Council [Data Governance Act COM/2020/767 final], Member States should entrust health data access bodies with powers to take decisions on access to and secondary use of health data. This could consist in	bodies with powers to take decisions on access to and secondary use of health data. This could consist in allocating new tasks to the competent bodies designated by Member States under Article 7(1) of Regulation […] [Data Governance Act COM/2020/767 final] or in designating existing or new sectoral bodies responsible for such tasks in relation to access to health data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			allocating new tasks to the competent bodies designated by Member States under Article 7(1) of Regulation […] [Data Governance Act COM/2020/767 final] or in designating existing or new sectoral bodies responsible for such tasks in relation to access to health data. ***Given the central role of the health data access bodies in the context of secondary use of electronic health data, and especially regarding the decision-making on granting or refusing a health data permit and preparing the data to make them***		

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			available to health data users, the members and staff of such bodies should have the necessary qualifications, experience and skills, including legal and technical expertise as regards the protection of personal data, specifically data concerning health, and expertise in the areas of ethics, healthcare, scientific research, cybersecurity, protection of intellectual property and trade secrets, artificial intelligence and other relevant areas. In addition, the decision-making process regarding the granting or refusal of the		

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			health data permit should involve ethical considerations. The staff of health access bodies should not have any conflict of interest that is prejudicial to their independence and the impartiality of their conduct.		
	Recital 43				
53	(43) The health data access bodies should monitor the application of Chapter IV of this Regulation and contribute to its consistent application throughout the		(43) The health data access bodies should monitor the application of Chapter IV of this Regulation and contribute to its consistent application throughout the	(43) The health data access bodies should monitor the application of Chapter IV of this Regulation and contribute to its consistent application throughout the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union. For that purpose, the health data access bodies should cooperate with each other and with the Commission, without the need for any agreement between Member States on the provision of mutual assistance or on such cooperation. The health data access bodies should also cooperate with stakeholders, including patient organisations. Since the secondary use of health data involves the processing of personal data concerning health, the relevant provisions of Regulation (EU) 2016/679 apply and the supervisory authorities		Union. For that purpose, the health data access bodies should cooperate with each other and with the Commission, without the need for any agreement between Member States on the provision of mutual assistance or on such cooperation. The health data access bodies should also cooperate with stakeholders, including patient organisations. ***The selection procedure for health stakeholders should be transparent, public and free of any conflict of interest.*** Since the secondary use of health data involves the processing of	Union. For that purpose, the health data access bodies should cooperate with each other and with the Commission, without the need for any agreement between Member States on the provision of mutual assistance or on such cooperation. The health data access bodies should also cooperate with stakeholders, including patient organisations. Since the secondary use of health data involves the processing of personal data concerning health, the relevant provisions of Regulation (EU) 2016/679 apply and the supervisory authorities	

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	under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 should be tasked with enforcing these rules. Moreover, given that health data are sensitive data and in a duty of loyal cooperation, the health data access bodies should inform the data protection authorities of any issues related to the data processing for secondary use, including penalties. In addition to the tasks necessary to ensure effective secondary use of health data, the health data access body should strive to expand the availability of additional health datasets,		personal data concerning health, the relevant provisions of Regulation (EU) 2016/679 apply and the supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 should ~~be tasked with~~***remain the only authorities competent for*** enforcing these rules. Moreover, given that health data are sensitive data and in a duty of loyal cooperation, the health data access bodies should inform the data protection authorities of any issues related to the data processing for secondary use, including	under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 should be tasked with enforcing these rules. Moreover, given that health data are sensitive data and in a duty of loyal cooperation, the health data access bodies should inform the data protection authorities of any issues related to the data processing for secondary use, including penalties. In addition to the tasks necessary to ensure effective secondary use of health data, the health data access body should strive to expand the availability of additional health datasets,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	support the development of AI in health and promote the development of common standards. They should apply tested techniques that ensure electronic health data is processed in a manner that preserves the privacy of the information contained in the data for which secondary use is allowed, including techniques for pseudonymisation, anonymisation, generalisation, suppression and randomisation of personal data. Health data access bodies can prepare datasets to the data user requirement linked to the		~~*penalties*~~***administrative fines and enforcement measures***. In addition to the tasks necessary to ensure effective secondary use of health data, the health data access body should strive to expand the availability of additional health datasets, ~~*support the development of AI in health*~~ and promote the development of common standards. They should apply tested ***state-of-the-art*** techniques that ensure electronic health data is processed in a manner that preserves the privacy of the information contained in the data for which secondary use is allowed,	support the development of AI in health and promote the development of common standards. They should apply tested techniques that ensure electronic health data is processed in a manner that preserves the privacy of the information contained in the data for which secondary use is allowed, including techniques for pseudonymisation, anonymisation, generalisation, suppression and randomisation of personal data. Health data access bodies can prepare datasets to the data user requirement linked to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	issued data permit. This includes rules for anonymization of microdata sets.		including techniques for pseudonymisation, anonymisation, generalisation, suppression and randomisation of personal data. ***In that regard, health data access bodies should cooperate across borders and agree on common definitions and techniques.*** Health data access bodies can prepare datasets to the data user requirement linked to the issued data permit. This includes rules for ~~*anonymization*~~***anonymisation*** of microdata sets.	issued data permit. This includes rules for anonymization of microdata sets.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 44				
54	(44) Considering the administrative burden for health data access bodies to inform the natural persons whose data are used in data projects within a secure processing environment, the exceptions provided for in Article 14(5) of Regulation (EU) 2016/679 should apply. Therefore, health data access bodies should provide general information concerning the conditions for the secondary use of their health data containing the information items listed		(44) ~~*Considering the administrative burden for health data access bodies to*~~***Health data access bodies should comply with the obligations laid down in Article 14 of Regulation (EU) 2016/679 and*** inform the natural persons whose data are used in data projects within a secure processing environment~~,~~. The exceptions provided for in Article 14(5) of Regulation (EU) 2016/679 ~~*should*~~***could*** apply. ~~*Therefore*~~***Where such***	(44) Considering the administrative burden for health data access bodies to inform the natural persons whose data are used in data projects within a secure processing environment, the exceptions provided for in Article 14(5) of Regulation (EU) 2016/679 should apply. Therefore, health data access bodies should provide general information concerning the conditions for the secondary use of their health data containing the information items listed	

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	in Article 14(1) and, where necessary to ensure fair and transparent processing, Article 14(2) of Regulation (EU) 2016/679, e.g. information on the purpose and the data categories processed. Exceptions from this rule should be made when the results of the research could assist in the treatment of the natural person concerned. In this case, the data user should inform the health data access body, which should inform the data subject or his health professional. Natural persons should be able to access the results of different research projects		***exceptions are applied***, health data access bodies should provide general information concerning the conditions for the secondary use of their health data containing the information items listed in Article 14(1) and, where necessary to ensure fair and transparent processing, Article 14(2) of Regulation (EU) 2016/679, e.g. information on the purpose and the data categories processed, ***enabling natural persons to understand whether their data are being made available for secondary use pursuant to data permits***. Exceptions from this rule	in Article 14(1) and, where necessary to ensure fair and transparent processing, Article 14(2) of Regulation (EU) 2016/679, e.g. information on the purpose and the data categories processed. Exceptions from this rule should be made when the results of the research could assist in the treatment of the natural person concerned. In this case, the data user should inform the health data access body, which should inform the data subject or his health professional. Natural persons should be able to access the results of different research projects	

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	on the website of the health data access body, ideally in an easily searchable manner. The list of the data permits should also be made public. In order to promote transparency in their operation, each health data access body should publish an annual activity report providing an overview of its activities.		should be made when the results of the research could assist in the treatment of the natural person concerned. In this case, the ***health*** data user should inform the health data access body, which should inform the ~~*data subject or his*~~***health professional treating the natural person concerned or, in the event that the treating*** health professional ***is not traceable, the natural person, with due regard for their stated wish not to be informed, while fully respecting the principles of medical confidentiality and professional secrecy***. Natural persons should be	on the website of the health data access body, ideally in an easily searchable manner. The list of the data permits should also be made public. In order to promote transparency in their operation, each health data access body should publish an annual activity report providing an overview of its activities.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			able to access the results of different research projects on the website of the health data access body, ideally in an easily searchable manner. The list of the data permits should also be made public. In order to promote transparency in their operation, each health data access body should publish an annual activity report providing an overview of its activities.		
	Recital 45				
55	(45) Regulation […] [Data		(45) Regulation […] [Data	(45) Regulation […] [Data	

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	Governance Act COM/2020/767 final] sets out the general rules for the management of data altruism. At the same time, given that the health sector manages sensitive data, additional criteria should be established through the rulebook foreseen in Regulation […] [Data Governance Act COM/2020/767 final]. Where such a rulebook foresees the use of a secure processing environment for this sector, this should comply with the criteria established in this Regulation. The health data access bodies should		Governance Act COM/2020/767 final] sets out the general rules for the management of data altruism. At the same time, given that the health sector manages sensitive data, additional criteria should be established through the rulebook foreseen in Regulation […] [Data Governance Act COM/2020/767 final]. Where such a rulebook foresees the use of a secure processing environment for this sector, this should comply with the criteria established in this Regulation. The health data access bodies should	Governance Act COM/2020/767 final] sets out the general rules for the management of data altruism. At the same time, given that the health sector manages sensitive data, additional criteria should be established through the rulebook foreseen in Regulation […] [Data Governance Act COM/2020/767 final]. Where such a rulebook foresees the use of a secure processing environment for this sector, this should comply with the criteria established in this Regulation. The health data access bodies should	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	cooperate with the bodies designated under Regulation […] [Data Governance Act COM/2020/767 final] to supervise the activity of data altruism organisations in the health or care sector.		cooperate with the bodies designated under Regulation […] [Data Governance Act COM/2020/767 final] to supervise the activity of data altruism organisations in the health or care sector.	cooperate with the bodies designated under Regulation […] [Data Governance Act COM/2020/767 final] to supervise the activity of data altruism organisations in the health or care sector.	
	Recital 46				
56	(46) In order to support the secondary use of electronic health data, the data holders should refrain from withholding the data, requesting unjustified fees that are not transparent nor		(46) In order to support the secondary use of electronic health data, the data holders should refrain from withholding the data, requesting unjustified fees that are not transparent nor	(46) In order to support the secondary use of electronic health data, the data holders should refrain from withholding the data, requesting unjustified fees that are not transparent nor	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	proportionate with the costs for making data available (and, where relevant, with marginal costs for data collection), requesting the data users to co-publish the research or other practices that could dissuade the data users from requesting the data. Where ethical approval is necessary for providing a data permit, its evaluation should be based on its own merits. On the other hand, Union institutions, bodies, offices and agencies, including EMA, ECDC and the Commission, have very important and insightful data. Access to data of such		proportionate with the costs for making data available (and, where relevant, with marginal costs for data collection), requesting the data users to co-publish the research or other practices that could dissuade the data users from requesting the data. Where ethical approval is necessary for providing a data permit, its evaluation should be based on its own merits. On the other hand, ***public sector bodies and*** Union institutions, bodies, offices and agencies~~, *including EMA, ECDC and the Commission*~~ ***with a legal mandate in the field of***	proportionate with the costs for making data available (and, where relevant, with marginal costs for data collection), requesting the data users to co-publish the research or other practices that could dissuade the data users from requesting the data. Where ethical approval is necessary for providing a data permit, its evaluation should be based on its own merits. On the other hand, Union institutions, bodies, offices and agencies, including EMA, ECDC and the Commission, have very important and insightful data. Access to data of such	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	institutions, bodies, offices and agencies should be granted through the health data access body where the controller is located.		***public health***, have very important and insightful data. Access to data of such institutions, bodies, offices and agencies should be granted through the health data access body where the controller is located.	institutions, bodies, offices and agencies should be granted through the health data access body where the controller is located.	
	Recital 47				
57	(47) Health data access bodies and single data holders should be allowed to charge fees based on the provisions of Regulation […] [Data Governance Act COM/2020/767 final] in		(47) Health data access bodies ~~*and single data holders*~~ should be allowed to charge fees based on the ***applicable*** provisions ~~*of*~~***under this*** Regulation […] ***and the provisions of***	(47) Health data access bodies and single data holders should be allowed to charge fees ~~based on the provisions of Regulation […] [Data Governance Act COM/2020/767 final]~~ in	

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	relation to their tasks. Such fees may take into account the situation and interest of SMEs, individual researchers or public bodies. Data holders should be allowed to also charge fees for making data available. Such fees should reflect the costs for providing such services. Private data holders may also charge fees for the collection of data. In order to ensure a harmonised approach concerning fee policies and structure, the Commission may adopt implementing acts. Provisions in Article 10 of the Regulation [Data Act		***the*** [Data Governance Act COM/2020/767 final] ***and the [Data Act COM/2022/68 final]*** in relation to their tasks. Such fees may take into account the situation and interest of SMEs, individual researchers or public bodies. ***Health*** data holders should be allowed to also charge fees for making data available. Such fees should reflect the costs for providing such services. Private ***health*** data holders may also charge fees for the collection of data. In order to ensure a harmonised approach concerning fee policies and structure, the	relation to their tasks. Such fees may take into account the situation and interest of SMEs, individual researchers or public bodies. **In particular, Member States may establish policies for health data access bodies in their jurisdiction allowing to charge reduced fees to certain categories of data users. On the other hand, health data access bodies should be able to cover the costs of their operation with fees, and this may lead to higher fees charged to certain categories of data users, established in a**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	COM/2022/68 final] should apply for fees charged under this Regulation.		Commission ~~*may*~~***should*** adopt implementing acts. Provisions in Article 10 of the Regulation [Data Act COM/2022/68 final] should apply for fees charged under this Regulation. ***Public sector bodies and Union institutions, bodies, offices and agencies with a legal mandate in the field of public health should not be charged fees.***	**proportionate, justified and transparent manner, if servicing their data access applications and data requests requires more work in aspects such as compliance with Chapter V of the GDPR.** Data holders should be allowed to also charge fees for making data available. Such fees should reflect the costs for providing such services. Private data holders may also charge fees for the collection of data. In order to ensure a harmonised approach concerning fee policies and ~~structure~~**structures**, the Commission may ~~adopt~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				~~implementing acts. Provisions in Article 10 of the Regulation [Data Act COM/2022/68 final] should apply for fees charged under this Regulation~~**issue guidelines on fee policies and fee structures**.	
	Recital 48				
58	(48) In order to strengthen the enforcement of the rules on the secondary use of electronic health data, appropriate measures that can lead to penalties or temporary or definitive		(48) In order to strengthen the enforcement of the rules on the secondary use of electronic health data, appropriate measures ***should be envisaged*** that can lead to	(48) In order to strengthen the enforcement of the rules on the secondary use of electronic health data, appropriate measures that can lead to penalties or temporary or definitive	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	exclusions from the EHDS framework of the data users or data holders that do not comply with their obligations. The health data access body should be empowered to verify compliance and give data users and holders the opportunity to reply to any findings and to remedy any infringement. The imposition of penalties should be subject to appropriate procedural safeguards in accordance with the general principles of law of the relevant Member State, including effective judicial protection and due process.		~~*penalties*~~***administrative fines or enforcement measures by health data access bodies*** or temporary or definitive exclusions from the EHDS framework of the ***health*** data users or ***health*** data holders that do not comply with their obligations. The health data access body should be empowered to verify compliance and give ***health*** data users and holders the opportunity to reply to any findings and to remedy any infringement. ***When deciding on the amount of the administrative fine or enforcement measure for each individual case,***	exclusions from the EHDS framework of the data users or data holders that do not comply with their obligations. The health data access body should be empowered to verify compliance and give data users and holders the opportunity to reply to any findings and to remedy any infringement. The imposition of penalties should be subject to appropriate procedural safeguards in accordance with the general principles of law of the relevant Member State, including effective judicial protection and due process.	

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			health data access bodies should take into account the margins for costs and criteria set out in this Regulation*~~The imposition of penalties should be subject to appropriate procedural safeguards in accordance with the general principles of law of the relevant Member State, including effective judicial protection and due process~~*.		
		Recital 49			
59	(49) Given the sensitivity of electronic health data, it		(49) Given the sensitivity of electronic health data, it	(49) Given the sensitivity of electronic health data, it	

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	is necessary to reduce risks on the privacy of natural persons by applying the data minimisation principle as set out in Article 5 (1), point (c) of Regulation (EU) 2016/679. Therefore, the use of anonymised electronic health data which is devoid of any personal data should be made available when possible and if the data user asks it. If the data user needs to use personal electronic health data, it should clearly indicate in its request the justification for the use of this type of data for the planned data processing activity. The personal		is necessary to reduce risks on the privacy of natural persons by applying the data minimisation principle as set out in Article 5 (1), point (c) of Regulation (EU) 2016/679. Therefore, ***common standards for data anonymisation should be further developed and*** the use of anonymised electronic health data which is devoid of any personal data should be made available when possible ~~*and if the data user asks it*~~. If the data user needs to use personal electronic health data, it should clearly indicate in its request the justification for the use of	is necessary to reduce risks on the privacy of natural persons by applying the data minimisation principle as set out in Article 5 (1), point (c) of Regulation (EU) 2016/679. Therefore, the use of anonymised electronic health data which is devoid of any personal data should be made available when possible and if the data user asks it. If the data user needs to use personal electronic health data, it should clearly indicate in its request the justification for the use of this type of data for the planned data processing activity. The personal	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data should only be made available in pseudonymised format and the encryption key can only be held by the health data access body. Data users should not attempt to re-identify natural persons from the dataset provided under this Regulation, subject to administrative or possible criminal penalties, where the national laws foresee this. However, this should not prevent, in cases where the results of a project carried out based on a data permit has a health benefit or impact to a concerned natural person (for instance,		this type of data for the planned data processing activity ***and the health data access body should determine the validity of that justification***. The personal electronic health data should only be made available in pseudonymised format and the encryption key can only be held by the health data access body. ***When providing access to an anonymised or pseudonymised dataset, a health data access body should use state-of-the-art anonymisation or pseudonymisation technology, ensuring to the maximum extent possible***	electronic health data should only be made available in pseudonymised format and the encryption key can only be held by the health data access body. Data users should not attempt to re-identify natural persons from the dataset provided under this Regulation, subject to administrative or possible criminal penalties, where the national laws foresee this. However, this should not prevent, in cases where the results of a project carried out based on a data permit has a health benefit or impact to a concerned natural person (for instance,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	discovering treatments or risk factors to develop a certain disease), the data users would inform the health data access body, which in turn would inform the concerned natural person(s). Moreover, the applicant can request the health data access bodies to provide the answer to a data request, including in statistical form. In this case, the data users would not process health data and the health data access body would remain sole controller for the data necessary to provide the answer to the data request.		***that natural persons cannot be re-identified. Health*** data users should not attempt to re-identify natural persons from the dataset provided under this Regulation, subject to administrative ***fines and the enforcement measures laid down in this Regulation*** or possible criminal penalties, where the national laws foresee this. However, this should not prevent, in cases where the results of a project carried out based on a data permit has a ***significant*** health benefit or impact to a concerned natural person (for instance, discovering treatments or	discovering treatments or risk factors to develop a certain disease), the data users would inform the health data access body, which in turn would inform the concerned natural person(s). Moreover, the applicant can request the health data access bodies to provide the answer to a data request, including in statistical form. In this case, the data users would not process health data and the health data access body would remain sole controller for the data necessary to provide the answer to the data request.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			risk factors to develop a certain disease), the ***health*** data users ~~*would*~~***to*** inform the health data access body, which in turn would inform the ***treating health professional of the*** concerned natural person~~*(s). Moreover, the*~~ ***or, in the event that the treating health professional is not traceable, the natural person, with due regard for any stated wish not to be informed. To that end, the health data user should be guided by ethical principles, and guidelines from EMA and the ECDC as regards what constitutes a significant finding.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Moreover, a health data applicant can request the health data access bodies to provide the answer to a ***health*** data request, including in ***an anonymised or aggregated*** statistical ~~*form*~~***format***. In this case, the ***health data user*** ~~*data users*~~ would not process health data and the health data access body would remain sole controller for the data necessary to provide the answer to the ***health*** data request.		
	Recital 50				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
60	(50) In order to ensure that all health data access bodies issue permits in a similar way, it is necessary to establish a standard common process for the issuance of data permits, with similar requests in different Member States. The applicant should provide health data access bodies with several information elements that would help the body evaluate the request and decide if the applicant may receive a data permit for secondary use of data, also ensuring coherence between		(50) In order to ensure that all health data access bodies issue permits in a similar way, it is necessary to establish a standard common process for the issuance of data permits, with similar requests in different Member States. The ***health data*** applicant should provide health data access bodies with several information elements that would help the body evaluate the ~~*request*~~***application*** and decide if the applicant may receive a data permit for secondary use of data, also	(50) In order to ensure that all health data access bodies issue permits in a similar way, it is necessary to establish a standard common process for the issuance of data permits, with similar requests in different Member States. The applicant should provide health data access bodies with several information elements that would help the body evaluate the request and decide if the applicant may receive a data permit for secondary use of data, also ensuring coherence between	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	different health data access bodies. Such information include: the legal basis under Regulation (EU) 2016/679 to request access to data (exercise of a task in the public interest assigned by law or legitimate interest), purposes for which the data would be used, description of the needed data and possible data sources, a description of the tools needed to process the data, as well as characteristics of the secure environment that are needed. Where data is requested in pseudonymised format, the data applicant should explain why this is		ensuring coherence between different health data access bodies. Such information ~~*include*~~***includes***: the legal basis under Regulation (EU) 2016/679 to request access to data (exercise of a task in the public interest assigned by law or legitimate interest), purposes for which the data would be used, ***the identity of the health data applicant as well as the specific persons who are authorised to have access to the electronic health data in the secure processing environment and how they are qualified vis-à-vis the intended secondary use,***	different health data access bodies. Such information include: the legal basis under Regulation (EU) 2016/679 to request access to data (exercise of a task in the public interest assigned by law or legitimate interest), purposes for which the data would be used, description of the needed data and possible data sources, a description of the tools needed to process the data, as well as characteristics of the secure environment that are needed. Where data is requested in pseudonymised format, the data applicant should explain why this is	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	necessary and why anonymous data would not suffice. An ethical assessment may be requested based on national law. The health data access bodies and, where relevant data holders, should assist data users in the selection of the suitable datasets or data sources for the intended purpose of secondary use. Where the applicant needs anonymised statistical data, it should submit a data request application, requiring the health data access body to provide directly the result. In order to ensure a harmonised approach		description of the needed data and possible data sources, a description of the tools needed to process the data, as well as characteristics of the secure environment that are needed***, a description of the safeguards planned to prevent any other use, misuse or possible re-identification, and an explanation of the expected benefits of the secondary use***. Where data is requested in pseudonymised format, the ***health*** data applicant should explain why this is necessary and why anonymous data would not suffice. An ethical	necessary and why anonymous data would not suffice. An ethical assessment may be requested based on national law. The health data access bodies and, where relevant data holders, should assist data users in the selection of the suitable datasets or data sources for the intended purpose of secondary use. Where the applicant needs anonymised statistical data, it should submit a data request application, requiring the health data access body to provide directly the result. In order to ensure a harmonised approach between health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	between health data access bodies, the Commission should support the harmonisation of data application, as well as data request.		assessment may be requested based on national law. ***A thorough assessment of*** the health data access ~~*bodies*~~***applications and documents submitted by the health data applicant should be required and the health data access body should only issue a data permit if all the conditions set out in this Regulation are met. The health data access body*** and, where relevant ***health*** data holders, should assist ***health*** data users in the selection of the suitable datasets or data sources for the intended purpose of secondary use.	data access bodies, the Commission should support the harmonisation of data application, as well as data request.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Where the ***health*** applicant needs ***data in an*** anonymised ***and aggregated*** statistical ~~*data*~~***format***, it should submit a data request application, requiring the health data access body to provide directly the result. ***A refusal of a data permit by the health data body should not preclude the health data applicant from submitting a new data access application.*** In order to ensure a harmonised approach between health data access bodies ***and to limit an unnecessary administrative burden for the health data applicants***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to the greatest extent possible, the Commission should support the harmonisation of ***health data access applications*** ~~*data application*~~, as well as ***health data requests, including by establishing, by means of implementing acts, templates for health data access applications and requests*** ~~*data request*~~.		
	Recital 50a				
60a			***(50a) A standard ethics assessment should be***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			carried out by ethics bodies within health data access bodies. Such assessment should be an important part of the process. However, where the health data applicant had previously obtained the approval of the competent ethics committee in accordance with national law for research purposes for which they are requesting data through the EHDS, the health data applicant should make that information available to the health data access body as part of the data access application.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 51				
61	(51) As the resources of health data access bodies are limited, they can apply prioritisation rules, for instance prioritising public institutions before private entities, but they should not make any discrimination between the national or from organisations from other Member States within the same category of priorities. The data user should be able to extend the duration of the data permit		(51) As the resources of health data access bodies are limited, they can apply prioritisation rules, for instance prioritising public institutions before private entities, but they should not make any discrimination between the national or from organisations from other Member States within the same category of priorities. The ***health*** data user should be able to extend the duration of the	(51) As the resources of health data access bodies are limited, they can apply prioritisation rules, for instance prioritising public institutions before private entities, but they should not make any discrimination between the national or from organisations from other Member States within the same category of priorities. The data user should be able to extend the duration of the data permit	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	in order, for example, to allow access to the datasets to reviewers of scientific publication or to enable additional analysis of the dataset based on the initial findings. This would require an amendment of the data permit and may be subject to an additonal fee. However, in all the cases, the data permit should reflect theses additionals uses of the dataset. Preferably, the data user should mention them in their initial request for the issuance of the data permit. In order to ensure a harmonised approach between health data access		data permit in order, for example, to allow access to the datasets to reviewers of scientific publication or to enable additional analysis of the dataset based on the initial findings. This would require an amendment of the ***health*** data permit and may be subject to an ~~additonal~~***additional*** fee. However, in all the cases, the data permit should reflect theses ~~additionals~~***additional*** uses of the dataset. Preferably, the ***health*** data user should mention them in their initial request for the issuance of the data permit. In order to ensure a harmonised	in order, for example, to allow access to the datasets to reviewers of scientific publication or to enable additional analysis of the dataset based on the initial findings. This would require an amendment of the data permit and may be subject to an ~~additonal~~**additional** fee. However, in all the cases, the data permit should reflect theses additionals uses of the dataset. Preferably, the data user should mention them in their initial request for the issuance of the data permit. In order to ensure a harmonised approach between health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies, the Commission should support the harmonisation of data permit.		approach between health data access bodies, the Commission should support the harmonisation of data permit.	bodies, the Commission should support the harmonisation of data permit.	
	Recital 52				
62	(52) As the COVID-19 crisis has shown, the Union institutions, bodies, offices and agencies, especially the Commission, need access to health data for a longer period and on a recurring basis. This is may be the case not only in specific circumstances in times of		(52) As the COVID-19 crisis has shown, the Union institutions, bodies, offices and agencies ***with a legal mandate in the field of public health***, especially the Commission, need access to health data for a longer period and on a recurring basis. This ~~is~~ may be the	(52) As the COVID-19 crisis has shown, the Union institutions, bodies, offices and agencies, especially the Commission, need access to health data for a longer period and on a recurring basis. This is may be the case not only in specific circumstances in times of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data may be required in specific Member States or throughout the whole territory of the Union.		case not only ~~in~~***for*** specific circumstances ***stipulated by Union or national law*** in times of crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data may be required in specific Member States or throughout the whole territory of the Union.	crisis but also to provide scientific evidence and technical support for Union policies on a regular basis. Access to such data may be required in specific Member States or throughout the whole territory of the Union.	
		Recital 53			
63	(53) For requests to access electronic health data from a single data holder in a		*deleted*	*(53)* For requests to access electronic health data from a single data holder in a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	single Member State and in order to alieviate the administrative burden for heath data access bodies of managing such request, the data user should be able to request this data directly from the data holder and the data holder should be able to issue a data permit while complying with all the requirements and safeguards linked to such request and permit. Multi-country requests and requests requiring combination of datasets from several data holders should always be channelled through health data access bodies. The data			single Member State and in order to alieviate the administrative burden for heath data access bodies of managing such request, the data user should be able to request this data directly from the data holder and the data holder should be able to issue a data permit while complying with all the requirements and safeguards linked to such request and permit. Multi-country requests and requests requiring combination of datasets from several data holders should always be channelled through health data access bodies. The data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	holder should report to the health data access bodies about any data permits or data requests they provide.			holder should report to the health data access bodies about any data permits or data requests they provide.	
	Recital 54				
64	(54) Given the sensitivity of electronic health data, data users should not have an unrestricted access to such data. All secondary use access to the requested electronic health data should be done through a secure processing environment. In order to ensure strong technical and		(54) Given the sensitivity of electronic health data, data users should not have an unrestricted access to such data***, in accordance with the data minimisation principle***. All secondary use access to the requested electronic health data should be done through a secure processing	(54) Given the sensitivity of electronic health data, data users should not have an unrestricted access to such data. All secondary use access to the requested electronic health data should be done through a secure processing environment. In order to ensure strong technical and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	security safeguards for the electronic health data, the health data access body or, where relevant, single data holder should provide access to such data in a secure processing environment, complying with the high technical and security standards set out pursuant to this Regulation. Some Member States took measures to locate such secure environments in Europe. The processing of personal data in such a secure environment should comply with Regulation (EU) 2016/679, including, where the secure environment is managed by		environment. In order to ensure strong technical and security safeguards for the electronic health data, the health data access body ~~*or, where relevant, single data holder*~~ should provide access to such data in a secure processing environment, complying with the high technical and security standards set out pursuant to this Regulation. Some Member States took measures to locate such secure environments in Europe. The processing of personal data in such a secure environment should comply with Regulation (EU) 2016/679, including,	security safeguards for the electronic health data, the health data access body or, where relevant, single data holder should provide access to such data in a secure processing environment, complying with the high technical and security standards set out pursuant to this Regulation. Some Member States took measures to locate such secure environments in Europe. The processing of personal data in such a secure environment should comply with Regulation (EU) 2016/679, including, where the secure environment is managed by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	a third party, the requirements of Article 28 and, where applicable, Chapter V. Such secure processing environment should reduce the privacy risks related to such processing activities and prevent the electronic health data from being transmitted directly to the data users. The health data access body or the data holder providing this service should remain at all time in control of the access to the electronic health data with access granted to the data users determined by the conditions of the issued data permit. Only non-		where the secure environment is managed by a third party, the requirements of Article 28 and, where applicable, Chapter V***. Nevertheless, in order to ensure the proper supervision and security of personal data, such environments need to be located in the Union if they are used to access personal health data***. Such secure processing environment should reduce the privacy risks related to such processing activities and prevent the electronic health data from being transmitted directly to the data users. The health data access body	a third party, the requirements of Article 28 and, where applicable, Chapter V. Such secure processing environment should reduce the privacy risks related to such processing activities and prevent the electronic health data from being transmitted directly to the data users. The health data access body or the data holder providing this service should remain at all time in control of the access to the electronic health data with access granted to the data users determined by the conditions of the issued data permit. Only non-personal	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	personal electronic health data which do not contain any electronic health data should be extracted by the data users from such secure processing environment. Thus, it is an essential safeguard to preserve the rights and freedoms of natural persons in relation to the processing of their electronic health data for secondary use. The Commission should assist the Member State in developing common security standards in order to promote the security and interoperability of the various secure environments.		or the data holder providing this service should remain at all time in control of the access to the electronic health data with access granted to the data users determined by the conditions of the issued data permit. Only non-personal electronic health data which do not contain any electronic health data should be extracted by the data users from such secure processing environment. Thus, it is an essential safeguard to preserve the rights and freedoms of natural persons in relation to the processing of their electronic health data for	electronic health data which do not contain any electronic health data should be extracted by the data users from such secure processing environment. Thus, it is an essential safeguard to preserve the rights and freedoms of natural persons in relation to the processing of their electronic health data for secondary use. The Commission should assist the Member State in developing common security standards in order to promote the security and interoperability of the various secure environments.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			secondary use. The Commission should assist the Member State in developing common security standards in order to promote the security and interoperability of the various secure environments.		
	Recital 55				
65	(55) For the processing of electronic health data in the scope of a granted permit, the health data access bodies and the data users should be joint controllers		(55) For the processing of electronic health data in the scope of a granted permit, the health data ***holders, the health data*** access bodies and the ***health*** data users	(55) For the processing of electronic health data in the scope of a granted permit, the health data access bodies and the data users should be joint controllers	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	in the sense of Article 26 of Regulation (EU) 2016/679, meaning that the obligations of joint controllers under that Regulation will apply. To support health data access bodies and data users, the Commission should, by means of an implementing act, provide a template for the joint controller arrangements health data access bodies and data users will have to enter into. In order to achieve an inclusive and sustainable framework for multi-country secondary use of electronic health data, a cross-border infrastructure		should ***each, in turn, be deemed a controller for a specific part of the process and according to their respective roles therein. The health data holder should be deemed controller for the disclosure of the requested personal electronic*** ~~*be joint controllers in the sense of Article 26 of Regulation (EU) 2016/679, meaning that the obligations of joint controllers under that Regulation will apply. To support*~~ health data ~~*access bodies and data users*~~***to the health data access body***, ***while the health data access body*** ~~*the*~~	in the sense of Article 26 of Regulation (EU) 2016/679, meaning that the obligations of joint controllers under that Regulation will apply. To support health data access bodies and data users, the Commission should, by means of an implementing act, provide a template for the joint controller arrangements health data access bodies and data users will have to enter into. In order to achieve an inclusive and sustainable framework for multi-country secondary use of electronic health data, a cross-border infrastructure should be established.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	should be established. HealthData@EU should accelerate the secondary use of electronic health data while increasing legal certainty, respecting the privacy of natural persons and being interoperable. Due to the sensitivity of health data, principles such as "privacy by design" and "bring questions to data instead of moving data" should be respected whenever possible. Authorised participants in HealthData@EU could be health data access bodies, research infrastructures established as an European Research Infrastructure		~~*Commission*~~ should~~*, by means of an implementing act, provide a template for the joint controller arrangements*~~ ***in turn be deemed controller for the processing of the personal electronic health data when preparing the data and making them available to the health data user. The*** health data ~~*access bodies and data users will have to enter into. In order to achieve an inclusive and sustainable framework for multi-country secondary use of electronic*~~***user should be deemed controller for the processing of personal electronic health data in***	HealthData@EU should accelerate the secondary use of electronic health data while increasing legal certainty, respecting the privacy of natural persons and being interoperable. Due to the sensitivity of health data, principles such as "privacy by design" and "bring questions to data instead of moving data" should be respected whenever possible. Authorised participants in HealthData@EU could be health data access bodies, research infrastructures established as an European Research Infrastructure Consortium ('ERIC') under	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Consortium ('ERIC') under Council Regulation (EC) No 723/2009[1] or similar structures established under another Union legislation, as well as other types of entities, including infrastructures under the European Strategy Forum on Research Infrastructures (ESFRI), infrastructures federated under the European Open Science Cloud (EOSC). Other authorised participants should obtain the approval of the joint controllership group for joining HealthData@EU. On the other hand, HealthData@EU should		***pseudonymised form in the secure processing environment pursuant to its data permit. The health data access body should be deemed a processor for processing carried out by the*** health data~~, a cross-border infrastructure should be established~~ ***user pursuant to a data permit in the secure processing environment***. HealthData@EU should accelerate the secondary use of electronic health data while increasing legal certainty, respecting the privacy of natural persons and being interoperable. Due to the sensitivity of	Council Regulation (EC) No 723/2009[1] or similar structures established under another Union legislation, as well as other types of entities, including infrastructures under the European Strategy Forum on Research Infrastructures (ESFRI), infrastructures federated under the European Open Science Cloud (EOSC). Other authorised participants should obtain the approval of the joint controllership group for joining HealthData@EU. On the other hand, HealthData@EU should enable the secondary use of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	enable the secondary use of different categories of electronic health data, including linking of the health data with data from other data spaces such as environment, agriculture, social etc. The Commission could provide a number of services within HealthData@EU, including supporting the exchange of information amongst health data access bodies and authorised participants for the handling of cross-border access requests, maintaining catalogues of electronic health data available through the infrastructure, network		health data, principles such as "privacy by design", ***"privacy by default",*** and "bring questions to data instead of moving data" should be respected whenever possible. Authorised participants in HealthData@EU could be health data access bodies, research infrastructures established as an European Research Infrastructure Consortium ('ERIC') under Council Regulation (EC) No 723/2009[1] or similar structures established under another Union legislation, as well as other types of entities, including infrastructures under the	different categories of electronic health data, including linking of the health data with data from other data spaces such as environment, agriculture, social etc. The Commission could provide a number of services within HealthData@EU, including supporting the exchange of information amongst health data access bodies and authorised participants for the handling of cross-border access requests, maintaining catalogues of electronic health data available through the infrastructure, network discoverability and metadata queries,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	discoverability and metadata queries, connectivity and compliance services. The Commission may also set up a secure environment, allowing data from different national infrastructures to be transmitted and analysed, at the request of the controllers. The Commission digital strategy promote the linking of the various common European data spaces. For the health sector, interoperability with the sectors such as the environmental, social, agricultural sectors may be relevant for additional insights on health		European Strategy Forum on Research Infrastructures (ESFRI), infrastructures federated under the European Open Science Cloud (EOSC). Other authorised participants should obtain the approval of the joint controllership group for joining HealthData@EU. On the other hand, HealthData@EU should enable the secondary use of different categories of electronic health data, including linking of the health data with data from other data spaces such as environment, agriculture, social etc. The Commission	connectivity and compliance services. The Commission may also set up a secure environment, allowing data from different national infrastructures to be transmitted and analysed, at the request of the controllers. The Commission digital strategy promote the linking of the various common European data spaces. For the health sector, interoperability with the sectors such as the environmental, social, agricultural sectors may be relevant for additional insights on health determinants. For the sake of IT efficiency,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	determinants. For the sake of IT efficiency, rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, like those being built for the exchange of evidences under the once only technical system of Regulation (EU) 2018/1724 of the European Parliament and of the Council[2]. _____ 1. Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 8.8.2009, p. 1).		could provide a number of services within HealthData@EU, including supporting the exchange of information amongst health data access bodies and authorised participants for the handling of cross-border access requests, maintaining catalogues of electronic health data available through the infrastructure, network discoverability and metadata queries, connectivity and compliance services. The Commission may also set up a secure environment, allowing data from different national infrastructures to be transmitted and analysed,	rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, like those being built for the exchange of evidences under the once only technical system of Regulation (EU) 2018/1724 of the European Parliament and of the Council[2]. _____ 1. Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 8.8.2009, p. 1). 2. Regulation (EU) 2018/1724 of the European Parliament and of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2. Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).		at the request of the controllers. The Commission digital strategy promote the linking of the various common European data spaces. For the health sector, interoperability with the sectors such as the environmental, social, agricultural sectors may be relevant for additional insights on health determinants. For the sake of IT efficiency, rationalisation and interoperability of data exchanges, existing systems for data sharing should be reused as much as possible, like those being built for the exchange of evidences	the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			under the once only technical system of Regulation (EU) 2018/1724 of the European Parliament and of the Council[2]. _____ 1. Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) (OJ L 206, 8.8.2009, p. 1). 2. Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 56				
66	(56) In case of cross-border registries or databases, such as the registries of European Reference Networks for Rare Diseases, which receive data from different healthcare providers in several Member States, the health data access body where the coordinator of the registry is located should be responsible for providing access to data.		(56) In case of cross-border registries or databases, such as the registries of European Reference Networks for Rare Diseases, which receive data from different healthcare providers in several Member States, the health data access body where the coordinator of the registry is located should be responsible for providing access to data.	(56) In case of cross-border registries or databases, such as the registries of European Reference Networks for Rare Diseases, which receive data from different healthcare providers in several Member States, the health data access body where the coordinator of the registry is located should be responsible for providing access to data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 57				
67	(57) The authorisation process to gain access to personal health data in different Member States can be repetitive and cumbersome for data users. Whenever possible, synergies should be established to reduce the burden and barriers for data users. One way to achieve this aim is to adhere to the "single application" principle whereby, with one application, the data user		(57) The authorisation process to gain access to personal health data in different Member States can be repetitive and cumbersome for data users. Whenever possible, synergies should be established to reduce the burden and barriers for data users. One way to achieve this aim is to adhere to the "single application" principle whereby, with one application, the data user	(57) The authorisation process to gain access to personal health data in different Member States can be repetitive and cumbersome for data users. Whenever possible, synergies should be established to reduce the burden and barriers for data users. One way to achieve this aim is to adhere to the "single application" principle whereby, with one application, the data user	

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	obtain authorisation from multiple health data access bodies in different Member States.		obtain authorisation from multiple health data access bodies in different Member States.	obtain authorisation from multiple health data access bodies in different Member States.	
	Recital 58				
68	(58) The health data access bodies should provide information about the available datasets and their characteristics so that data users can be informed of elementary facts about the dataset and assess their possible relevance to them. For this reason, each dataset should include, at least,		(58) The health data access bodies should provide information about the available datasets and their characteristics so that data users can be informed of elementary facts about the dataset and assess their possible relevance to them. For this reason, each dataset should include, at least,	(58) The health data access bodies should provide information about the available datasets and their characteristics so that data users can be informed of elementary facts about the dataset and assess their possible relevance to them. For this reason, each dataset should include, at least,	

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	information concerning the source, nature of data and conditions for making data available. Therefore, an EU datasets catalogue should be established to facilitate the discoverability of datasets available in the EHDS; to help data holders to publish their datasets; to provide all stakeholders, including the general public, also taking into account people with disabilities, with information about datasets placed on the EHDS (such as quality and utility labels, dataset information sheets); to provide the data users with up-to-date data quality		information concerning the source, nature of data and conditions for making data available. Therefore, an EU datasets catalogue should be established to facilitate the discoverability of datasets available in the EHDS; to help data holders to publish their datasets; to provide all stakeholders, including the general public, also taking into account people with disabilities, with information about datasets placed on the EHDS (such as quality and utility labels, dataset information sheets); to provide the data users with up-to-date data quality and utility information	information concerning the source, nature of data and conditions for making data available. Therefore, an EU datasets catalogue should be established to facilitate the discoverability of datasets available in the EHDS; to help data holders to publish their datasets; to provide all stakeholders, including the general public, also taking into account people with disabilities, with information about datasets placed on the EHDS (such as quality and utility labels, dataset information sheets); to provide the data users with up-to-date data quality and utility information	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and utility information about datasets.		about datasets.	about datasets.	
	Recital 59				
69	(59) Information on the quality and utility of datasets increases the value of outcomes from data intensive research and innovation significantly, while, at the same time, promoting evidence-based regulatory and policy decision-making. Improving the quality and utility of datasets through informed customer choice		(59) Information on the quality and utility of datasets increases the value of outcomes from data intensive research and innovation significantly, while, at the same time, promoting evidence-based regulatory and policy decision-making. Improving the quality and utility of datasets through informed customer choice and	(59) Information on the quality and utility of datasets increases the value of outcomes from data intensive research and innovation significantly, while, at the same time, promoting evidence-based regulatory and policy decision-making. Improving the quality and utility of datasets through informed customer choice and	

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	and harmonising related requirements at Union level, taking into account existing Union and international standards, guidelines, recommendations for data collection and data exchange (i.e. FAIR principles: Findable, Accessible, Interoperable and Reusable), benefits also data holders, health professionals, natural persons and the Union economy overall. A data quality and utility label for datasets would inform data users about the quality and utility characteristics of a dataset and enable them to		harmonising related requirements at Union level, taking into account existing Union and international standards, guidelines, recommendations for data collection and data exchange (i.e. FAIR principles: Findable, Accessible, Interoperable and Reusable), benefits also data holders, health professionals, natural persons and the Union economy overall. A data quality and utility label for datasets would inform data users about the quality and utility characteristics of a dataset and enable them to choose the datasets that best	harmonising related requirements at Union level, taking into account existing Union and international standards, guidelines, recommendations for data collection and data exchange (i.e. FAIR principles: Findable, Accessible, Interoperable and Reusable), benefits also data holders, health professionals, natural persons and the Union economy overall. A data quality and utility label for datasets would inform data users about the quality and utility characteristics of a dataset and enable them to choose the datasets that best	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	choose the datasets that best fit their needs. The data quality and utility label should not prevent datasets from being made available through the EHDS, but provide a transparency mechanism between data holders and data users. For example, a dataset that does not fulfil any requirement of data quality and utility should be labelled with the class representing the poorest quality and utility, but should still be made available. Expectations set in frameworks described in Article 10 of Regulation […] [AI Act COM/2021/206 final] and		fit their needs. The data quality and utility label should not prevent datasets from being made available through the EHDS, but provide a transparency mechanism between data holders and data users. For example, a dataset that does not fulfil any requirement of data quality and utility should be labelled with the class representing the poorest quality and utility, but should still be made available. Expectations set in frameworks described in Article 10 of Regulation […] [AI Act COM/2021/206 final] and its relevant documentation	fit their needs. The data quality and utility label should not prevent datasets from being made available through the EHDS, but provide a transparency mechanism between data holders and data users. For example, a dataset that does not fulfil any requirement of data quality and utility should be labelled with the class representing the poorest quality and utility, but should still be made available. Expectations set in frameworks described in Article 10 of Regulation […] [AI Act COM/2021/206 final] and its relevant documentation	

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	its relevant documentation specified in Annex IV should be taken into account when developing the data quality and utility framework. Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support these activities.		specified in Annex IV should be taken into account when developing the data quality and utility framework. ***The labels should be subject to the evaluation by the health data access bodies.*** Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support these activities.	specified in Annex IV should be taken into account when developing the data quality and utility framework. Member States should raise awareness about the data quality and utility label through communication activities. The Commission could support these activities.	
		Recital 60			
70					

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	(60) The EU datasets catalogue should minimise the administrative burden for the data holders and other database users; be user-friendly, accessible and cost-effective, connect national data catalogues and avoid redundant registration of datasets. The EU datasets catalogue could be aligned with the data.europa.eu initiative and without prejudice to the requirements set out in the Regulation […] [Data Governance Act COM/2020/767 final]. Member states should ensure that national data catalogues are interoperable		(60) The EU datasets catalogue should minimise the administrative burden for the data holders and other database users; be user-friendly, accessible and cost-effective, connect national data catalogues and avoid redundant registration of datasets. The EU datasets catalogue could be aligned with the data.europa.eu initiative and without prejudice to the requirements set out in the Regulation […] [Data Governance Act COM/2020/767 final]. Member states should ensure that national data catalogues are interoperable	(60) The EU datasets catalogue should minimise the administrative burden for the data holders and other database users; be user-friendly, accessible and cost-effective, connect national data catalogues and avoid redundant registration of datasets. The EU datasets catalogue could be aligned with the data.europa.eu initiative and without prejudice to the requirements set out in the Regulation […] [Data Governance Act COM/2020/767 final]. Member states should ensure that national data catalogues are interoperable	

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	with existing dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.		with existing dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.	with existing dataset catalogues from European research infrastructures and other relevant data sharing infrastructures.	
	Recital 61				
71	(61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is		(61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is	(61) Cooperation and work is ongoing between different professional organisations, the Commission and other institutions to set up minimum data fields and other characteristics of different datasets (registries for instance). This work is	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	more advanced in areas such as cancer, rare diseases, and statistics and shall be taken into account when defining new standards. However, many datasets are not harmonised, raising comparability issues and making cross-border research difficult. Therefore, more detailed rules should be set out in implementing acts to ensure a harmonised provision, coding and registration of electronic health data. Member States should work towards delivering sustainable economic and social benefits of European electronic health systems		more advanced in areas such as cancer, rare diseases, ***cardiovascular and metabolic diseases, risk factor assessment,*** and statistics and shall be taken into account when defining new standards ***and disease-specific harmonised templates for structured data elements***. However, many datasets are not harmonised, raising comparability issues and making cross-border research difficult. Therefore, more detailed rules should be set out in implementing acts to ensure a harmonised provision, coding and registration of	more advanced in areas such as cancer, rare diseases, and statistics and ~~shall~~**should** be taken into account when defining new standards. However, many datasets are not harmonised, raising comparability issues and making cross-border research difficult. Therefore, more detailed rules should be set out in implementing acts to ensure a harmonised ~~provision,~~ coding and registration of electronic health data**. Such datasets may include data from registries of rare diseases, orphan drugs databases, cancer registries and registries of**	

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	and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of healthcare and ensuring access to safe and high-quality healthcare.		electronic health data. Member States should work towards delivering sustainable economic and social benefits of European electronic health systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of healthcare and ensuring access to safe and high-quality healthcare. ***Existing health data infrastructures and registries put in place by institutions and stakeholders can contribute to defining and implementing data***	**highly relevant infectious diseases**. Member States should work towards delivering sustainable economic and social benefits of European electronic health systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of healthcare and ensuring access to safe and high-quality healthcare.	

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			standards, to ensuring interoperability and should be leveraged to allow for continuity and build on existing expertise.		
	Recital 62				
72	(62) The Commission should support Member States in building capacity and effectiveness in the area of digital health systems for primary and secondary use of electronic health data. Member States should be supported to strengthen their capacity. Activities at		(62) The Commission should support Member States in building capacity and effectiveness in the area of digital health systems for primary and secondary use of electronic health data. Member States should be supported to strengthen their capacity. Activities at	(62) The Commission should support Member States in building capacity and effectiveness in the area of digital health systems for primary and secondary use of electronic health data. Member States should be supported to strengthen their capacity. Activities at	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union level, such as benchmarking and exchange of best practices are relevant measures in this respect.		Union level, such as benchmarking and exchange of best practices are relevant measures in this respect.	Union level, such as benchmarking and exchange of best practices are relevant measures in this respect.	
		Recital 62a			
72a			***(62a) Improving digital health literacy for both natural persons and their health professionals is key in order to achieve trust, safety and appropriate use of health data and thus to achieve successful implementation of this Regulation. Improving***		

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			digital health literacy is fundamental in order to empower natural persons to have true control over their health data and actively manage their health and care, and understand the implications of the management of such data for both primary and secondary use. Member States, including regional and local authorities, should therefore support digital health literacy and public awareness, while ensuring that the implementation of this Regulation contributes to reducing inequalities and		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			does not discriminate against people lacking digital skills. Particular attention should be given to persons with disabilities and vulnerable groups including migrants and the elderly. Health professionals and IT operators should have sufficient training in working with new digital infrastructures to ensure cybersecurity and ethical management of health data.		
	Recital 63				

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73	(63) The use of funds should also contribute to attaining the objectives of the EHDS. Public procurers, national competent authorities in the Member States, including digital health authorities and health data access bodies, as well as the Commission should make references to applicable technical specifications, standards and profiles on interoperability, security and data quality, as well as other requirements developed under this Regulation when defining		(63) The use of funds should also contribute to attaining the objectives of the EHDS. Public procurers, national competent authorities in the Member States, including digital health authorities and health data access bodies, as well as the Commission should make references to applicable technical specifications, standards and profiles on interoperability, security and data quality, as well as other requirements developed under this Regulation when defining	(63) The use of funds should also contribute to attaining the objectives of the EHDS. Public procurers, national competent authorities in the Member States, including digital health authorities and health data access bodies, as well as the Commission should make references to applicable technical specifications, standards and profiles on interoperability, security and data quality, as well as other requirements developed under this Regulation when defining	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the conditions for public procurement, calls for proposals and allocation of Union funds, including structural and cohesion funds.		the conditions for public procurement, calls for proposals and allocation of Union funds, including structural and cohesion funds. ***To procure or fund services provided by controllers and processors established in the Union that process personal electronic health data, they should be required to demonstrate that they will store the data in the Union and that they are not subject to third country law that conflicts with Union data protection rules. Union funds should be distributed transparently and sufficiently among the***	the conditions for public procurement, calls for proposals and allocation of Union funds, including structural and cohesion funds.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Member States, ensuring it is adequate and taking into account different levels of health system digitalisation and the costs involved in making national data infrastructures interoperable and compatible with the requirements of the EHDS. Making data available for secondary use requires additional resources for healthcare systems, in particular public systems. That additional burden for public entities should be addressed and minimised to the greatest possible extent during the implementation phase of		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the EHDS.		
	Recital 63a				
73a			***(63a) The economic costs of implementing this Regulation should be borne at both Member State and Union level, and a fair sharing of that burden between national and Union funds should be found. The initial Union funding to achieve a timely application of the EHDS is limited to what can be mobilised under the 2021-2027 Multiannual***		

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			Financial Framework (MFF) where EUR 220 million can be made available under the EU4Health and Digital Europe programmes. The successful and coherent application of the EHDS across all Member States will however require higher funding. The implementation of the EHDS requires appropriate investments in capacity building and training and a well-funded commitment to public consultation and engagement. The Commission should therefore mobilise further resources for the EHDS as		

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			part of the review of the 2021-2027 MFF and for the forthcoming MFF under the principle that new initiatives should be matched with new funding.		
		Recital 63a			
73b				**(63a) Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital health authority, a health data access body or a health data user to transfer or**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				give access to anonymous non-personal electronic health data within the scope of this Regulation held in the Union should be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State, compliant with Union law.	

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	Recital 64				
74	(64) Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically foreseen in the Data Governance Act. Even in situations of the use of state of the art anonymization techniques, there remains a residual risk that the capacity to re-identify could be or become available, beyond the means reasonably likely to be		(64) Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically foreseen in the Data Governance Act. Even in situations of the use of state of the art anonymization techniques, there remains a residual risk that the capacity to re-identify could be or become available, beyond the means reasonably likely to be used. Such residual risk is present	(64) Certain categories of electronic health data can remain particularly sensitive even when they are in anonymised format and thus non-personal, as already specifically foreseen in the Data Governance Act. Even in situations of the use of state of the art anonymization techniques, there remains a residual risk that the capacity to re-identify could be or become available, beyond the means reasonably likely to be used. Such residual risk is present	

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	used. Such residual risk is present in relation to rare diseases (a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Union), where the limited numbers of case reduce the possibility to fully aggregate the published data in order to preserve the privacy of natural persons while also maintaining an appropriate level of granularity in order to remain meaningful. It can affect different types of health data depending on the level of granularity and description of the		in relation to rare diseases (a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Union), where the limited numbers of case reduce the possibility to fully aggregate the published data in order to preserve the privacy of natural persons while also maintaining an appropriate level of granularity in order to remain meaningful. It can affect different types of health data depending on the level of granularity and description of the characteristics of data	in relation to rare diseases (a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Union), where the limited numbers of case reduce the possibility to fully aggregate the published data in order to preserve the privacy of natural persons while also maintaining an appropriate level of granularity in order to remain meaningful. It can affect different types of health data depending on the level of granularity and description of the characteristics of data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	characteristics of data subjects, the number of people affected or and for instance in cases of data included in electronic health records, disease registries, biobanks, person generated data etc. where the identification characteristics are broader and where, in combination with other information (e.g. in very small geographical areas) or through the technological evolution of methods which had not been available at the moment of anonymisation, can lead to the re-identification of the data subjects using means that		subjects, the number of people affected or and for instance in cases of data included in electronic health records, disease registries, biobanks, person generated data etc. where the identification characteristics are broader and where, in combination with other information (e.g. in very small geographical areas) or through the technological evolution of methods which had not been available at the moment of anonymisation, can lead to the re-identification of the data subjects using means that are beyond those reasonably likely to be used. The	subjects, the number of people affected or and for instance in cases of data included in electronic health records, disease registries, biobanks, person generated data etc. where the identification characteristics are broader and where, in combination with other information (e.g. in very small geographical areas) or through the technological evolution of methods which had not been available at the moment of anonymisation, can lead to the re-identification of the data subjects using means that are beyond those reasonably likely to be used. The	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	are beyond those reasonably likely to be used. The realisation of such risk of re-identification of natural persons would present a major concern and is likely to put the acceptance of the policy and rules on secondary use provided for in this Regulation at risk. Furthermore, aggregation techniques are less tested for non-personal data containing for example trade secrets, as in the reporting on clinical trials, and enforcement of breaches of trade secrets outside the Union is more difficult in the absence of a		realisation of such risk of re-identification of natural persons would present a major concern and is likely to put the acceptance of the policy and rules on secondary use provided for in this Regulation at risk. Furthermore, aggregation techniques are less tested for non-personal data containing for example trade secrets, as in the reporting on clinical trials, and enforcement of breaches of trade secrets outside the Union is more difficult in the absence of a sufficient international protection standard. Therefore, for these types of	realisation of such risk of re-identification of natural persons would present a major concern and is likely to put the acceptance of the policy and rules on secondary use provided for in this Regulation at risk. Furthermore, aggregation techniques are less tested for non-personal data containing for example trade secrets, as in the reporting on clinical trials, and enforcement of breaches of trade secrets outside the Union is more difficult in the absence of a sufficient international protection standard. Therefore, for these types of	

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	sufficient international protection standard. Therefore, for these types of health data, there remains a risk for re-identification after the anonymisation or aggregation, which could not be reasonably mitigated initially. This falls within the criteria indicated in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final]. These types of health data would thus fall within the empowerment set out in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final] for transfer to third countries.		health data, there remains a risk for re-identification after the anonymisation or aggregation, which could not be reasonably mitigated initially. This falls within the criteria indicated in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final]. These types of health data would thus fall within the empowerment set out in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final] for transfer to third countries. The protective measures, proportional to the risk of re-identification, would need to take into account	health data, there remains a risk for re-identification after the anonymisation or aggregation, which could not be reasonably mitigated initially. This falls within the criteria indicated in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final]. These types of health data would thus fall within the empowerment set out in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final] for transfer to third countries. The protective measures, proportional to the risk of re-identification, would need to take into account	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	The protective measures, proportional to the risk of re-identification, would need to take into account the specificities of different data categories or of different anonymization or aggregation techniques and will be detailed in the context of the Delegated Act under the empowerment set out in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final].		the specificities of different data categories or of different anonymization or aggregation techniques and will be detailed in the context of the Delegated Act under the empowerment set out in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final].	the specificities of different data categories or of different anonymization or aggregation techniques and will be detailed in the context of the Delegated Act under the empowerment set out in Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final].	
		Recital 64a			
74a					

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			(64a) The functioning of the EHDS involves processing of a large quantity of personal and non-personal health data of a highly sensitive nature. Article 8(3) of the Charter of Fundamental Rights of the European Union (the 'Charter') requires control over the processing of such health data by an independent authority. The control of the compliance with the requirements of protection and security by an independent supervisory authority, carried out on the basis of Union law, is an essential component of		

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			the protection of individuals with regard to the processing of personal data and cannot be fully ensured in the absence of a requirement to retain the electronic health data in question within the Union. Therefore, taking into account the need to mitigate the risks of unlawful access and ineffective supervision, in compliance with the principle of proportionality, this Regulation should require Member States to store electronic health data within the Union. Such storage requirements		

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			should ensure a uniform high level of protection for data subjects across the Union, preserve the proper functioning of the internal market, in line with Article 114 TFEU, which constitutes the legal basis of this Regulation, and serve to enhance citizens' trust in the EHDS.		
	Recital 64a				
74b				**(64a) The processing of large amounts of personal health data for the purposes foreseen in the**	

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				EHDS, as part of data processing activities in the context of servicing data access applications, data permits and data requests entails higher risks of unauthorised access to such personal data, as well as the possibility of cybersecurity incidents. Personal health data are particularly sensitive as they often constitute intimate information, covered by medical secrecy, the disclosure of which to unauthorised third parties can cause significant distress. Taking fully into consideration the	

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				principles outlined in the case law of the Court of Justice of the European Union, this Regulation ensures full respect for fundamental rights, for the right to privacy and for the principle of proportionality. In order to ensure the full integrity and confidentiality of personal electronic health data under the Regulation, to guarantee a particularly high level of protection and security, and to reduce the risk of unlawful access to that personal electronic health data, the Regulation makes provision for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				personal electronic health data to be stored and processed within the Union for the purpose of carrying out the tasks foreseen by this Regulation, unless an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 applies.	
	Recital 64b				
74c			***(64b) The obligation to store electronic health data in the Union does not preclude transfers of those***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data to third countries or international organisations by means of granting access to electronic health data. Access to data through the secure processing environment can entail the transfer of personal data, as defined in Chapter V of Regulation (EU) 2016/679. It is possible to reconcile a general requirement to store personal data in the Union with specific transfers being allowed in compliance with Union law on personal data protection, for instance in the context of scientific research, provision of care		

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			or international cooperation. In particular, when personal data are transferred from the Union to controllers, processors or other recipients in third countries or to international organisations, the level of protection of natural persons ensured in the Union under Regulation (EU) 2016/679 should not be undermined, including in cases of onward transfers of personal data from the third country or international organisation to controllers, processors in the same or another third country or international		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			organisation. Transfers of personal health data to third countries and international organisations can only be carried out in full compliance with Chapter V of Regulation (EU) 2016/679. For instance, controllers and processors processing personal electronic health data remain subject to Article 48 of that Regulation on transfers or disclosures not authorised by Union law and should comply with this provision in the case of an access request stemming from a third country. In accordance with the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			conditions of Article 9(4) of Regulation (EU) 2016/679, Member States can maintain or introduce further conditions, including limitations, in relation to transfers of personal health data to third countries or international organisations.		
	Recital 64c				
74d			***(64c) Access to electronic health data for entities from third countries should take place only on the basis***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of the reciprocity principle. Making available of health data to a third country can take place only where the Commission has established by means of a delegated act that the third country concerned allows for the use of health data by Union entities under the same conditions and with the same safeguards as within the Union. The Commission should monitor that list and provide for a periodic review thereof. Where the Commission finds that a third country no longer ensures access on the same terms , that third country		

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			should be removed from that list.		
	Recital 65				
75	(65) In order to promote the consistent application of this Regulation, a European Health Data Space Board (EHDS Board) should be set up. The Commission should participate in its activities and chair it. It should contribute to the consistent application of this Regulation throughout the Union, including by helping Member State to		(65) In order to promote the consistent application of this Regulation, ***including cross-border interoperability of health data, and potential mechanisms of funding support to ensure equal development of data systems across the Union in respect of the primary and secondary use of electronic health data,*** a	(65) In order to promote the consistent application of this Regulation, a European Health Data Space Board (EHDS Board) should be set up. The Commission should participate in its activities and chair it. It should contribute to the consistent application of this Regulation throughout the Union, including by helping Member State to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	coordinate the use of electronic health data for healthcare, certification, but also concerning the secondary use of electronic health data. Given that, at national level, digital health authorities dealing with the primary use of electronic health data may be different to the health data access bodies dealing with the secondary use of electronic health data, the functions are different and there is a need for distinct cooperation in each of these areas, the EHDS Board should be able to set up subgroups dealing with these two functions, as well		European Health Data Space Board (EHDS Board) should be set up. The Commission should participate in its activities and chair it. ~~#~~***The EHDS Board*** should contribute to the consistent application of this Regulation throughout the Union, including by helping Member State to coordinate the use of electronic health data for healthcare, certification, but also concerning the secondary use of electronic health data. Given that, at national level, digital health authorities dealing with the primary use of electronic health data may be different	coordinate the use of electronic health data for healthcare, certification, but also concerning the secondary use of electronic health data. Given that, at national level, digital health authorities dealing with the primary use of electronic health data may be different to the health data access bodies dealing with the secondary use of electronic health data, the functions are different and there is a need for distinct cooperation in each of these areas, the EHDS Board should be able to set up subgroups dealing with these two functions, as well	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	as other subgroups, as needed. For an efficient working method, the digital health authorities and health data access bodies should create networks and links at national level with different other bodies and authorities, but also at Union level. Such bodies could comprise data protection authorities, cybersecurity, eID and standardisation bodies, as well as bodies and expert groups under Regulations […], […], […] and […] [Data Governance Act, Data Act, AI Act and Cybersecurity Act].		to the health data access bodies dealing with the secondary use of electronic health data, the functions are different and there is a need for distinct cooperation in each of these areas, the EHDS Board should be able to set up subgroups dealing with these two functions, as well as other subgroups, as needed. For an efficient working method, the digital health authorities and health data access bodies should create networks and links at national level with different other bodies and authorities, but also at Union level. Such bodies could comprise	as other subgroups, as needed. For an efficient working method, the digital health authorities and health data access bodies should create networks and links at national level with different other bodies and authorities, but also at Union level. Such bodies could comprise data protection authorities, cybersecurity, eID and standardisation bodies, as well as bodies and expert groups under Regulations […], […], […] and […] [Data Governance Act, Data Act, AI Act and Cybersecurity Act].	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data protection authorities, cybersecurity, eID and standardisation bodies, as well as bodies and expert groups under Regulations […], […], […] and […] [Data Governance Act, Data Act, AI Act and Cybersecurity Act]. ***The EHDS Board should operate in line with its Code of Conduct, impartially, independently, in the public interest and transparently, with open publication of meeting dates and minutes of its discussions as well as of an annual report. It is furthermore appropriate to lay down sufficient***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			guarantees to ensure that members of the EHDS Board do not have any conflicts of interest.		
	Recital 65a				
75a			***(65a) An advisory forum should be set up to advise the EHDS Board in the fulfilment of its tasks by providing stakeholder input on matters pertaining to this Regulation. The advisory forum should be composed of representatives of patients, consumers, health***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			professionals, industry, scientific researchers and academia. It should have a balanced composition and represent the views of different relevant stakeholders. Both commercial and non-commercial interests should be represented.		
	Recital 66				
76	(66) In order to manage the cross-border infrastructures for primary and secondary use of electronic health data, it is necessary to		(66) In order to manage the cross-border infrastructures for primary and secondary use of electronic health data, it is necessary to	(66) In order to manage the cross-border infrastructures for primary and secondary use of electronic health data, it is necessary to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	create the Joint controllership group for authorised participants (e.g. to ensure the compliance with data protection rules and this Regulation for the processing operations performed in such infrastructures).		create the Joint controllership group for authorised participants (e.g. to ensure the compliance with data protection rules and this Regulation for the processing operations performed in such infrastructures).	create the Joint controllership group for authorised participants (e.g. to ensure the compliance with data protection rules and this Regulation for the processing operations performed in such infrastructures).	
	Recital 66a				
76a			***(66a) Any natural person should have the right to lodge a complaint with a digital health authority or with a health data access body, in particular in the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Member State of his or her habitual residence, and the right to an effective judicial remedy in accordance with Article 47 of the Charter if the natural person considers that his or her rights under this Regulation have been infringed or where the digital health authority or health data access body does not act on a complaint, partially or wholly rejects or dismisses a complaint or does not act where such action is necessary to protect the rights of the natural person. The investigation following a complaint		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			should be carried out, subject to judicial review, to the extent that is appropriate in the specific case. The digital health authority or health data access body should inform the natural person of the progress and the outcome of the complaint within a reasonable period. If the case requires further investigation or coordination with another digital health authority or health data access body, intermediate information should be given to the natural person. In order to facilitate the submission of complaints, each digital		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health authority and health data access body should take measures such as providing a complaint submission form which can also be completed electronically, without excluding the possibility of using other means of communication. Where the complaint concerns the rights of natural persons, the health data access body should inform the supervisory authorities under Regulation (EU) 2016/679 and send them a copy of the complaint.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 66b				
76b			***(66b) Where a natural person considers that his or her rights under this Regulation have been infringed, he or she should have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal data, to lodge a complaint on his or her behalf.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Recital 66c				
76c			***(66c) Any natural or legal person has the right to bring an action for annulment of decisions of the EHDS Board before the Court of Justice under the conditions provided for in Article 263 TFEU. As addressees of such decisions, the digital health authorities or health data access bodies concerned which wish to challenge them have to bring an action within two months***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of being notified of them, in accordance with Article 263 TFEU. In accordance with Article 263 TFEU, a health data holder, a health data applicant, a health data user or a complainant can bring an action for annulment against the decisions of the EHDS Board which concern them within two months of their publication on the website of the EHDS Board.. Without prejudice to this right under Article 263 TFEU, each natural or legal person should have an effective judicial remedy before the competent		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			national court against a decision of a digital health authority or health data access body which produces legal effects concerning that person. Such a decision concerns in particular the exercise of investigative, corrective and authorisation powers by the health data access body or the dismissal or rejection of complaints. However, the right to an effective judicial remedy does not encompass measures taken by digital health authorities and health data access bodies which are not legally binding, such as opinions		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			issued or advice provided. Proceedings against a digital health authority or health data access body should be brought before the courts of the Member State where the digital health authority or health data access body is established and should be conducted in accordance with that Member State's procedural law. Those courts should exercise full jurisdiction, which should include jurisdiction to examine all questions of fact and law relevant to the dispute before them. Where a complaint has been rejected or dismissed by a		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			digital health authority or health data access body, the complainant can bring proceedings before the courts in the same Member State.		
		Recital 66d			
76d			***(66d) Where a court seised of proceedings against a decision by a digital health authority or health data access body has reason to believe that proceedings concerning the same access to electronic health data by the same health***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data user, such as for the same purpose for processing for secondary use, are brought before a competent court in another Member State, it should contact that court in order to confirm the existence of such related proceedings. If related proceedings are pending before a court in another Member State, any court other than the court first seised should be able to stay its proceedings or be able to, on request of one of the parties, decline jurisdiction in favour of the court first seised if that court has jurisdiction over the proceedings in question		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and its law permits the consolidation of such related proceedings. Proceedings should be deemed to be related where they are so closely connected that it is expedient to hear and determine them together in order to avoid the risk of irreconcilable judgments resulting from separate proceedings.		
	Recital 66e				
76e			***(66e) For proceedings against a health data***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			holder or health data user, the plaintiff should have the choice of bringing the action before the courts of the Member States where the health data holder or health data user has an establishment or where the natural person resides, unless the health data holder is a public authority of a Member State acting in the exercise of its public powers.		
	Recital 66f				
76f			***(66f) The digital health***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			authority, health data access body, health data holder or health data user should compensate any damage which a person could suffer as a result of processing that infringes this Regulation. The digital health authority, health data access body, health data holder or health data user should be exempt from liability if it proves that it was not in any way responsible for the damage. The concept of damage should be broadly interpreted in the light of the case-law of the Court of Justice in a manner which fully reflects the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			objectives of this Regulation. This is without prejudice to any claims for damage deriving from the violation of other rules in Union or national law. Processing that infringes this Regulation should also include processing that infringes delegated and implementing acts adopted in accordance with this Regulation and national law specifying rules related to this Regulation. Natural persons should receive full and effective compensation for the damage they have suffered. Where digital health authorities, health data access bodies, health		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data holders or health data users are involved in the same processing, each actor should be held liable for the entire extent of the damage. However, where they are joined to the same judicial proceedings, in accordance with Member State law, it should be possible to apportion compensation according to the responsibility of each digital health authority, health data access body, health data holder or health data user for the damage caused by the processing, provided that full and effective compensation of the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural person who suffered the damage is ensured. Any digital health authority, health data access body, health data holder or health data user which has paid full compensation should be able to subsequently institute recourse proceedings against other digital health authorities, health data access bodies, health data holders or health data users involved in the same processing.		
	Recital 66g				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
76g			***(66g) Where specific rules on jurisdiction are contained in this Regulation, in particular as regards proceedings seeking a judicial remedy including compensation, against a digital health authority, health data access body, health data holder or health data user, general jurisdiction rules such as those of Regulation (EU) No 1215/2012 of the European Parliament and of the Council[1] should not prejudice the application of such specific rules.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			_____ *1. Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (OJ L 351, 20.12.2012, p. 1).*		
	Recital 66h				
76h			*(66h) In order to strengthen the enforcement of the rules of this Regulation, penalties including administrative fines should be imposed for*		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			any infringement of this Regulation, in addition to, or instead of, appropriate measures imposed by the digital health authority or health data access body pursuant to this Regulation. In the case of a minor infringement or if the fine likely to be imposed would constitute a disproportionate burden for a natural person, it should be possible to issue a reprimand instead of a fine. Due regard should however be given to the nature, gravity and duration of the infringement, the intentional character of the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			infringement, actions taken to mitigate the damage suffered, the degree of responsibility or any relevant previous infringements, the manner in which the infringement became known to the digital health authority or health data access body, compliance with measures ordered against the health data holder or health data user, adherence to a code of conduct and any other aggravating or mitigating factor. The imposition of penalties, including administrative fines, should be subject to appropriate procedural		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			safeguards in accordance with the general principles of Union law and the Charter, including effective judicial protection and due process.		
	Recital 66i				
76i			***(66i) Member States should be able to lay down the rules on criminal penalties for infringements of this Regulation, including for infringements of national rules adopted pursuant to and within the limits of this***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation. Such criminal penalties could also involve the deprivation of profits obtained through infringements of this Regulation. However, the imposition of criminal penalties for infringements of such national rules and of administrative penalties should not lead to a breach of the principle of ne bis in idem, as interpreted by the Court of Justice.		
	Recital 66j				
76j			***(66j) It is appropriate to***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			lay down provisions enabling health data access bodies to apply administrative fines for certain infringements of this Regulation whereby certain infringements are to be regarded as serious infringements, such as the re-identification of natural persons, downloading personal health data outside of the secure processing environment and processing of data for prohibited uses or outside a data permit. This Regulation should indicate infringements and the upper limit and criteria for setting the related		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			administrative fines, which should be determined by the competent health data access body in each individual case, taking into account all the relevant circumstances of the specific situation, with due regard in particular to the nature, gravity and duration of the infringement and of its consequences and the measures taken to ensure compliance with the obligations under this Regulation and to prevent or mitigate the consequences of the infringement. Where administrative fines are		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			imposed on an undertaking, an undertaking should be understood to be an undertaking in accordance with Articles 101 and 102 TFEU for those purposes. Where administrative fines are imposed on persons that are not an undertaking, the health data access body should take account of the general level of income in the Member State as well as the economic situation of the person in considering the appropriate amount of the fine. The consistency mechanism could also be used to promote the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			consistent application of administrative fines. It should be for the Member States to determine whether and to which extent public authorities should be subject to administrative fines. Imposing an administrative fine or giving a warning does not affect the application of other powers of the health data access bodies or of other penalties under this Regulation.		
	Recital 66k				
76k					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(66k) The legal systems of Denmark and Estonia do not provide for administrative fines as set out in this Regulation. It should be possible to apply the rules on administrative fines in a manner such that in Denmark the fine is imposed by competent national courts as a criminal penalty, and that in Estonia the fine is imposed by the supervisory authority in the framework of a misdemeanour procedure, provided that such an application of the rules in those Member States has an equivalent effect to administrative		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			fines imposed by supervisory authorities. Therefore the competent national courts should take into account the recommendation by the health data access body initiating the fine. In any event, the fines imposed should be effective, proportionate and dissuasive.		
	Recital 66l				
76l			***(66l) Where this Regulation does not harmonise administrative***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			penalties or where necessary in other cases, for example in cases of serious infringements of this Regulation, Member States should implement a system which provides for effective, proportionate and dissuasive penalties. The nature of such penalties, criminal or administrative, should be determined by national law.		
	Recital 67				
77	(67) Since the objectives of this Regulation: to		(67) Since the objectives of this Regulation: to empower	(67) Since the objectives of this Regulation: to empower	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	empower natural persons through increased control of their personal health data and support their free movement by ensuring that health data follows them; to foster a genuine single market for digital health services and products; to ensure a consistent and efficient framework for the reuse of natural persons' health data for research, innovation, policy-making and regulatory activities cannot be sufficiently achieved by the Member States, through coordination measures alone, as shown by the evaluation of the digital aspects of the		natural persons through increased control of their personal health data and support their free movement by ensuring that health data follows them; to foster a genuine single market for digital health services and products; to ensure a consistent and efficient framework for the reuse of natural persons' health data for research, innovation, policy-making and regulatory activities cannot be sufficiently achieved by the Member States, through coordination measures alone, as shown by the evaluation of the digital aspects of the Directive	natural persons through increased control of their personal health data and support their free movement by ensuring that health data follows them; to foster a genuine single market for digital health services and products; to ensure a consistent and efficient framework for the reuse of natural persons' health data for research, innovation, policy-making and regulatory activities cannot be sufficiently achieved by the Member States, through coordination measures alone, as shown by the evaluation of the digital aspects of the Directive	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Directive 2011/24/EU but can rather, by reason of harmonising measures for rights of natural persons in relation to their electronic health data, interoperability of electronic health data and a common framework and safeguards for the primary and secondary use of electronic health data, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article,		2011/24/EU but can rather, by reason of harmonising measures for rights of natural persons in relation to their electronic health data, interoperability of electronic health data and a common framework and safeguards for the primary and secondary use of electronic health data, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article,	2011/24/EU but can rather, by reason of harmonising measures for rights of natural persons in relation to their electronic health data, interoperability of electronic health data and a common framework and safeguards for the primary and secondary use of electronic health data, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	this Regulation does not go beyond what is necessary in order to achieve those objectives.		this Regulation does not go beyond what is necessary in order to achieve those objectives.	this Regulation does not go beyond what is necessary in order to achieve those objectives.	
	Recital 68				
78	(68) In order to ensure that EHDS fulfils its objectives, the power to adopt acts in accordance with Article 290 Treaty on the Functioning of the European Union should be delegated to the Commission in respect of different provisions of primary and secondary use of electronic health data. It		(68) In order to ensure that EHDS fulfils its objectives, the power to adopt acts in accordance with Article 290 Treaty on the Functioning of the European Union should be delegated to the Commission in respect of different provisions of primary and secondary use of electronic health data. It	(68) In order to ensure that EHDS fulfils its objectives, the power to adopt acts in accordance with Article 290 Treaty on the Functioning of the European Union should be delegated to the Commission in respect of different provisions of primary and secondary use of electronic health data. It	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their		is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts	is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.		systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	
	Recital 69				
79	(69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised		(69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised	(69) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).		in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	
	Recital 69a				
79a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(69a) In accordance with Article 42 of Regulation (EU) 2018/1725, the Commission should, when preparing delegated acts or implementing acts, consult the European Data Protection Supervisor where there is an impact on the protection of individuals' rights and freedoms with regard to the processing of personal data, and where such an act is of particular importance for the protection of individuals' rights and freedoms with regard to the processing of personal data, the Commission can also		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			consult the European Data Protection Board. The Commission should moreover consult the European Data Protection Board in the cases specified in Regulation (EU) 2016/679 and when relevant in the context of this Regulation.		
	Recital 70				
80	(70) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by		(70) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by	(70) Member States should take all necessary measures to ensure that the provisions of this Regulation are implemented, including by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation.		laying down effective, proportionate and dissuasive penalties for their infringement. ***When deciding on the amount of the penalty for each individual case*** ~~*For certain specific infringements,*~~ Member States should take into account the margins and criteria set out in this Regulation. ***Re-identification of natural persons should be considered a particularly serious breach of this Regulation. Member States should be able to consider criminalising re-identification by health data users so that it serves***	laying down effective, proportionate and dissuasive penalties for their infringement. For certain specific infringements, Member States should take into account the margins and criteria set out in this Regulation.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			as a deterrent measure.		
	Recital 71				
81	(71) In order to assess whether this Regulation reaches its objectives effectively and efficiently, is coherent and still relevant and provides added value at Union level the Commission should carry out an evaluation of this Regulation. The Commission should carry out a partial evaluation of this Regulation 5 years after its entry into force, on the		(71) In order to assess whether this Regulation reaches its objectives effectively and efficiently, is coherent and still relevant and provides added value at Union level the Commission should carry out an evaluation of this Regulation. The Commission should carry out a partial evaluation of this Regulation 5 years after its entry into force, ~~*on the*~~	(71) In order to assess whether this Regulation reaches its objectives effectively and efficiently, is coherent and still relevant and provides added value at Union level the Commission should carry out an evaluation of this Regulation. The Commission should carry out a partial evaluation of this Regulation 5 years after its entry into force, on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	self-certification of EHR systems, and an overall evaluation 7 years after the entry into force of this Regulation. The Commission should submit reports on its main findings following each evaluation to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions.		~~*self-certification of EHR systems,*~~ and an overall evaluation 7 years after the entry into force of this Regulation. The Commission should submit reports on its main findings following each evaluation to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions.	self-certification of EHR systems, and an overall evaluation 7 years after the entry into force of this Regulation. The Commission should submit reports on its main findings following each evaluation to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions.	
	Recital 72				
82	(72) For a successful cross-border implementation of		(72) For a successful cross-border implementation of	(72) For a successful cross-border implementation of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	EHDS, the European Interoperability Framework[1] to ensure legal, organisational, semantic and technical interoperability should be considered as common reference. _____ 1. European Commission, European Interoperability Framework.		EHDS, the European Interoperability Framework[1] to ensure legal, organisational, semantic and technical interoperability should be considered as common reference. _____ 1. European Commission, European Interoperability Framework.	EHDS, the European Interoperability Framework[1] to ensure legal, organisational, semantic and technical interoperability should be considered as common reference. _____ 1. European Commission, European Interoperability Framework.	
		Recital 73			
83	(73) The evaluation of the digital aspects of Directive		(73) The evaluation of the digital aspects of Directive	(73) The evaluation of the digital aspects of Directive	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2011/24/EU shows limited effectiveness of eHealth Network, but also strong potential for EU work in this area, as shown by the work during pandemic. Therefore, the article 14 of the Directive will be repealed and replaced by the current Regulation and the Directive will be amended accordingly.		2011/24/EU shows limited effectiveness of eHealth Network, but also strong potential for EU work in this area, as shown by the work during pandemic. Therefore, the article 14 of the Directive will be repealed and replaced by the current Regulation and the Directive will be amended accordingly.	2011/24/EU shows limited effectiveness of eHealth Network, but also strong potential for EU work in this area, as shown by the work during pandemic. Therefore, the article 14 of the Directive will be repealed and replaced by the current Regulation and the Directive will be amended accordingly.	
	Recital 74				
84	(74) The European Data Protection Supervisor and the European Data		(74) The European Data Protection Supervisor and the European Data	(74) The European Data Protection Supervisor and the European Data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on […].		Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered ~~an~~***Joint*** opinion ***n. 03/2022 on 12 July 2022*** ~~on […]~~.	Protection Board were consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on […].	
		Recital 75			
85	(75) This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 of the Treaty. The measures provided for in this Regulation should not		(75) This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 of the Treaty. The measures provided for in this Regulation should not	(75) This Regulation should not affect the application of the rules of competition, and in particular Articles 101 and 102 of the Treaty. The measures provided for in this Regulation should not	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	be used to restrict competition in a manner contrary to the Treaty.		be used to restrict competition in a manner contrary to the Treaty.	be used to restrict competition in a manner contrary to the Treaty.	
	Recital 76				
86	(76) Given the need for technical preparation, this Regulation should apply from [12 months after entry into force],		(76) Given the need for technical preparation, this Regulation should apply from [~~12~~24 months after entry into force],	(76) Given the need for technical preparation, this Regulation should apply from [12 months after entry into force],	
	Formula				
87	HAVE ADOPTED THIS		HAVE ADOPTED THIS	HAVE ADOPTED THIS	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	REGULATION:		REGULATION:	REGULATION:	
	Chapter I				
88	Chapter I General provisions		Chapter I General provisions	Chapter I General provisions	
	Article 1				
89	Article 1 Subject matter and scope		Article 1 Subject matter and scope	Article 1 Subject matter and scope	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 1(1)				
90	1. This Regulation establishes the European Health Data Space ('EHDS') by providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data.		1. This Regulation establishes the European Health Data Space ('EHDS') by providing for rules, common standards and practices, infrastructures and a governance framework for the primary and secondary use of electronic health data.	1. This Regulation establishes the European Health Data Space ('EHDS') by providing for **common** rules, ~~common~~ standards ~~and practices~~, infrastructures and a governance framework **with a view to facilitating access to electronic health data** for the **purposes of** primary and secondary use of ~~electronic health~~ **these** data.	
	Article 1(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
91	2. This Regulation:		2. This Regulation:	2. This Regulation:	
		Article 1(2), point (a)			
92	(a) strengthens the rights of natural persons in relation to the availability and control of their electronic health data;		(a) ~~*strengthens*~~***specifies*** the rights of natural persons in relation to the availability**,** ***sharing*** and control of their electronic health data;	(a) ~~strengthens~~**specifies and complements** the rights **laid down in the Regulation (EU) 2016/679** of natural persons in relation to the ~~availability and control~~**primary and secondary use** of their **personal** electronic health data;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 1(2), point (b)				
93	(b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems (‘EHR systems’) in the Union;		(b) lays down rules for the placing on the market, making available on the market or putting into service of electronic health records systems (‘EHR systems’) in the Union;	(b) lays down **common** rules for **electronic health records systems (‘EHR systems’) in relation to two mandatory software components, namely the ‘European interoperability component for EHR** ~~the placing on the market, making available on the market or putting into service of electronic health records~~ systems**’ and the** (‘**European logging component for** EHR systems’ **as defined in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 2(2), subparagraphs (nc) and (nd) and wellness applications that claim interoperability with EHR systems in relation to those two components in the Union **for primary use**;	
	Article 1(2), point (c)				
94	(c) lays down rules and mechanisms supporting the secondary use of electronic health data;		(c) lays down rules and mechanisms supporting the secondary use of electronic health data;	(c) lays down **common** rules and mechanisms ~~supporting the~~**for primary and** secondary use of electronic health data;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 1(2), point (d)				
95	(d) establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the Union;		(d) establishes a mandatory cross-border infrastructure enabling the primary use of electronic health data across the Union;	(d) establishes a ~~mandatory~~ cross-border infrastructure enabling the primary use of **personal** electronic health data across the Union;	
	Article 1(2), point (e)				
96	(e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data.		(e) establishes a mandatory cross-border infrastructure for the secondary use of electronic health data.	(e) establishes a ~~mandatory~~ cross-border infrastructure for the secondary use of electronic health data~~.~~**;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 1(2), point (f)				
96a				**(f) establishes governance and coordination on national and European level for both primary and secondary use of electronic health data.**	
	Article 1(3)				
97	3. This Regulation applies to:		3. This Regulation applies to:	~~3. This Regulation applies to:~~	
	Article 1(3), point (a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
98	(a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;		(a) manufacturers and suppliers of EHR systems and wellness applications, ***and of products claiming interoperability with EHR systems,*** placed on the market and put into service in the Union and the users of such products;	~~(a) manufacturers and suppliers of EHR systems and wellness applications placed on the market and put into service in the Union and the users of such products;~~	
		Article 1(3), point (b)			
99	(b) controllers and processors established in the Union processing electronic health data of		(b) controllers and processors established in the Union processing electronic health data of	~~(b) controllers and processors established in the Union processing electronic health data of~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union citizens and third-country nationals legally residing in the territories of Member States;		Union citizens and third-country nationals legally residing in the territories of Member States;	~~Union citizens and third-country nationals legally residing in the territories of Member States;~~	
		Article 1(3), point (c)			
100	(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);		(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);	~~(c) controllers and processors established in a third country that has been connected to or are interoperable with MyHealth@EU, pursuant to Article 12(5);~~	
		Article 1(3), point (d)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
101	(d) data users to whom electronic health data are made available by data holders in the Union.		(d) data users to whom electronic health data are made available by data holders in the Union.	~~(d) data users to whom electronic health data are made available by data holders in the Union.~~	
	Article 1(3a)				
101a				**3a. This Regulation shall be without prejudice to Regulations (EU) 2016/679, (EU) 2018/1725, (EU) No 536/2014 and (EC) No 223/2009.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 1(4)				
102	4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, […] [Data Governance Act COM/2020/767 final] and […] [Data Act COM/2022/68 final].		4. This Regulation shall be without prejudice to other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) 2016/679, (EU) 2018/1725, ***(EU) 2022/868 and*** […] [Data ~~*Governance Act COM/2020/767*~~ ***Act COM/2022/68*** final] and ~~*[…] [Data Act COM/2022/68*~~	4. This Regulation ~~shall be without prejudice to~~ **complements** other Union legal acts regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data in relation to electronic health data, in particular Regulations (EU) ~~2016/679, (EU) 2018/1725,~~**2022/868 and** […] [Data ~~Governance Act COM/2020/767~~**Act COM/2022/68** final]**. In the event of a specific conflict with these**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			~~final]~~ ***Directive 2002/58/EC of the European Parliament and of the Council***[1]. _____ ***1. Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) (OJ L 201, 31.7.2002, p. 37).***	**Regulations, the rules set out in this Regulation shall prevail** ~~and […] [Data Act COM/2022/68 final]~~.	
		Article 1(4a)			
102a			***4a. References to the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			provisions of Regulation (EU) 2016/679 shall be understood also as references to the corresponding provisions of Regulation (EU) 2018/1725 for Union institutions and bodies, where relevant.		
	Article 1(5)				
103	5. This Regulation shall be without prejudice to Regulations (EU) 2017/745 and […] [AI Act COM/2021/206 final], as regards the security of		5. This Regulation shall be without prejudice to Regulations (EU) 2017/745 and […] [AI Act COM/2021/206 final], as regards the security of	5. This Regulation shall be without prejudice to Regulations (EU) 2017/745**, (EU) 2017/746** and […] [AI Act COM/2021/206 final], as regards the security– of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	medical devices and AI systems that interact with EHR systems.		medical devices and AI systems that interact with EHR systems.	medical devices**, in vitro diagnostic medical devices** and AI systems that interact with EHR systems.	
	Article 1(5a)				
103a			***5a. This Regulation shall be without prejudice to Regulation (EU) No 536/2014 and Directive (EU) 2016/943[1].*** _____ ***1. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).		
	Article 1(6)				
104	6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.		6. This Regulation shall not affect the rights and obligations laid down in Union or national law concerning data processing for the purposes of reporting, complying with information requests or demonstrating or verifying compliance with legal obligations.	6. This Regulation shall ~~not affect the rights and obligations laid down in~~ **be without prejudice to** Union or national law ~~concerning~~**regarding electronic health** data processing for the purposes of reporting, complying with **access to** information requests or demonstrating or verifying compliance	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				with legal obligations **or Union or national law regarding the granting of access to and disclosure of official documents**. [[AMENDED AND MOVED TO ARTICLE 6A]] [MOD.SU.1.rev1]	
	Article 1(6a)				
104a				**6a. This Regulation shall be without prejudice to specific provisions in Union or national law**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				providing for access to electronic health data for further processing by public bodies of the Member States, Union institutions, bodies and agencies, or by private entities entrusted under Union or national law with a task of public interest, for the purpose of carrying out such task. Further, this Regulation shall not affect access to electronic health data for secondary use agreed in the framework of contractual or administrative arrangements between public or private entities.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 1(7)				
104b				**7. This Regulation shall not apply to the processing of electronic health data for purposes of public security, national security, defence and law enforcement, including the prevention, investigation, detection and prosecution of criminal offences. The powers of competent authorities for the prevention, investigation, detection and prosecution**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				of criminal offences established by law to obtain electronic health data are unaffected. Likewise, electronic health data held by courts for the purpose of judicial proceedings are out of scope of this Regulation.	
	Article 2				
105	Article 2 Definitions		Article 2 Definitions	Article 2 Definitions	
	Article 2(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
106	1. For the purposes of this Regulation, following definitions shall apply:		1. For the purposes of this Regulation, following definitions shall apply:	1. For the purposes of this Regulation, following definitions shall apply:	
	Article 2(1), point (a)				
107	(a) the definitions in Regulation (EU) 2016/679;		(a) the definitions in Regulation (EU) 2016/679;	(a) the definitions ~~in~~**of ‘personal data’, ‘processing’, ‘pseudonymisation’, ‘controller’, ‘processor’, ‘third party’, ‘consent’, ‘genetic data’, ‘data concerning health’, ‘international organisation’ pursuant to**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 4(1), (2), (5), (7), (8), (10), (11), (13), (15) and (26) of the Regulation (EU) 2016/679;	
	Article 2(1), point (b)				
108	(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU;		(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) of Article 3 of the Directive 2011/24/EU;	(b) the definitions of 'healthcare', 'Member State of affiliation', 'Member State of treatment', 'health professional', 'healthcare provider', 'medicinal product' and 'prescription', pursuant to Article 3 (a), (c), (d), (f), (g), (i) and (k) ~~of Article 3~~ of the Directive 2011/24/EU;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(1), point (c)				
109	(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), (8), (10), (11) and (14) of [Data Governance Act COM/2020/767 final];		(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2***, points*** (1), (8), (10), (11) and (14) of ~~*[Data Governance Act COM/2020/767 final]*~~***Regulation (EU) 2022/868***;	(c) the definitions of 'data', 'access', 'data altruism', 'public sector body' and 'secure processing environment', pursuant to Article 2 (1), ~~(8), (10~~**(13), (16)**, (~~11~~**17**) and (~~14~~**20**) of ~~[Data Governance Act COM/2020/767 final]~~ **Regulation (EU) 2022/868**;	
	Article 2(1), point (d)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
110	(d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020;		(d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', 'risk', 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), (18), (22) and (23) of the Regulation (EU) 2019/1020;	(d) the definitions of 'making available on the market', 'placing on the market', 'market surveillance', 'market surveillance authority', 'non-compliance', 'manufacturer', 'importer', 'distributor', 'economic operator', 'corrective action', ~~'risk'~~, 'recall' and 'withdrawal', pursuant to Article 2 (1), (2), (3), (4), (7), (8), (9), (10), (13), (16), ~~(18),~~ (22) and (23) of the Regulation (EU) 2019/1020;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(1), point (e)				
111	(e) the definitions of ‘medical device’, ‘intended purpose’, ‘instructions for use’, ‘performance’, ‘health institution’ and ‘common specifications’, pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;		(e) the definitions of ‘medical device’, ‘intended purpose’, ‘instructions for use’, ‘performance’, ‘health institution’ and ‘common specifications’, pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;	(e) the definitions of ‘medical device’, ‘intended purpose’, ‘instructions for use’, ‘performance’, ‘health institution’ and ‘common specifications’, pursuant to Article 2 (1), (12), (14), (22), (36) and (71) of the Regulation (EU) 2017/745;	
	Article 2(1), point (f)				
112	(f) the definitions of ‘electronic identification’,		(f) the definitions of ‘electronic identification’,	(f) the definitions of ‘electronic identification’,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	‘electronic identification means’ and ‘person identification data’ pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.		‘electronic identification means’ and ‘person identification data’ pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014.	‘electronic identification means’ and ‘person identification data’ pursuant to Article 3 (1), (2) and (3) of the Regulation (EU) No 910/2014~~.~~**;**	
	Article 2(1), point (g)				
112a				**(g) the definition of ‘contracting authorities’ pursuant to Article 2(1)(1) of the Directive 2014/24/EU;**	
	Article 2(1), point (h)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
112b				**(h) the definition of 'public health' pursuant to Article 38(c) of the Regulation (EC) No 1338/2008.**	
	Article 2(2)				
113	2. In addition, for the purposes of this Regulation the following definitions shall apply:		2. In addition, for the purposes of this Regulation the following definitions shall apply:	2. In addition, for the purposes of this Regulation the following definitions shall apply:	
	Article 2(2), point (a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
114	(a) ‘personal electronic health data’ means data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, processed in an electronic form;		(a) ‘personal electronic health data’ means data concerning health and genetic data as defined in Regulation (EU) 2016/679, ~~*as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services,*~~***that are*** processed in an electronic form;	(a) ‘personal electronic health data’ means **personal** data concerning health and **personal** genetic data as defined in ~~Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services~~**Article 4, (13) and (15) of Regulation (EU) 2016/679**, processed in an electronic form;	
	Article 2(2), point (b)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
115	(b) 'non-personal electronic health data' means data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679;		(b) 'non-personal electronic health data' means data concerning health and ***aggregated*** genetic data in electronic format that falls outside the definition of personal data provided in Article ~~*4(1)*~~***4, point (1),*** of Regulation (EU) 2016/679; ***where personal and non-personal data in a data set are inextricably linked, the entire dataset shall be processed as personal electronic health data;***	(b) '~~non-personal~~**anonymous** electronic health data' means data ~~concerning~~**related to** health**, processed in an electronic form, which does not relate to an identified or identifiable natural person or data concerning health processed in a such manner that the data subject is not or no longer identifiable.** ~~and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				~~Regulation (EU) 2016/679;~~	
		Article 2(2), point (c)			
116	(c) 'electronic health data' means personal or non-personal electronic health data;		(c) 'electronic health data' means personal or non-personal electronic health data;	(c) 'electronic health data' means personal **electronic health data or anonymous**~~or non-personal~~ electronic health data~~;~~	
		Article 2(2), point (d)			
117	(d) 'primary use of electronic health data' means the processing of		(d) 'primary use of electronic health data' means the processing of	(d) 'primary use of electronic health data' means the processing of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;		~~*personal*~~ electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services;	personal electronic health data for the provision of ~~health services~~ **healthcare** to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social ~~security~~, administrative or reimbursement services;	
	Article 2(2), point (e)				
118	(e) ‘secondary use of		(e) ‘secondary use of	(e) ‘secondary use of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data' means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use;		electronic health data' means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of ~~*the secondary use*~~***Chapter IV of this Regulation***;	electronic health data' means the processing of electronic health data for purposes set out in ~~Chapter IV~~**Article 34** of this Regulation~~. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data~~**, other than the initial purposes for which they were** collected ~~for the purpose of the secondary use;~~**or produced.**	
		Article 2(2), point (f)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
119	(f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;		(f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;	(f) 'interoperability' means the ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact ~~towards mutually beneficial goals~~, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications or devices, through the processes they support;	
		Article 2(2), point (g)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
120	(g) ‘European electronic health record exchange format’ means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;		(g) ‘European electronic health record exchange format’ means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;	~~(g) ‘European electronic health record exchange format’ means a structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers;~~	
		Article 2(2), point (h)			
121	(h) ‘registration of electronic health data’		(h) ‘registration of electronic health data’	(h) ‘registration of electronic health data’	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application;		means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application;	means the recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application;	
		Article 2(2), point (i)			
122	(i) ‘electronic health data access service’ means an online service, such as a		(i) ‘electronic health data access service’ means an online service, such as a	(i) ‘electronic health data access service’ means an online service, such as a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;		portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;	portal or a mobile application, that enables natural persons not acting in their professional role to access their own electronic health data or electronic health data of those natural persons whose electronic health data they are legally authorised to access;	
		Article 2(2), point (j)			
123	(j) 'health professional access service' means a service, supported by an EHR system, that enables health professionals to		(j) 'health professional access service' means a service, supported by an EHR system, that enables health professionals to	(j) 'health professional access service' means a service, supported by an EHR system, that enables health professionals to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access data of natural persons under their treatment;		access data of natural persons under their ~~*treatment*~~***care***;	access data of natural persons under their treatment;	
		Article 2(2), point (k)			
124	(k) 'data recipient' means a natural or legal person that receives data from another controller in the context of the primary use of electronic health data;		(k) '***health*** data recipient' means a ~~*natural or legal person that receives data from another controller*~~***recipient as defined in Article 4, point (9), of Regulation (EU) 2016/679,*** in the context of the primary use of electronic health data;	~~(k) 'data recipient' means a natural or legal person that receives data from another controller in the context of the primary use of electronic health data;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(2), point (l)				
125	(l) ‘telemedicine’ means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;		(l) ‘telemedicine’ means the provision of healthcare services, including remote care ~~*and online pharmacies,*~~ through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;	~~(l) ‘telemedicine’ means the provision of healthcare services, including remote care and online pharmacies, through the use of information and communication technologies, in situations where the health professional and the patient (or several health professionals) are not in the same location;~~	
	Article 2(2), point (m)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
126	(m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes;		(m) 'EHR' (electronic health record) means a collection of electronic health data related to a natural person and collected in the health system, processed for ***the purpose of the provision of*** healthcare ~~***purposes***~~***services***;	(m) 'EHR' (electronic health record) means a collection of **personal** electronic health data related to a natural person and collected in the health system, processed for **the provision of** healthcare ~~purposes~~;	
		Article 2(2), point (n)			
127	(n) 'EHR system' (electronic health record system) means any		(n) 'EHR system' (electronic health record system) means any	(n) 'EHR system' (electronic health record system) means any **system**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records;		~~appliance~~***product (hardware*** or software***) primarily*** intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing or viewing electronic health records ***between health professionals or that can be reasonably expected by the manufacturer to be used for those purposes***;	**where the** appliance or software **allows to store, intermediate, export, import, convert, edit or view personal electronic health data that belongs to the priority categories of personal electronic health data as referred to in Article 5(1) of this Regulation and is** intended by the manufacturer to be used ~~for storing, intermediating, importing, exporting, converting, editing or viewing electronic~~**by healthcare providers in providing patient care or by patient to access to their** health ~~records~~**data**;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(2), point (na)				
127a				**(na) 'putting into service' means the first use, for its intended purpose, in the Union, of an EHR system covered by this Regulation;**	
	Article 2(2), point (nb)				
127b				**(nb) 'software component' or 'component' means a**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				discrete part of software which provides specific functionality or performs specific functions or procedures and which can operate independently or in conjunction with other components. Components are designed to be reusable and to integrate seamlessly with other components within a larger software system;	
	Article 2(2), point (nc)				
127c				**(nc) 'European interoperability**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				component for EHR systems' (or 'the interoperability component') means a software component of the EHR system which provides and receives personal electronic health data referred to in Article 5 in the format referred to in Article 6 of this Regulation; The European interoperability component is independent of the European logging component;	
	Article 2(2), point (nd)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
127d				**(nd) 'European logging component for EHR systems' (or 'the logging component') means a software component of the EHR system which provides logging information relating to accesses of health professionals or other individuals to personal electronic health data referred to in Article 5, in the format defined in Annex II.3.4 of this Regulation; The European logging component is independent of the European interoperability**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				component;	
	Article 2(2), point (ne)				
127e				**(ne) 'harmonised components of EHR systems' means the European interoperability component for EHR systems and the European logging component for EHR systems;**	
	Article 2(2), point (o)				
128					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(o) ‘wellness application’ means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles;		*deleted*	*(o)* ‘wellness application’ means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles;	
		Article 2(2), point (p)			
129	(p) ‘CE marking of conformity’ means a marking by which the manufacturer indicates that the EHR system is in		(p) ‘CE marking of conformity’ means a marking by which the manufacturer indicates that the EHR system is in	(p) ‘CE marking of conformity’ means a marking by which the manufacturer indicates that the EHR system is in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing;		conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing;	conformity with the applicable requirements set out in this Regulation and other applicable Union legislation providing for its affixing **pursuant to Regulation (EC) No 765/2008**;	
	Article 2(2), point (pa)				
129a				**(pa) 'risk' means the combination of the degree of severity of a harm and the probability of an occurrence of a hazard causing the harm to health, safety and**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				information security;	
		Article 2(2), point (q)			
130	(q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, might have led or might lead to any of the following:		(q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, ~~*might have*~~***has*** led or ~~*might*~~***is likely to*** lead to any of the following:	(q) 'serious incident' means any malfunction or deterioration in the characteristics or performance of an EHR system made available on the market that directly or indirectly leads, might have led or might lead to any of the following:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(2), point (q)(i)				
131	(i) the death of a natural person or serious damage to a natural person's health;		(i) the death of a natural person or serious damage to a natural person's health ***or rights***;	(i) the death of a natural person or serious damage to a natural person's health;	
	Article 2(2), point (q)(ii)				
132	(ii) a serious disruption of the management and operation of critical infrastructure in the health sector;		(ii) a serious disruption of the management and operation of critical infrastructure in the health sector;	(ii) a serious disruption of the management and operation of critical infrastructure in the health sector;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(2), point (r)				
133	(r) ‘national contact point for digital health’ means an organisational and technical gateway for the provision of cross-border digital health information services for primary use of electronic health data, under the responsibility of the Member States;		(r) ‘national contact point for digital health’ means an organisational and technical gateway for the provision of cross-border digital health information services for primary use of electronic health data, under the responsibility of the Member States;	~~(r) ‘national contact point for digital health’ means an organisational and technical gateway for the provision of cross-border digital health information services for primary use of electronic health data, under the responsibility of the Member States;~~	
	Article 2(2), point (s)				
134	(s) ‘central platform for		(s) ‘central platform for	~~(s) ‘central platform for~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	digital health' means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health;		digital health' means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health;	~~digital health' means an interoperability platform providing services to support and facilitate the exchange of electronic health data between national contact points for digital health;~~	
	Article 2(2), point (t)				
135	(t) 'MyHealth@EU' means the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the		(t) 'MyHealth@EU' means the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the	~~(t) 'MyHealth@EU' means the cross-border infrastructure for primary use of electronic health data formed by the combination of national contact points for digital health and the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	central platform for digital health;		central platform for digital health;	~~central platform for digital health;~~	
		Article 2(2), point (u)			
136	(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;		(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;	~~(u) 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(2), point (v)				
137	(v) ‘central platform for secondary use of electronic health data’ means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;		(v) ‘central platform for secondary use of electronic health data’ means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;	~~(v) ‘central platform for secondary use of electronic health data’ means an interoperability platform established by the Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data;~~	
	Article 2(2), point (x)				
138					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;		(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;	~~(x) 'HealthData@EU' means the infrastructure connecting national contact points for secondary use of electronic health data and the central platform;~~	
	Article 2(2), point (qa)				
138a				**(qa) 'care' means a professional service the purpose of which is to address the specific needs of a person who, on account of impairment or other physical or mental conditions requires assistance to carry out**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				essential activities of daily living in order to support their personal autonomy.	
	Article 2(2), point (y)				
139	(y) 'data holder' means any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as Union institutions, bodies, offices and agencies who has the right or obligation, in accordance with this Regulation, applicable Union law or		(y) '***health*** data holder' means any natural or legal person, which is an entity or a body in the health***, social security*** or care ***sector or in the reimbursement services*** sector, or ~~*performing*~~***performs*** research in relation to these sectors, as well as Union institutions, bodies, offices and agencies ~~*who has the*~~	~~(y)~~**(xb)** '**health** data holder' means any natural or legal person, ~~which is an entity or a~~**public authority, agency or other** body in the ~~health or care sector, or performing research in relation to these~~**healthcare or the care** sectors~~,~~**;** as well as ~~Union institutions, bodies, offices and agencies who has the right or~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;		~~*right or obligation*~~***, and which***, in accordance with this Regulation, applicable Union law or national legislation implementing Union law~~*, or in the case of non-personal data, through control of the technical design of a product and related services,*~~***:*** ***(i) is a controller as set out in Regulation (EU) 2016/679 and has the right or obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, to process personal electronic health***	~~obligation, in accordance with this Regulation, applicable Union law or national legislation implementing Union law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access or exchange certain data;~~**any natural or legal person developing products or services intended for the health, healthcare or care sectors; developing or manufacturing wellness applications; performing**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data; or ***(ii) has*** the ability to make available, including to register, provide, restrict access or exchange ~~*certain data*~~***non-personal electronic health data, through control of the technical design of a product and related services***;	**research in relation to the health, healthcare or care sectors; or acting as a mortality registry; as well as any Union institution, body, office or agency; who has either:**	
	Article 2(2), point (a)				
139a				**(a) the right or obligation, in accordance with applicable Union law or**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				national legislation, to process personal electronic health data for the provision of healthcare or care or for public health, reimbursement, research, innovation, policy making, official statistics, patient safety or regulatory purposes, in its capacity as a controller or joint controller; or	
	Article 2(2), point (b)				
139b				**(b) the ability to make available, including to**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				register, provide, restrict access or exchange anonymous electronic health data, through control of the technical design of a product and related services.	
	Article 2(2), point (ya)				
139c				**(ya) 'health data intermediation entity' means a legal person able to make available, including to register, provide, process, restrict access or exchange electronic health data**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				provided by data holders for secondary use.	
	Article 2(2), point (z)				
140	(z) ‘data user’ means a natural or legal person who has lawful access to personal or non-personal electronic health data for secondary use;		(z) ‘***health*** data user’ means a natural or legal person***, as well as a Union institution, body, office or agency, which has been granted*** ~~*who has*~~ lawful access***, in accordance with this Regulation, to*** ~~*to personal or non-personal*~~ electronic health data for secondary use ***pursuant to a data permit or a health data request***;	(z) ‘**health** data user’ means a natural or legal person who has lawful access to ~~personal or non-personal~~ electronic health data for secondary use **based on a data permit or a data request pursuant to this Regulation**;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(2), point (za)				
140a			***(za) 'health data applicant' means any natural or legal person with a demonstrable professional link to the areas of health care, public health or medical research and that submits an application for health data;***		
	Article 2(2), point (aa)				
141					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(aa) 'data permit' means an administrative decision issued to a data user by a health data access body or data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in this Regulation;		(aa) '***health*** data permit' means an administrative decision issued to a data user by a health data access body or data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in this Regulation;	(aa) ~~'~~data permit' means an administrative decision issued to a **health** data user by a health data access body or **a single health** data holder to process ~~the~~**certain** electronic health data specified in the data permit for ~~the~~**specific** secondary use purposes ~~specified in the data permit~~ based on conditions laid down in **Chapter IV of** this Regulation;	
		Article 2(2), point (ab)			
142	(ab) 'dataset' means a		(ab) 'dataset' means a	(ab) 'dataset' means a	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	structured collection of electronic health data;		structured collection of electronic health data;	structured collection of electronic health data;	
	Article 2(2), point (aba)				
142a				**(aba) 'datasets of high impact for the secondary use of electronic health data' means datasets the re-use of which is associated with important benefits because of their relevance for health research;**	
	Article 2(2), point (ac)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
143	(ac) ‘dataset catalogue’ means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;		(ac) ‘dataset catalogue’ means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;	(ac) ‘dataset catalogue’ means a collection of datasets descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal;	
		Article 2(2), point (ad)			
144	(ad) ‘data quality’ means		(ad) ‘data quality’ means	(ad) ‘data quality’ means	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the degree to which characteristics of electronic health data are suitable for secondary use;		the degree to which characteristics of electronic health data are suitable for secondary use;	the degree to which ~~characteristics~~**the elements** of electronic health data are **assessed and considered** suitable for **their intended primary and** secondary use;	
		Article 2(2), point (ae)			
145	(ae) ‘data quality and utility label’ means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.		(ae) ‘data quality and utility label’ means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	(ae) ‘data quality and utility label’ means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 2(2), point (aea)				
145a			***(aea) 'wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data specifically for providing information on, managing, maintaining or improving the health of individual persons, or the delivery of care.***		
	Chapter II				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
146	Chapter II Primary use of electronic health data		Chapter II Primary use of electronic health data	Chapter II Primary use of electronic health data	
	Section 1				
147	Section 1 Access to and transmission of personal electronic health data for primary use		Section 1 Access to and transmission of personal electronic health data for primary use	Section 1 Access to and transmission of personal electronic health data for primary use	
	Article 2A				
147a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 2A **Registration of personal electronic health data** [MOVED FROM ARTICLE 7]	
	Article 2a(1)				
147b				**1. Member States shall ensure that, where data is processed in electronic format for the provision of healthcare, healthcare providers shall register**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the relevant personal health data falling fully or partially under at least the priority categories referred to in Article 5 in the electronic format in an EHR system. [MOVED FROM ARTICLE 7(1) AND AMENDED]	
	Article 2a(1a)				
147c				**1a. Where they process data in an electronic format,**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				healthcare providers shall ensure that the personal electronic health data of the natural persons they treat are updated with information related to the healthcare provided. [MOVED FROM ARTICLE 4(1)(b) AND AMENDED]	
	Article 2a(2)				
147d				**2. Where personal electronic health data is registered in a Member**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				State of treatment that is not the Member State of affiliation of the person concerned, the Member State of treatment shall ensure that the registration is performed under the identification data of the natural person in the Member State of affiliation. [MOVED FROM ARTICLE 7(2) AND AMENDED]	
	Article 2a(3)				
147e					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				3. The Commission shall, by means of implementing acts, determine data quality requirements, including semantics, uniformity, consistency of data registration, accuracy and completeness, for the registration of personal electronic health data in EHR system as relevant.	
	Article 2a(3c)				
147f				**Those implementing acts shall be adopted in accordance with the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				examination procedure referred to in Article 68(2). [MOVED FROM ARTICLE 7(3) AND AMENDED]	
	Article 3				
148	Article 3 Rights of natural persons in relation to the primary use of their personal electronic health data		Article 3 Rights of natural persons in relation to the primary use of their personal electronic health data	~~Article 3~~ ~~Rights of natural persons in relation to the primary use of their personal electronic health data~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 3(1)				
149	1. Natural persons shall have the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form.		1. Natural persons shall have the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form.	~~1. Natural persons shall have the right to access their personal electronic health data processed in the context of primary use of electronic health data, immediately, free of charge and in an easily readable, consolidated and accessible form.~~ [MOVED TO ARTICLE 8A, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 3(2)				
150	2. Natural persons shall have the right to receive an electronic copy, in the European electronic health record exchange format referred to in Article 6, of at least their electronic health data in the priority categories referred to in Article 5.		2. Natural persons shall have the right to receive an electronic copy, in the European electronic health record exchange format referred to in Article 6, of at least their electronic health data***, or at the request of the natural person, a printed copy thereof, in accordance with*** ~~*in the priority categories referred to in*~~ Article ~~5~~***15(3) of Regulation (EU) 2016/679***.	~~2. Natural persons shall have the right to receive an electronic copy, in the European electronic health record exchange format referred to in Article 6, of at least their electronic health data in the priority categories referred to in Article 5.~~ [MOVED TO ARTICLE 8A, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 3(2a)				
150a			***2a. The rights referred to in paragraphs 1 and 2 shall be deemed complementary to and be without prejudice to the rights and obligations established by Article 15 of Regulation (EU) 2016/679.***		
	Article 3(3)				
151	3. In accordance with Article 23 of Regulation (EU) 2016/679, Member		3. In accordance with Article ~~23~~***23(1) , point (i),*** of Regulation (EU)	~~3. In accordance with Article 23 of Regulation (EU) 2016/679, Member~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	States may restrict the scope of this right whenever necessary for the protection of the natural person based on patient safety and ethics by delaying their access to their personal electronic health data for a limited period of time until a health professional can properly communicate and explain to the natural person information that can have a significant impact on his or her health.		2016/679, Member States may restrict the scope of ***rights referred to in this Article*** ~~*this right*~~ whenever necessary for the protection of the natural person based on patient safety and ethics by delaying their access to their personal electronic health data for a limited period of time until a health professional can properly communicate and explain to the natural person information that can have a significant impact on ~~*his*~~***him*** or her ~~*health*~~.	~~States may restrict the scope of this right whenever necessary for the protection of the natural person based on patient safety and ethics by delaying their access to their personal electronic health data for a limited period of time until a health professional can properly communicate and explain to the natural person information that can have a significant impact on his or her health.~~ [MOVED ARTICLE 8A, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 3(4)				
152	4. Where the personal health data have not been registered electronically prior to the application of this Regulation, Member States may require that such data is made available in electronic format pursuant to this Article. This shall not affect the obligation to make personal electronic health data registered after the application of this Regulation available in electronic format pursuant		*deleted*	~~4. Where the personal health data have not been registered electronically prior to the application of this Regulation, Member States may require that such data is made available in electronic format pursuant to this Article. This shall not affect the obligation to make personal electronic health data registered after the application of this Regulation available in electronic format pursuant~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to this Article.			~~to this Article.~~ DELETED	
	Article 3(5), first subparagraph				
153	5. Member States shall:		5. Member States shall:	~~5.~~ ~~Member States shall:~~	
	Article 3(5), first subparagraph, point (a)				
154	(a) establish one or more electronic health data access services at national,		(a) establish one or more electronic health data access services at national,	~~(a)~~ ~~establish one or more electronic health data access services at national,~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2;		regional or local level enabling the exercise of rights referred to in ~~*paragraphs 1 and 2*~~***this Article***;	~~regional or local level enabling the exercise of rights referred to in paragraphs 1 and 2;~~	
		Article 3(5), first subparagraph, point (b)			
155	(b) establish one or more proxy services enabling a natural person to authorise other natural persons of their choice to access their electronic health data on their behalf.		(b) establish one or more proxy services enabling a natural person to ***legally*** authorise other natural persons of their choice to access their electronic health data on their behalf ***for a specified or indeterminate period and if needed, for a specific***	~~(b) establish one or more proxy services enabling a natural person to authorise other natural persons of their choice to access their electronic health data on their behalf.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			purpose only, or enabling legal representatives of patients to access electronic health data of the natural persons whose affairs they administer, in accordance with national law.		
	Article 3(5), second subparagraph				
156	The proxy services shall provide authorisations free of charge, electronically or on paper. They shall enable guardians or other representatives to be authorised, either		The proxy services shall provide authorisations ***in a transparent and easily understandable way,*** free of charge, electronically or on paper. ***Natural persons and those acting on their behalf***	~~The proxy services shall provide authorisations free of charge, electronically or on paper. They shall enable guardians or other representatives to be authorised, either~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	automatically or upon request, to access electronic health data of the natural persons whose affairs they administer. Member States may provide that authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.		***shall be informed about their authorisation rights, how to exercise them, and what they can expect from the authorisation process.*** ***The electronic health data access services as well as the proxy services*** ~~*They*~~ shall ~~*enable guardians or other*~~***be easily accessible for persons with disabilities, vulnerable groups or persons with low digital literacy.*** ***The proxy services shall enable legal*** representatives ***of patients*** to be authorised,	~~automatically or upon request, to access electronic health data of the natural persons whose affairs they administer. Member States may provide that authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.~~ [MOVED TO A NEW ARTICLE 8G SEE AMENDMENTS IN THAT	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			either automatically or upon request, to access electronic health data of the natural persons whose affairs they administer ***either for a specific purpose and time period or without limitation for the purpose of such administration***. Member States may provide that authorisations do not apply whenever necessary for reasons related to the protection of the natural person, and in particular based on patient safety and ethics. The proxy services shall be interoperable among Member States.	ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			The proxy services shall provide an easy complaint mechanism with a contact point designated to inform individuals of a way to seek redress or remedy if they believe that their authorisation rights have been violated.		
	Article 3(5a)				
156a			***5a. In addition to the electronic services referred to in this Article, Member States shall also establish easily accessible support services for natural***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			persons with adequately trained staff dedicated to assisting them with exercising their rights referred to in this Article.		
		Article 3(6)			
157	6. Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information		6. Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services ~~or~~***and*** applications linked to these services. That information shall be	~~6. Natural persons may insert their electronic health data in their own EHR or in that of natural persons whose health information they can access, through electronic health data access services or applications linked to these services. That information shall be~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	shall be marked as inserted by the natural person or by his or her representative.		marked as inserted by the natural person or by ~~*his or her representative*~~***their legal representative and as non-validated. That information shall only be considered as a clinical fact if validated by a health professional. Without prejudice to the right to insert data, health professionals shall not be obliged to validate any inserted data in the EHR***.	~~marked as inserted by the natural person or by his or her representative.~~ [MOVED TO A NEW ARTICLE 8B, SEE AMENDMENTS IN THAT ARTICLE]	
		Article 3(6a)			
157a			***6a. Natural persons shall***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			have the right to download their electronic health data from their own EHR or the data of natural persons whose health information they can access through electronic health data access services and applications linked to these services.		
		Article 3(7)			
158	7. Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU)		7. Member States shall ensure that ***electronic health data services referred to in paragraph 5, point (a), of this Article***	~~7. Member States shall ensure that, when exercising the right to rectification under Article 16 of Regulation (EU) 2016/679,~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2016/679, natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article.		***allow for the possibility for natural persons to easily request rectification of their personal data online as a way to exercise their*** ~~*, when exercising the*~~ right to rectification under Article 16 of Regulation (EU) 2016/679~~,~~**.** Natural persons ~~*can easily request rectification online through the electronic*~~***shall not have the possibility of directly changing data inserted by*** health ~~*data access services referred to in paragraph 5, point (a), of this Article*~~***professionals. Such rectifications of clinical facts shall be validated, without undue delay, by a***	~~natural persons can easily request rectification online through the electronic health data access services referred to in paragraph 5, point (a), of this Article.~~ [MOVED TO A NEW ARTICLE 8C, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			registered healthcare professional with a relevant specialisation who is responsible for the natural person's treatment. The original data holder shall be responsible for the rectification.		
	Article 3(8), first subparagraph				
159	8. Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their		8. Natural persons shall have the right to ~~*give access to or*~~ request a ***health*** data holder from the health or social security sector ***or reimbursement services,*** to transmit ***all or part of*** their	~~8. Natural persons shall have the right to give access to or request a data holder from the health or social security sector to transmit their electronic health data to a data recipient of their~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder.		electronic health data to a ***health*** data recipient of their choice from the health or social security sector ***or reimbursement services***, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder. ***The health data recipient shall be clearly identified by the natural persons to the health data holder and their affiliation to the health or social security sector shall be demonstrated. Health data holders and their processors shall comply with the request and shall***	~~choice from the health or social security sector, immediately, free of charge and without hindrance from the data holder or from the manufacturers of the systems used by that holder.~~ [MOVED TO A NEW ARTICLE 8D(1), SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			transmit the data in the format provided for in Article 5.		
	Article 3(8), second subparagraph				
160	Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format		Natural persons shall have the right that, where the ***health*** data holder and the ***health*** data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the ***health*** data holder shall transmit the data in the European electronic health record	~~Natural persons shall have the right that, where the data holder and the data recipient are located in different Member States and such electronic health data belongs to the categories referred to in Article 5, the data holder shall transmit the data in the European electronic health record exchange format referred to~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	referred to in Article 6 and the data recipient shall read and accept it.		exchange format referred to in Article 6 and the ***health*** data recipient shall read and accept it.	~~in Article 6 and the data recipient shall read and accept it.~~ [MOVED TO A NEW ARTICLE 8D(2), SEE AMENDMENTS IN THAT ARTICLE]	
		Article 3(8), third subparagraph			
161	By way of derogation from Article 9 of Regulation […] [Data Act COM/2022/68 final], the data recipient shall not be required to		By way of derogation from Article 9 of Regulation […] [Data Act COM/2022/68 final], the ***health*** data recipient shall not be	~~By way of derogation from Article 9 of Regulation […] [Data Act COM/2022/68 final], the data recipient shall not be required to~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	compensate the data holder for making electronic heath data available.		required to compensate the ***health*** data holder for making electronic ~~*heath*~~***health*** data available. ***A health data holder, a health data recipient or a third party shall not directly or indirectly charge data subjects a fee, compensation or costs for sharing data or accessing it.***	~~compensate the data holder for making electronic heath data available.~~ [MOVED TO ARTICLE 9A]	
		Article 3(8), fourth subparagraph			
162	Natural persons shall have the right that, where priority categories of personal		Natural persons shall have the right that, where priority categories of personal	~~Natural persons shall have the right that, where priority categories of personal~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.		electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.	~~electronic health data referred to in Article 5 are transmitted or made available by the natural person according to the European electronic health record exchange format referred to in Article 6, such data shall be read and accepted by other healthcare providers.~~ [MOVED TO A NEW ARTICLE 8D(4), SEE AMENDMENTS IN THAT ARTICLE]	
		Article 3(9)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
163	9. Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.		9. ~~*Notwithstanding*~~***Without prejudice to*** Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of ***specific health professionals or categories of*** health professionals to all or part of their electronic health data. ***When restricting the information, natural persons shall be made aware that restricting access may impact the provision of healthcare provided to them. Such restrictions shall apply also for cross-border transfers***	~~9. Notwithstanding Article 6(1), point (d), of Regulation (EU) 2016/679, natural persons shall have the right to restrict access of health professionals to all or part of their electronic health data. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms.~~ [MOVED TO A NEW ARTICLE 7E, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of electronic health data. The fact that a restriction has been made by the natural person shall not be visible to healthcare providers. Member States shall establish the rules and specific safeguards regarding such restriction mechanisms. ***Those rules shall include the possibility of modifying restrictions and of restricting access to anyone except the health professional who inserted the electronic health data. Those rules shall also establish the conditions of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			medical liability as a consequence of applying restrictions to electronic health data. The Commission shall establish guidelines regarding the implementation of this paragraph.		
	Article 3(10)				
164	10. Natural persons shall have the right to obtain information on the healthcare providers and health professionals that have accessed their electronic health data in the		10. Natural persons shall have the right to obtain information***, including through automatic notifications,*** on the healthcare providers and health professionals that	~~10. Natural persons shall have the right to obtain information on the healthcare providers and health professionals that have accessed their electronic health data in the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	context of healthcare. The information shall be provided immediately and free of charge through electronic health data access services.		have accessed their electronic health data, ***including access provided in accordance with Article 4(4), and on the substance of the accessed data. Natural persons shall have the possibility of disabling those notifications. In order to demonstrate compliance with this right, all relevant entities shall maintain a system of automated recording for at least three years showing who and when has accessed electronic health data*** ~~*in the context of healthcare*~~. The information shall be provided immediately and free of	~~context of healthcare. The information shall be provided immediately and free of charge through electronic health data access services.~~ [MOVED TO A NEW ARTICLE 7E, SEE AMENDMENTS IN THAT ARTICLE]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			charge through electronic health data access services. ***Member States may provide for restrictions to this right in exceptional circumstances, where there are factual indications that disclosure would endanger the vital interests or rights of the health professional or the care of the natural person.***		
		Article 3(11)			
165	11. The supervisory authority or authorities responsible for monitoring		11. The supervisory authority or authorities responsible for monitoring	~~11. The supervisory authority or authorities responsible for monitoring~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the application of Regulation (EU) 2016/679 shall also be responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this		the application of Regulation (EU) 2016/679 shall also be responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. ~~*They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the*~~	~~the application of Regulation (EU) 2016/679 shall also be responsible for monitoring the application of this Article, in accordance with the relevant provisions in Chapters VI, VII and VIII of Regulation (EU) 2016/679. They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation, within the remit of their respective competences.		~~*enforcement of this Regulation, within the remit of their respective competences.*~~	~~Regulation, within the remit of their respective competences.~~ [MOVED TO ARTICLE 11A, SEE AMENDMENTS IN THAT ARTICLE]	
		Article 3(12)			
166	12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the		12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this	~~12. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	rights set out in this Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		Article***, including technical and organisational measures to ensure the process of authentication of the authorised person referred to in paragraph 5, point (b), of this Article***. Those implementing acts shall be adopted in accordance with the ~~advisory~~***examination*** procedure referred to in Article ~~68(2)~~***68(2a)***.	~~Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).~~ [MOVED TO A NEW ARTICLE 8D(4), SEE AMENDMENTS IN THAT ARTICLE]	
		Article 3(12a)			
166a			***12a. Member States, including regional and***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			local authorities, shall provide easily understandable information to natural persons in relation to the use of the electronic health records and primary use of their personal electronic health data laid down in this Article. Such guidance shall take into account different user groups, including persons with disabilities and vulnerable groups, without compromising the quality and the scope of the information.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 4				
167	Article 4 Access by health professionals to personal electronic health data		Article 4 Access by health professionals to personal electronic health data	~~Article 4~~ ~~Access by health professionals to personal electronic health data~~	
	Article 4(-1)				
167a			***-1. Access to EHR for primary use shall be strictly limited to healthcare providers.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 4(1)				
168	1. Where they process data in an electronic format, health professionals shall:		1. Where they process data in an electronic format, health professionals shall:	~~1. Where they process data in an electronic format, health professionals shall:~~	
	Article 4(1), point (a)				
169	(a) have access to the electronic health data of natural persons under their treatment, irrespective of the Member State of affiliation and the Member State of treatment;		(a) have access***, based on the data minimisation and purpose limitation principles,*** to the electronic health data of natural persons under their treatment ***and exclusively for the purpose of that***	~~(a) have access to the electronic health data of natural persons under their treatment, irrespective of the Member State of affiliation and the Member State of treatment;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			treatment, including relevant administration, irrespective of the Member State of affiliation and the Member State of treatment***, in accordance with Article 9(2), point (h), of Regulation 2016/679***;	[MOVED TO A NEW ARTICLE 7A(1), SEE AMENDMENTS IN THAT ARTICLE]	
	Article 4(1), point (b)				
170	(b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.		(b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.	~~(b) ensure that the personal electronic health data of the natural persons they treat are updated with information related to the health services provided.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO A NEW ARTICLE 2A(1A), SEE AMENDMENTS IN THAT ARTICLE]	
	Article 4(2)				
171	2. In line with the data minimisation principle provided for in Regulation (EU) 2016/679, Member States may establish rules providing for the categories of personal electronic health data required by		2. In line with the data minimisation ~~*principle*~~***and purpose limitation principles*** provided for in Regulation (EU) 2016/679, Member States ~~*may*~~***shall*** establish rules providing for the categories of personal	~~2. In line with the data minimisation principle provided for in Regulation (EU) 2016/679, Member States may establish rules providing for the categories of personal electronic health data required by different~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	different health professions. Such rules shall not be based on the source of electronic health data.		electronic health data required by different ***categories of*** health professions ***or different healthcare tasks***. Such rules shall not be based on the source of electronic health data.	~~health professions. Such rules shall not be based on the source of electronic health data.~~ [MOVED TO A NEW ARTICLE 7A(2), SEE AMENDMENTS IN THAT ARTICLE]	
	Article 4(2a)				
171a			***2a. In the case of treatment in a Member State other than the Member State of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			affiliation, the rules referred to in paragraphs 1a and 2 of the Member States of treatment shall apply.		
	Article 4(2b)				
171b			***2b. The Commission shall issue guidelines for the implementation of paragraphs 1, 2 and 2a, including time limitations for the access by health professionals to electronic health data of natural persons.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 4(3)				
172	3. Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access		3. Member States ***and, where appropriate, local or regional authorities*** shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals***, including for cross-border care,*** through health professional access services***, where the processing of health data is necessary and for the purposes of Article 9(2),***	~~3. Member States shall ensure that access to at least the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	services, free of charge.		***point (h), of Regulation 2016/679***. Health professionals who are in possession of recognised electronic identification means shall have the right to use those health professional access services, free of charge. ***The electronic health data in the electronic health records shall be structured in a user-friendly manner to allow for easy use by health professionals.***	[MOVED TO ARTICLE 7B SEE AMENDMENTS IN THAT ARTICLE]	
		Article 4(3a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
172a			***3a. Member States shall establish policies aimed at providing health professionals with the digital skills, competences, infrastructures and tools required to fulfil the obligations set out in paragraph 1.***		
		Article 4(4)			
173	4. Where access to electronic health data has been restricted by the natural person, the		4. Where access to electronic health data has been restricted by the natural person, the	~~4. Where access to electronic health data has been restricted by the natural person, the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person, including where the provider or professional is informed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare		healthcare provider or health professionals shall not be informed of the ***restricted*** content of the electronic health data without prior ~~*authorisation by the natural person, including where the provider or professional is informed of the existence and nature of the restricted electronic health data*~~***explicit consent pursuant to Article 9(2), point (a), of Regulation (EU) 2016/679 by the natural person***. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural	~~healthcare provider or health professionals shall not be informed of the content of the electronic health data without prior authorisation by the natural person, including where the provider or professional is informed of the existence and nature of the restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.		person, the healthcare provider or health professional may get access to the restricted electronic health data. Following such access, the healthcare provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.	~~provider or health professional shall inform the data holder and the natural person concerned or his/her guardians that access to electronic health data had been granted. Member States' law may add additional safeguards.~~ [MOVED TO A NEW ARTICLE 7A(3), SEE AMENDMENTS IN THAT ARTICLE]	
		Article 5			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
174	Article 5 Priority categories of personal electronic health data for primary use		Article 5 Priority categories of personal electronic health data for primary use	Article 5 Priority categories of personal electronic health data for primary use	
	Article 5(1), first subparagraph				
175	1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the		1. Where data is processed in electronic format, Member States shall implement access to and exchange of personal electronic health data for primary use fully or partially falling under the	1. **For the purposes of this Chapter,** where data is processed in electronic format, ~~Member States shall implement access to and exchange~~**the priority categories** of personal electronic health data ~~for~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	following categories:		following categories ***making use of the International Classification of Diseases (ICD) codes, where applicable***:	~~primary use fully or partially falling under~~**shall be** the following**:** ~~categories:~~	
	Article 5(1), first subparagraph, point (a)				
176	(a) patient summaries;		(a) patient summaries;	(a) patient summaries;	
	Article 5(1), first subparagraph, point (b)				
177	(b) electronic prescriptions;		(b) electronic prescriptions;	(b) electronic prescriptions;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 5(1), first subparagraph, point (c)				
178	(c) electronic dispensations;		(c) electronic dispensations;	(c) electronic dispensations;	
	Article 5(1), first subparagraph, point (d)				
179	(d) medical images and image reports;		(d) medical images and image reports;	(d) medical images and **related** image reports;	
	Article 5(1), first subparagraph, point (e)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
180	(e) laboratory results;		(e) laboratory results, ***medical test results and other complementary and diagnostic results***;	(e) laboratory results **and related laboratory reports**;	
	Article 5(1), first subparagraph, point (f)				
181	(f) discharge reports.		(f) ***patient*** discharge reports~~.~~**;**	(f) **hospital** discharge reports.	
	Article 5(1), first subparagraph, point (fa)				
181a			***(fa) medical directives of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the natural persons and information about consent for substances of human origin and organ donations.		
	Article 5(1), second subparagraph				
182	The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I.		The main characteristics of the categories of electronic health data in the first subparagraph shall be as set out in Annex I ***and limited to those categories***.	The main characteristics of the **priority** categories of **personal** electronic health data ~~in the first subparagraph~~ shall be as set out in Annex I.	
	Article 5(1), third subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
183	Access to and exchange of electronic health data for primary use may be enabled for other categories of personal electronic health data available in the EHR of natural persons.		***Member States may provide for*** access to and exchange of electronic health data for primary use ~~*may be enabled*~~ for other categories of personal electronic health data available in the EHR of natural persons.	**1A.** ~~Access to and exchange of~~ **Member States may provide by virtue of national law that additional categories of personal** electronic health data **shall be accessed and exchanged** for primary use **pursuant to this Chapter. The Commission may, by means of implementing acts, lay down cross-border specifications for these data categories pursuant to Article 6(1A) and Article 12(8)**~~may be enabled for other categories of personal electronic health data available in the EHR of~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				~~natural persons~~.	
	Article 5(2)				
184	2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of priority categories of electronic health data in paragraph 1. Such delegated acts may also amend Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data and		2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend ~~*the list of priority categories of electronic health data in paragraph 1. Such delegated acts may also amend*~~ Annex I by adding, modifying or removing the main characteristics of the priority categories of electronic health data***, as***	2. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend ~~the list of priority categories of electronic health data in paragraph 1. Such delegated acts may also amend~~ Annex I by adding, modifying or removing the main characteristics of the priority categories of **personal** electronic health data ~~and indicating, where~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	indicating, where relevant, deferred application date. The categories of electronic health data added through such delegated acts shall satisfy the following criteria:		***laid down in paragraph 1*** ~~*and indicating, where relevant, deferred application date. The categories of electronic health data added through such delegated acts shall satisfy the following criteria:*~~	~~relevant, deferred application date. The categories of electronic health data added through such delegated acts~~ **as referred to in paragraph 1. The amendments** shall satisfy the following **cumulative** criteria:	
		Article 5(2), point (a)			
185	(a) the category is relevant for health services provided to natural persons;		*deleted*	(a) the ~~category~~**characteristic** is relevant for ~~health services~~ **healthcare** provided to natural persons;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 5(2), point (b)				
186	(b) according to the most recent information, the category is used in a significant number of EHR systems used in Member States;		*deleted*	(b) ~~according to the most recent information, the category~~ **the characteristic as modified** is used in **the majority of Member States according to the most recent information** ~~a significant number of EHR systems used in Member States~~;	
	Article 5(2), point (c)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
187	(c) international standards exist for the category that have been examined for the possibility of their application in the Union.		*deleted*	(c) ~~international standards exist for the category that have been examined for the possibility of their application in the Union~~**the changes are aimed to adapt the priority categories to the technical evolution and international standards**.	
	Article 6				
188	Article 6 European electronic health		Article 6 European electronic health	Article 6 European electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	record exchange format		record exchange format	record exchange format	
	Article 6(1)				
189	1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format. The format shall include the following elements:		1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article 5, setting out the European electronic health record exchange format***, taking into account its Recommendation (EU) 2019/243***. The format shall include the following	1. The Commission shall, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data referred to in Article ~~5~~**5(1)**, setting out the European electronic health record exchange format**. Such format shall be commonly used, machine-readable and allow transmission of personal**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			elements:	**electronic health data between different software applications, devices and healthcare providers. The format should support transmission of structured and unstructured health data**. The format shall include the following elements:	
		Article 6(1), point (a)			
190	(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the content		(a) ***harmonised*** datasets containing electronic health data and defining structures, such as ***minimum*** data fields and data groups for	(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the ~~content~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	representation of clinical content and other parts of the electronic health data;		the content representation of clinical content and other parts of the electronic health ***data, which can be enlarged to include disease-specific*** data;	representation of clinical content and other parts of the electronic health data;	
	Article 6(1), point (b)				
191	(b) coding systems and values to be used in datasets containing electronic health data;		(b) coding systems and values to be used in datasets containing electronic health data;	(b) coding systems and values to be used in datasets containing electronic health data;	
	Article 6(1), point (c)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
192	(c) technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.		(c) technical ***interoperability*** specifications for the exchange of electronic health data, including its content representation, standards and profiles***, and for the translation of electronic health data***.	(c) technical specifications for the exchange of electronic health data, including its content representation, standards and profiles.	
		Article 6(-1)(2)			
192a	2. Those implementing acts shall be adopted in accordance with the advisory procedure referred			~~2.~~ Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient. Moved reference text			procedure referred to in Article 68(2). ~~Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.~~ [MOVED FROM ARTICLE 6(2)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[FIRST SENTENCE MOVED TO PARA 1 IN THIS ARTICLE. SECOND SENTENCE MOVED AND AMENDED IN PARA 3 IN THIS ARTICLE] Moved from row 193 [193 - 192a]	
	Article 6(1a)				
192b			***1a. The Commission shall***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			ensure that those implementing acts contain the latest versions of healthcare coding systems and nomenclatures and that they are updated regularly in order to keep up with the revisions of the healthcare coding systems and nomenclatures.		
	Article 6(-1a)				
192c				**-1a. The Commission may, by means of implementing acts, lay down technical specifications that extend**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the European electronic health record exchange format to additional categories of electronic health data referred to in Article 5(1A). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	
		Article 6(2)			
193	2. Those implementing acts shall be adopted in accordance with the advisory procedure referred		2. Those implementing acts shall be adopted in accordance with the ~~*advisory*~~***examination***	Moved to row 192a [193 - 192a]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to in Article 68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient.		procedure referred to in Article ~~*68(2). Member States shall ensure that where the priority categories of personal electronic health data referred to in Article 5 are provided by a natural person directly or transmitted to a healthcare provider by automatic means in the format referred to in paragraph 1, such data shall be read and accepted by the data recipient*~~***68(2a)**.		
		Article 6(3)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
194	3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1 and such data shall be read and accepted by the data recipient.		3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the format referred to in paragraph 1 ***across the continuum of care*** and such data shall be read and accepted by the data recipient.	3. Member States shall ensure that the priority categories of personal electronic health data referred to in Article 5 are issued in the **European electronic health record exchange** format referred to in paragraph 1**. Where** ~~and~~ such data ~~shall be read and accepted by~~**are transmitted by automatic means for primary use the receiving provider shall accept the format of** the data ~~recipient~~**and be able to read it**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 7				
195	Article 7 Registration of personal electronic health data		Article 7 Registration of personal electronic health data	~~Article 7~~ ~~Registration of personal electronic health data~~ [MOVED TO THE NEW ARTICLE 2A]	
	Article 7(1)				
196	1. Member States shall ensure that, where data is processed in electronic		1. Member States shall ensure that, where ***health*** data is processed ~~*in*~~	~~1. Member States shall ensure that, where data is processed in electronic~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	format, health professionals systematically register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in the electronic format in an EHR system.		~~*electronic format*~~, health professionals ~~*systematically*~~ register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in the electronic format in an EHR system.	~~format, health professionals systematically register the relevant health data falling under at least the priority categories referred to in Article 5 concerning the health services provided by them to natural persons, in the electronic format in an EHR system.~~ [MOVED TO ARTICLE 2A(1) SEE AMENDMENTS IN THAT ARTICLE]	
		Article 7(1a)			
196a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			1a. Member States may provide for natural persons to have the right to object to the registration of their personal health data in an EHR system. ***If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanisms.*** Plenary AM 555		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 7(2)				
197	2. Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.		2. Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.	~~2. Where electronic health data of a natural person is registered in a Member State that is not the Member State of affiliation of that person, the Member State of treatment shall ensure that the registration is performed under the person identification data of the natural person in the Member State of affiliation.~~ [MOVED TO ARTICLE 2A(2) SEE AMENDMENTS	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				IN THAT ARTICLE]	
	Article 7(3), first subparagraph				
198	3. The Commission shall, by means of implementing acts, determine the requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. Those implementing acts shall establish the following:		3. The Commission shall~~, by means of implementing acts, determine the~~ ***adopt delegated acts in accordance with Article 67 to supplement this Regulation by determining the data quality*** requirements for the ***electronic*** registration of ~~*electronic*~~ health data by healthcare providers and natural persons, as relevant. ~~*Those implementing acts*~~	~~3. The Commission shall, by means of implementing acts, determine the requirements for the registration of electronic health data by healthcare providers and natural persons, as relevant. Those implementing acts shall establish the following:~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			~~*shall establish the following:*~~		
	Article 7(3), first subparagraph, point (a)				
199	(a) categories of healthcare providers that are to register health data electronically;		*deleted*	~~(a) categories of healthcare providers that are to register health data electronically;~~	
	Article 7(3), first subparagraph, point (b)				
200	(b) categories of health data that are to be registered systematically in electronic format by healthcare		*deleted*	~~(b) categories of health data that are to be registered systematically in electronic format by healthcare~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	providers referred to in point (a);			~~providers referred to in point (a);~~	
	Article 7(3), first subparagraph, point (c)				
201	(c) data quality requirements pertaining to the electronic registration of health data.		*deleted*	~~(c) data quality requirements pertaining to the electronic registration of health data.~~	
	Article 7(3), second subparagraph				
202	Those implementing acts shall be adopted in accordance with the		~~*Those implementing acts*~~***When health data are registered or updated,***	~~Those implementing acts shall be adopted in accordance with the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	advisory procedure referred to in Article 68(2).		***electronic health records*** shall ~~*be adopted in accordance with the advisory procedure referred to in Article 68(2)*~~***identify the health professional, time and health care provider that carried out the registration or the update. Member States may provide for other aspects of data registration to be recorded***.	~~advisory procedure referred to in Article 68(2).~~). [MOVED FROM ARTICLE 2A (3) SEE AMENDMENTS IN THAT ARTICLE]	
	Article 7(3a)				
202a			***3a. Where the personal health data have not been***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			registered electronically prior to the application of this Regulation, Member States may require that such data be made available in electronic format pursuant to this Article. This shall not affect the obligation to make personal electronic health data, registered after the application of this Regulation, available in electronic format, pursuant to this Article.		
	Article 7A				
202b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 7A **Access by health professionals to personal electronic health data** [MOVED FROM ARTICLE 4]	
	Article 7a, first paragraph				
202c				**1. Member States shall ensure that where health professionals process personal health data in an electronic format, they**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				shall have access to the personal electronic health data of natural persons under their treatment, through the health professional access services referred to in Article 7B, irrespective of the Member State of affiliation and the Member State of treatment. [MOVED FROM ARTICLE 4(1)(a)]	
	Article 7a, 1A.				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
202d				**1A. Where the Member States of affiliation of the natural person under treatment and the Member States of treatment differ, cross-border access to the electronic health data of the natural person under treatment shall be provided through the infrastructure referred to in Article 12.**	
	Article 7a, 2.				
202e					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2. The access referred to in paragraphs 1 and 1A shall include at least the priority categories in Article 5. In line with the principles provided for in Article 5 of the Regulation (EU) 2016/679, Member States may also establish rules providing for the categories of personal electronic health data accessible by different health professionals. Such rules shall take into account the possibility of restrictions imposed in according to Article 8E.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 4(2) AND AMENDED]	
		Article 7a, 3.			
202f				**3. Where access to electronic health data has been restricted by the natural person pursuant to Article 8E, the healthcare provider or health professional shall not be informed of the content of the electronic health data without prior authorisation by the natural person. The**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				healthcare provider or health professional shall be informed exclusively about the existence of restricted electronic health data. In cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person as referred to in Article 9(2)(c) of the Regulation (EU) 2016/679, the healthcare provider or health professional may get access to the restricted electronic health data. Such events shall be logged in a clear and understandable format	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and shall be easily accessible for the natural persons. Member States' law may set out additional safeguards. [MOVED FROM ARTICLE 4(4) AND AMENDED]	
	Article 7b				
202g				**Article 7B** **Health professional access services**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 7b, first paragraph				
202h				**For the provision of healthcare, Member States shall ensure that access to the priority categories of electronic health data referred to in Article 5 is made available to health professionals through health professional access services. Those services shall be accessible only to health professionals who are in possession of electronic identification means recognised pursuant to Article 6 of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Regulation (EU) No 910/2014 or other electronic identification means compliant with common specifications referred to in Article 23 and the access shall be free of charge. [MOVED FROM ARTICLE 4(3) AND AMENDED]	
	Article 8				
203	Article 8 Telemedicine in the context		Article 8 Telemedicine in the context	~~Article 8~~ ~~Telemedicine in the context~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of cross-border healthcare		of cross-border healthcare	~~of cross-border healthcare~~	
	Article 8, first paragraph				
204	Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.		Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions ***and in a non-discriminatory manner***, accept the provision of the services of the same type by healthcare providers located in other Member States, ***without prejudice to the same rights and obligations to access and register electronic health data***.	~~Where a Member State accepts the provision of telemedicine services, it shall, under the same conditions, accept the provision of the services of the same type by healthcare providers located in other Member States.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 8A				
204a				**Article 8A** **Right of natural persons to access their personal electronic health data**	
	Article 8a(1)				
204b				**1. Natural persons shall have the right to access their personal electronic health data, at a minimum**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data that belongs in the priority categories in Article 5, processed for the provision of healthcare through the electronic health data access services referred to in Article 8G. The access shall be provided immediately after the personal electronic health data has been registered in an EHR system, adhering to technological practicability, free of charge and in an easily readable, consolidated and accessible form. [MOVED FROM ARTICLE	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				3(1) AND AMENDED]	
	Article 8a(2)				
204c				**2. Natural persons shall have the right to receive an electronic copy, free of charge, through the electronic health data access services referred to in Article 8G, in the European electronic health record exchange format referred to in Article 6, of at least their personal electronic health data in the priority categories referred to in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 5. [MOVED FROM ARTICLE 3(2) AMENDED]	
	Article 8a(3)				
204d				**3. In accordance with Article 23 of Regulation (EU) 2016/679, Member States may restrict the scope of the rights referred to in paragraphs 1 and 2, in particular whenever necessary for the protection of the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				natural person based on patient safety and ethics by delaying their access to their personal electronic health data for a limited period of time until a health professional can properly communicate and explain to the natural person information that can have a significant impact on their health. MOVED FROM ARTICLE 3(3)]	
	Article 8B				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
204e				**Article 8B** **Right of natural persons to insert information in their own EHR**	
	Article 8b(1)				
204f				**Member States law may provide that natural persons or their representatives as referred to in Article 8G(2) have the right to insert information in their own EHR through**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronic health data access services or applications linked to these services as referred to in Article 8G. That information shall in such cases be clearly distinguishable as inserted by the natural person or by his or her representative. Natural persons shall not have the possibility to directly alter the electronic health data and related information inserted by health professionals. [MOVED FROM ARTICLE	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				3(6)]	
	Article 8C				
204g				**Article 8C** **Right of natural persons to rectification**	
	Article 8c(1)				
204h				**When exercising the right to rectification under Article 16 of Regulation (EU) 2016/679,**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				natural persons shall be able to easily request, online through the electronic health data access services referred to in Article 8G, the controller of the personal electronic health data, to rectify their personal electronic health data. [MOVED FROM ARTICLE 3(7) AND AMENDED]	
	Article 8c(2)				
204i					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Member States law may also enable natural persons to exercise other rights pursuant to Chapter III of Regulation (EU) 2016/679 online through the electronic health data access services referred to in Article 8G.	
	Article 8D				
204j				**Article 8D** **Right to data portability for natural persons**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 8d(1)				
204k				**1. Natural persons shall have the right to give access to or request a healthcare provider to transmit, all or part of their electronic health data that belongs to the priority categories as referred to in Article 5 to another provider of their choice from the healthcare sector, without delay, free of charge and without hindrance from the transmitting provider or from the manufacturers of the systems used by that**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				provider. [MOVED FROM ARTICLE 3(8) SUBPARA 1] [MOD.PU.16.rev1]	
	Article 8d(2)				
2041				**2. Natural persons shall have the right that, where healthcare providers are located in different Member States and such electronic health data belongs to the priority categories referred to in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 5, the transmitting provider transmits the data in the European electronic health record exchange format referred to in Article 6 through the cross border infrastructure as referred to in Article 12. The receiving healthcare provider shall accept such data and shall be able to read it. [MOVED FROM ARTICLE 3(8) SUBPARA 2]	
	Article 8d(3)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
204 m				**3. Where natural persons have received an electronic copy of their priority categories of personal electronic health data as referred to in Article 8A(2), they shall be able to transmit that data to healthcare providers of their choice in the European electronic health record exchange format referred to in Article 6 The receiving provider shall accept such data and be able to read it, as appropriate.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(8) SUBPARA 4] [MOD.PU.16.rev1]	
	Article 8d(4)				
204n				**4. The Commission shall, by means of implementing acts, determine the requirements concerning the technical implementation of the rights set out in this Article. Those implementing acts shall be adopted in accordance with the examination**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				procedure referred to in Article 68(2). [MOVED FROM ARTICLE 3(12)]	
	Article 8E				
204o				**Article 8E** **Right to restrict access and information on access**	
	Article 8e(1), first subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
204p				**1. Natural persons shall have the right to restrict access of health professionals and healthcare providers to their personal electronic health data referred to in Article 8A. Member States laws may provide that such restriction of access may be derogated under the same conditions as those laid down in Article 7A(3).**	
	Article 8e(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
204q				**Member States shall establish the rules and specific safeguards regarding such restriction mechanisms, including the restriction of this right in a justified and proportionate manner.** [MOVED FROM ARTICLE 3(9)]	
	Article 8e(2)				
204r					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2. Natural persons shall have the right to obtain information on any access to their personal electronic health data through the health professional access service made in the context of healthcare. The information shall be provided without delay and free of charge through electronic health data access services. The information shall include, at least, the following:	
	Article 8e(2a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
204s				**(a) the healthcare provider or other individuals who accessed the personal electronic health data;**	
	Article 8e(2), third subparagraph				
204t				**(b) the date and time of access;**	
	Article 8e(2), fourth subparagraph				
204u					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(c) the personal electronic health data that was accessed. [MOVED FROM ARTICLE 3(10)]	
	Article 8a(3)				
204v				**3. The Commission shall, by means of implementing acts, determine the requirements for the technical implementation of the rights set out in this Article. Those**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	
	Article 8F				
204w				**Article 8F** **Right of natural person to object**	
	Article 8f(1)				
204x					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				1. Member States laws may provide that natural persons have the right to object to the access to their personal electronic health data registered in an EHR system through the electronic health data access services referred to in Articles 7B and 8G. In such cases, Member States should ensure that the exercise of this right is reversible.	
	Article 8f(1)				
204y				**If a Member State**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanism. In particular, Member States may allow for the possibility of the healthcare provider or health professional to get access to the personal electronic health data in cases where processing is necessary in order to protect the vital interests of the data subject or of another natural person as referred to in Article 9(2)(c) of the Regulation (EU) 2016/679, even if the patient has exercised the right to object.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 8f(2)				
204z				**2. With regard to cross-border access to personal electronic health data referred to in Article 5, Member States laws may provide for natural persons to have the right to object to their personal electronic health data being made available for cross-border access and exchange through the cross-border infrastructure as referred to in Article 12.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 8f(2)				
204aa				**If a Member State provides for such a right, it shall establish the rules and specific safeguards regarding such objection mechanism.**	
	Article 8G				
204ab				**Article 8G** **Electronic health data**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				access services for natural persons and their representatives	
	Article 8g(1)				
204ac				**1. Member States shall ensure that one or more electronic health data access services at national, regional or local level are established, enabling natural persons access to their personal electronic health data and the exercise of rights referred to in Articles 8A to 8F.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(5)(a)]	
	Article 8g(2)				
204ad				**2. Member States shall ensure that one or more proxy services are established as a functionality of health data access services enabling natural persons to:**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 8g(2), point (a)				
204ae				**(a) authorise other natural persons of their choice to access their personal electronic health data, or part thereof, on their behalf; and;**	
	Article 8g(2), point (b)				
204af				**(b) have access to the personal electronic health data of natural persons whose affairs they administer as legal**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				guardians	
	Article 8g(second subparagraph)				
204ag				**in an equivalent manner as they access their personal electronic health data and to manage those authorisations.**	
	Article 8g(second subparagraph)				
204ah				**The proxy services shall provide authorisations free of charge,**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronically or on paper.	
	Article 8g(second subparagraph)				
204a i				**Member States shall establish rules regarding such authorisations, actions of guardians and representatives. The proxy services shall be interoperable among Member States.** [MOVED FROM ARTICLE 3(5)(b) AND SUBPARA 2]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 8g(5), second subparagraph				
204aj				**2a. For the purposes of paragraph 2, the Commission shall, by means of implementing acts, lay down the technical specifications to ensure the interoperability of the proxy services of the Member States. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 8g(3)				
204ak				**3. The access to the electronic health data services as referred to in paragraph 1 shall be free of charge for the natural persons and their representatives.**	
	Article 9				
205	Article 9		Article 9	Article 9	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Identification management		Identification management	Identification management	
	Article 9(1)				
206	1. Where a natural person uses telemedicine services or personal health data access services referred to in Article 3(5), point (a), that natural person shall have the right to identify electronically using any electronic identification means which is recognised pursuant to Article 6 of Regulation (EU) No 910/2014.		1. Where a natural person ***or a health professional uses,*** ~~*uses*~~ telemedicine services or personal health data access services referred to in Article 3(5), point (a), ***Article 4(3) and where applicable, Article 8*** that natural person ***or health professional*** shall have the right to identify electronically using any electronic identification means which is recognised	1. Where a natural person uses ~~telemedicine services or~~ personal health data access services referred to in Article ~~3(5), point (a)~~**8G**, that natural person shall have the right to identify electronically using any electronic identification means which is recognised pursuant to Article 6 of Regulation (EU) No 910/2014. **Member States may provide**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			pursuant to Article 6 of Regulation (EU) No 910/2014***, including eID schemes where such systems are offered***.	**complementary mechanisms to ensure appropriate identity matching in cross-border situations.**	
	Article 9(2)				
207	2. The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Regulation		2. The Commission shall~~, *by means of implementing acts, determine*~~ ***adopt delegated acts in accordance with Article 67 to supplement this Regulation by determining*** the requirements for the interoperable, cross-border identification and	2. The Commission shall, by means of implementing acts, determine the requirements for the interoperable, cross-border identification and authentication mechanism for natural persons and health professionals~~, in accordance with Regulation~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(EU) No 910/2014 as amended by [COM(2021) 281 final]. The mechanism shall facilitate the transferability of electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		authentication mechanism for natural persons and health professionals, in accordance with Regulation (EU) No 910/2014 ~~*as amended by [COM(2021) 281 final]*~~. The mechanism shall facilitate the transferability of electronic health data in a cross-border context. ~~*Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).*~~	~~(EU) No 910/2014 as amended by [COM(2021) 281 final].~~ The mechanism shall facilitate the transferability of **personal** electronic health data in a cross-border context. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	
		Article 9(3)			
208					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	3. The Commission shall implement services required by the interoperable, cross-border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border digital health infrastructure referred to in Article 12(3).		3. The Commission***, in cooperation with Member States,*** shall implement services required by the interoperable, cross-border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border digital health infrastructure referred to in Article 12(3).	3. The Commission shall implement services required by the interoperable, cross-border identification and authentication mechanism referred to in paragraph 2 of this Article at Union level, as part of the cross-border ~~digital health~~ infrastructure referred to in Article 12(3).	
		Article 9(4)			
209	4. The digital health authorities and the Commission shall		4. ~~*The digital health*~~***Member States' competent*** authorities and	4. The ~~digital health authorities~~ **Member States** and the Commission shall	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	implement the cross-border identification and authentication mechanism at Union and Member States' level, respectively.		the Commission shall implement the cross-border identification and authentication mechanism at Union and Member States' level, respectively, ***in accordance with Regulation (EU) No 910/2014***.	implement the cross-border identification and authentication mechanism at ~~Union and~~ Member States' **and Union** -level, respectively.	
	Article 9A				
209a				**Article 9A** **Compensation for making personal electronic health data available**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 9a(1)				
209b				**By way of derogation from Article 9 of Regulation […] [Data Act COM/2022/68 final], where personal electronic health data is transmitted in accordance with Article 8D, the receiving provider shall not be required to compensate the transmitting provider for making electronic heath data available.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(8) SUBPARA 3]	
	Section 1a				
209c				**Section 1a Governance for primary use of electronic health data**	
	Article 10				
210	Article 10 Digital health authority		Article 10 Digital health authority	Article 10 Digital health authority	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 10(1)				
211	1. Each Member State shall designate a digital health authority responsible for the implementation and enforcement of this Chapter at national level. The Member State shall communicate the identity of the digital health authority to the Commission by the date of application of this Regulation. Where a designated digital health authority is an entity consisting of multiple		1. Each Member State shall designate a digital health authority responsible for the implementation and enforcement of this Chapter at national level. The Member State shall communicate the identity of the digital health authority to the Commission by the date of application of this Regulation. Where a designated digital health authority is an entity consisting of multiple	1. Each Member State shall designate **one or more** ~~a~~ digital health ~~authority~~**authorities** responsible for the implementation and enforcement of this Chapter at national level. The Member State shall ~~communicate the~~ **inform the Commission of the** identity of the digital health authority ~~to the Commission~~ by the date of application of this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.		organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.	Regulation. Where a **Member State** designated **more than one** digital health authority ~~is an entity consisting~~**and where the digital health authority consists** of multiple organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.	
	Article 10(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
212	2. Each digital health authority shall be entrusted with the following tasks:		2. Each digital health authority shall be entrusted with the following tasks ***and powers***:	2. ~~Each~~ **The** digital health authority shall be entrusted with the following tasks:	
		Article 10(2), point (a)			
213	(a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;		(a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;	(a) ensure the implementation of the rights and obligations provided for in Chapters II and III by adopting necessary national, regional or local technical solutions and by establishing relevant rules and mechanisms;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 10(2), point (b)				
214	(b) ensure that complete and up to date information about the implementation of rights and obligations provided for in in Chapters II and III is made readily available to natural persons, health professionals and healthcare providers;		(b) ensure that complete and up to date information about the implementation of rights and obligations provided for in in Chapters II and III is made readily available to natural persons, health professionals and healthcare providers ***and that appropriate training initiatives are undertaken at the local, regional and national level***;	(b) ensure that complete and up to date information about the implementation of rights and obligations provided for in in Chapters II and III is made readily available to natural persons, health professionals and healthcare providers;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 10(2), point (c)				
215	(c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;		(c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;	(c) in the implementation of technical solutions referred to in point (a), enforce their compliance with Chapter II, III and Annex II;	
	Article 10(2), point (d)				
216	(d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise		(d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise	(d) contribute, at Union level, to the development of technical solutions enabling natural persons and health professionals to exercise	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	their rights and obligations set out in this Chapter;		their rights and obligations set out in this Chapter;	their rights and obligations set out in this Chapter;	
	Article 10(2), point (e)				
217	(e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council[1]. _____ 1. Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the		(e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council[1]. _____ 1. Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the	(e) facilitate for persons with disabilities to exercise their rights listed in Article 3 of this Regulation in accordance with Directive (EU) 2019/882 of the European Parliament and of the Council[1]. _____ 1. Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)		accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)	accessibility requirements for products and services (Text with EEA relevance) (OJ L 151, 7.6.2019, p. 70)	
	Article 10(2), point (f)				
218	(f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;		(f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;	(f) supervise the national contact points for digital health and cooperate with other digital health authorities and the Commission on further development of MyHealth@EU;	
	Article 10(2), point (g)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
219	(g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;		(g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;	(g) ensure the implementation, at national level, of the European electronic health record exchange format, in cooperation with national authorities and stakeholders;	
		Article 10(2), point (h)			
220	(h) contribute, at Union level, to the development of the European electronic health record exchange format and to the		(h) contribute, at Union level, ***and, where relevant, in cooperation at local and regional level within the Member States,*** to the	(h) contribute, at Union level, to the development of the European electronic health record exchange format and to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	elaboration of common specifications addressing interoperability, security, safety or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;		development of the European electronic health record exchange format and to the elaboration of common specifications addressing ***quality,*** interoperability, security, safety***, ease of use, accessibility, non-discrimination*** or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;	elaboration of common specifications addressing interoperability, security, safety or fundamental right concerns in accordance with Article 23 and of the specifications of the EU database for EHR systems and wellness applications referred to in Article 32;	
		Article 10(2), point (i)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
221	(i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;		(i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;	(i) where applicable, perform market surveillance activities in accordance with Article 28, while ensuring that any conflict of interest is avoided;	
	Article 10(2), point (j)				
222	(j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity		(j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity	(j) build national capacity for implementing interoperability and security of the primary use of electronic health data and participate in information exchanges and capacity	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	building activities at Union level;		building activities at Union level;	building activities at Union level;	
		Article 10(2), point (k)			
223	(k) offer, in compliance with national legislation, telemedicine services and ensure that such services are easy to use, accessible to different groups of natural persons and health professionals, including natural persons with disabilities, do not discriminate and offer the possibility of choosing between in person and		(k) offer, in compliance with national legislation, telemedicine services and ensure that such services are easy to use, accessible ***and equitable*** to different groups of natural persons and health professionals, including natural persons with disabilities, ~~*do not discriminate*~~***under the same non-discriminatory conditions*** and offer the	~~(k) offer, in compliance with national legislation, telemedicine services and ensure that such services are easy to use, accessible to different groups of natural persons and health professionals, including natural persons with disabilities, do not discriminate and offer the possibility of choosing between in person and~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	digital services;		possibility of choosing between in person and digital services;	~~digital services;~~	
		Article 10(2), point (l)			
224	(l) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;		(l) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;	(l) cooperate with market surveillance authorities, participate in the activities related to handling of risks posed by EHR systems and of serious incidents and supervise the implementation of corrective actions in accordance with Article 29;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			I do not see any changes in EP or Council text		
	Article 10(2), point (m)				
225	(m) cooperate with other relevant entities and bodies at national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals, industry associations;		(m) cooperate with other relevant entities and bodies at ***local, regional,*** national or Union level, to ensure interoperability, data portability and security of electronic health data~~, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals, industry~~	(m) cooperate with other relevant entities and bodies at national or Union level, to ensure interoperability, data portability and security of electronic health data, as well as with stakeholders representatives, including patients' representatives, healthcare providers, health professionals~~,~~ **and** industry associations;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			~~*associations*~~;		
		Article 10(2), point (n)			
226	(n) cooperate with supervisory authorities in accordance with Regulation (EU) 910/2014, Regulation (EU) 2016/679 and Directive (EU) 2016/1148 of the European Parliament and of the Council[1] with other relevant authorities, including those competent for cybersecurity, electronic identification, the European Artificial Intelligence Board, the Medical Device		(n) cooperate with supervisory authorities in accordance with Regulation (EU) 910/2014, Regulation (EU) 2016/679 and Directive (EU) 2016/1148 of the European Parliament and of the Council[1] with other relevant authorities, including those competent for cybersecurity, electronic identification, the European Artificial Intelligence Board, the Medical Device	(n) cooperate with supervisory authorities in accordance with Regulation (EU) 910/2014, Regulation (EU) 2016/679~~ and ~~**,** Directive (EU) ~~2016/1148 of the European Parliament and of the Council~~[1] **2022/2555 and** with other relevant authorities, including those competent for cybersecurity, electronic identification~~, the European Artificial Intelligence~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Coordination Group, the European Data Innovation Board and the competent authorities under Regulation […] [Data Act COM/2022/68 final]; _____ 1. Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).		Coordination Group, the European Data Innovation Board and the competent authorities under Regulation […] [Data Act COM/2022/68 final]; _____ 1. Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).	~~Board, the Medical Device Coordination Group, the European Data Innovation Board and the competent authorities under Regulation […] [Data Act COM/2022/68 final];~~**;** _____ ~~1. Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (OJ L 194, 19.7.2016, p. 1).~~	
		Article 10(2), point (o)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
227	(o) draw up, in collaboration where relevant with market surveillance authorities, an annual activity report, which shall contain a comprehensive overview of its activities. The report shall be transmitted to the Commission. The annual activity report shall follow a structure that is agreed at Union level within EHDS Board, to support benchmarking pursuant to Article 59. The report shall contain at least information concerning:		(o) draw up, in collaboration where relevant with market surveillance authorities, an annual activity report, which shall contain a comprehensive overview of its activities. The report shall be transmitted to the Commission. The annual activity report shall follow a structure that is agreed at Union level within EHDS Board, to support benchmarking pursuant to Article 59. The report shall contain at least information concerning:	~~(o) draw up, in collaboration where relevant with market surveillance authorities, an annual activity report, which shall contain a comprehensive overview of its activities. The report shall be transmitted to the Commission. The annual activity report shall follow a structure that is agreed at Union level within EHDS Board, to support benchmarking pursuant to Article 59. The report shall contain at least information concerning:~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[LETTER O MOVED TO ARTICLE 10A, SEE AMENDMENTS IN THAT ARTICLE]	
	Article 10(2), point (o)(i)				
228	(i) measures taken to implement this Regulation;		(i) measures taken to implement this Regulation;	~~(i) measures taken to implement this Regulation;~~	
	Article 10(2), point (o)(ii)				
229					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(ii) percentage of natural persons having access to different data categories of their electronic health records;		(ii) percentage of natural persons having access to different data categories of their electronic health records;	~~(ii) percentage of natural persons having access to different data categories of their electronic health records;~~	
		Article 10(2), point (o)(iii)			
230	(iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;		(iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;	~~(iii) information on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;~~	
		Article 10(2), point (o)(iv)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
231	(iv) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;		(iv) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;	~~(iv) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;~~	
		Article 10(2), point (o)(v)			
232	(v) volumes of electronic		(v) volumes of electronic	~~(v) volumes of electronic~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data of different categories shared across borders through MyHealth@EU;		health data of different categories shared across borders through MyHealth@EU;	~~health data of different categories shared across borders through MyHealth@EU;~~	
		Article 10(2), point (o)(vi)			
233	(vi) level of natural person satisfaction with MyHealth@EU services;		(vi) level of natural person satisfaction with MyHealth@EU services;	~~(vi) level of natural person satisfaction with MyHealth@EU services;~~	
		Article 10(2), point (o)(vii)			
234	(vii) number of certified EHR systems and labelled		(vii) number of certified EHR systems and labelled	~~(vii) number of certified EHR systems and labelled~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	wellness applications enrolled in the EU database;		wellness applications enrolled in the EU database;	~~wellness applications enrolled in the EU database;~~	
	Article 10(2), point (o)(viii)				
235	(viii) number of non-compliance cases with the mandatory requirements;		(viii) number of non-compliance cases with the mandatory requirements;	~~(viii) number of non-compliance cases with the mandatory requirements;~~	
	Article 10(2), point (o)(ix)				
236	(ix) a description of its activities carried out in relation to engagement with and consultation of relevant		(ix) a description of its activities carried out in relation to engagement with and consultation of relevant	~~(ix) a description of its activities carried out in relation to engagement with and consultation of relevant~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;		stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;	~~stakeholders, including representatives of natural persons, patient organisations, health professionals, researchers, and ethical committees;~~	
		Article 10(2), point (o)(x)			
237	(x) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.		(x) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.	~~(x)~~ ~~information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, and artificial intelligence.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 10(3)				
238	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by entrusting the digital health authorities with additional tasks necessary to carry out the missions conferred on them by this Regulation and to modify the content of the annual report.		*deleted*	~~3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation by entrusting the digital health authorities with additional tasks necessary to carry out the missions conferred on them by this Regulation and to modify the content of the annual report.~~	
	Article 10(3a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
238a			***3a. The digital health authorities and the data protection authorities shall consult each other and cooperate in the enforcement of this Regulation, within the remit of their respective competences.***		
		Article 10(4)			
239	4. Each Member State shall ensure that each digital health authority is provided with the human, technical		4. Each Member State shall ensure that each digital health authority is provided with the human, technical	~~4. Each Member State shall ensure that each digital health authority is provided with the human, technical~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers.		and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers.	~~and financial resources, premises and infrastructure necessary for the effective performance of its tasks and exercise of its powers.~~	
		Article 10(5)			
240	5. In the performance of its tasks, the digital health authority shall actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall avoid any conflicts of interest.		5. ~~*In the performance of its tasks, the digital health authority*~~***Members of the digital health authority shall avoid any conflicts of interest. Members shall not have financial or other interests in industries or economic activities which could affect their***	5. In the performance of its tasks, the digital health authority shall ~~actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority shall~~ avoid any conflicts of interest.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			impartiality. They shall undertake to act in the public interest and in an independent manner, and shall ~~*actively cooperate with stakeholders' representatives, including patients' representatives. Members of the digital health authority*~~***make an annual declaration of their financial interests. All indirect interests which could relate to such industries or economic activities*** shall ~~*avoid any conflicts*~~***be entered in a register available to the public, upon request. The Commission may adopt guidance on what is likely***	[SEE ALSO ARTICLE 10(2)(m)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to constitute a conflict of interest ***together with the procedure to be followed in such cases***.		
	Article 10(5a)				
240a			***5a. In the performance of their tasks, the digital health authorities shall actively cooperate and consult with relevant stakeholders' representatives, including patients' representatives, health care providers and health professionals' representatives, including***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health professional associations, consumer organisations and industry associations. Stakeholders shall declare any conflict of interest.		
	Article 10A				
240b				**Article 10A** **Reporting by digital health authority**	
	Article 10a(1), first subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
240c				**1. The digital health authority shall publish a biennial activity report, which shall contain a comprehensive overview of its activities. If a Member State designates more than one digital health authority, one of them shall be responsible for the report and request necessary information from the other digital health authorities. The biennial activity report shall follow a structure that is agreed at Union level within EHDS Board. The report shall contain at**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				least information concerning: It appears in the wrong order but is ok on the structure and when exporting	
	Article 10a(1), second subparagraph				
240d				**(a) measures taken to implement this Regulation;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 10a(1), third subparagraph				
240e				**(b) percentage of natural persons having access to different data categories of their electronic health records;**	
	Article 10a(1), fourth subparagraph				
240f				**(c) formation on the handling of requests from natural persons on the exercise of their rights pursuant to this Regulation;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 10a(1), fifth subparagraph			
240g				**(d) number of healthcare providers of different types, including pharmacies, hospitals and other points of care, connected to MyHealth@EU calculated a) in absolute terms, b) as share of all healthcare providers of the same type and c) as share of natural persons that can use the services;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 10a(1), sixth subparagraph				
240h				**(e) volumes of electronic health data of different categories shared across borders through MyHealth@EU;**	
	Article 10a(1), seventh subparagraph				
240i				[MOVED FROM ARTICLE 10(2)(o)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 10a(2)				
240j				**2. The report shall be drawn up in collaboration with market surveillance authorities as referred to in Article 28 of this Regulation, where relevant.** [FROM ARTICLE 10(2)(o)]	
	Article 10a(3)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
240k				**3. The report shall be sent to the Commission and the EHDS Board within 6 months after the end date of the 2 years reporting period.** [FROM ARTICLE 10A(1) AND AMENDED]	
	Article 11				
241	Article 11 Right to lodge a complaint		Article 11 Right to lodge a complaint	Article 11 Right to lodge a complaint	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with a digital health authority		with a digital health authority	with a digital health authority	
	Article 11(1)				
242	1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority. Where the complaint concerns the rights of natural persons pursuant to Article 3 of this Regulation, the digital health authority		1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority***, where their rights laid down in this Regulation are affected***. Where the complaint concerns the rights of natural persons	1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the digital health authority**, related to the provisions in this Chapter**. Where the complaint concerns the rights of natural persons pursuant to ~~Article~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	shall inform the supervisory authorities under Regulation (EU) 2016/679.		pursuant to Article 3 of this Regulation ***or Regulation (EU) 2016/679***, the digital health authority shall ~~*inform the*~~ ***send a copy of the complaint to and consult with the competent*** supervisory ***authority under Regulation (EU) 2016/679 in order to facilitate its assessment and investigation. The decision of the digital health authority shall not prejudice any measures taken by the data protection*** authorities***, which shall be competent to treat the complaint in separate proceedings, pursuant to their tasks and***	~~3~~**Articles 8A to 8F** of this Regulation, the digital health authority shall ~~inform~~**transmit the complaint to** the supervisory authorities under Regulation (EU) 2016/679 **and shall consult and cooperate with them in the handling of such complaints**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			powers under Regulation (EU) 2016/679.		
	Article 11(2)				
243	2. The digital health authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken.		2. The digital health authority with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken***, including, where applicable, that the complaint was referred to the relevant supervisory authority under Regulation (EU) 2016/679, and that***	2. The **competent** digital health authority with which the complaint has been lodged shall inform the complainant**, in accordance with national law,** of the progress of the proceedings and of the decision taken.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the supervisory authority will, from that moment on, be the sole point of contact for the complainant in that matter.		
	Article 11(3)				
244	3. Digital health authorities shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.		3. Digital health authorities shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.	3. Digital health authorities **in different Member States** shall cooperate to handle and resolve complaints **related to the cross-border exchange and access to personal electronic health data**, including by exchanging all relevant information by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronic means, without undue delay.	
	Article 11(3a)				
244a			***3a. Each digital health authority shall facilitate submitting complaints, in particular by providing a complaint submission form which can also be completed electronically, without excluding the possibility of using other means of communication.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 11a				
244b			***Article 11a*** ***Right to an effective judicial remedy against a digital health authority***		
	Article 11a(1)				
244c			***1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			decision of a digital health authority concerning them.		
	Article 11a(2)				
244d			***2. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy where the digital health authority which is competent pursuant to Article 10 does not handle a complaint or does not inform the natural or legal person within three months***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			about the progress or outcome of the complaint lodged pursuant to Article 11.		
	Article 11a(3)				
244e			***3. Proceedings against a digital health authority shall be brought before the courts of the Member States where the digital health authority is established.***		
	Article 11A				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
244f				**Article 11A** **Relationship with data protection supervisory authorities**	
	Article 11a(1)				
244g				**1. The supervisory authority or authorities responsible for monitoring and enforcement of Regulation (EU) 2016/679 shall also be competent for monitoring and enforcement of the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				application of Articles 8A to 8F, in accordance with the relevant provisions of Regulation (EU) 2016/679. They shall be competent to impose administrative fines up to the amount referred to in Article 83(5) of that Regulation. Those supervisory authorities and the digital health authorities referred to in Article 10 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 3(11)]	
	Section 2				
245	Section 2 Cross-border infrastructure for primary use of electronic health data		Section 2 Cross-border infrastructure for primary use of electronic health data	Section 2 Cross-border infrastructure for primary use of **personal** electronic health data	
	Article 12				
246	Article 12		Article 12	Article 12	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	MyHealth@EU		MyHealth@EU	MyHealth@EU	
	Article 12(1)				
247	1. The Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States.		1. The Commission shall establish a central platform for digital health to provide services to support and facilitate the exchange of electronic health data between national contact points for digital health of the Member States.	1. The Commission shall establish a central **and interoperability** platform for digital health**, MyHealth@EU,** to provide services to support and facilitate the exchange of **personal** electronic health data between national contact points for digital health of the Member States.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 12(2)				
248	2. Each Member State shall designate one national contact point for digital health to ensure the connection to all other national contact points for digital health and to the central platform for digital health. Where a designated national contact point is an entity consisting of multiple organisations responsible for implementing different services, the Member State shall communicate to the Commission a description of the separation of tasks		2. Each Member State shall designate one national contact point for digital health to ensure the connection to all other national contact points for digital health and to the central platform for digital health. Where a designated national contact point is an entity consisting of multiple organisations responsible for implementing different services, the Member State shall communicate to the Commission a description of the separation of tasks	2. Each Member State shall designate one national contact point for digital health**. The national contact point shall be an organisational and technical gateway for the provision of cross-border digital health information services in the context of healthcare of personal electronic health data, enabling and ensuring** ~~to ensure~~ the connection to all other national contact points for digital health and to the central platform for digital	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	between the organisations. The national contact point for digital health shall be considered an authorised participant in the infrastructure. Each Member State shall communicate the identity of its national contact point to the Commission by [the date of application of this Regulation]. Such contact point may be established within the digital health authority established by Article 10 of this Regulation. Member States shall communicate to the Commission any subsequent modification of the identity of those contact		between the organisations. The national contact point for digital health shall be considered an authorised participant in the infrastructure. Each Member State shall communicate the identity of its national contact point to the Commission by [the date of application of this Regulation]. Such contact point may be established within the digital health authority established by Article 10 of this Regulation. Member States shall communicate to the Commission any subsequent modification of the identity of those contact	health **in cross-border infrastructure MyHealth@EU**. Where a designated national contact point is an entity consisting of multiple organisations responsible for implementing different services, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. ~~The national contact point for digital health shall be considered an authorised participant in the infrastructure~~. Each Member State shall ~~communicate~~ **inform of** the identity of its national	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	points. The Commission and the Member States shall make this information publicly available.		points. The Commission and the Member States shall make this information publicly available.	contact point to the Commission by [the date of application of this Regulation]. Such contact point may be established within the digital health authority established by Article 10 of this Regulation. Member States shall ~~communicate to~~ **inform** the Commission **of** any subsequent modification of the identity of those contact points. The Commission and the Member States shall make this information publicly available.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 12(3)				
249	3. Each national contact point for digital health shall enable the exchange of the personal electronic health data referred to in Article 5 with all other national contact points. The exchange shall be based on the European electronic health record exchange format.		3. Each national contact point for digital health shall enable the exchange of the personal electronic health data referred to in Article 5 with all other national contact points. The exchange shall be based on the European electronic health record exchange format.	3. Each national contact point for digital health shall enable the exchange of the personal electronic health data referred to in Article ~~5 with all~~**5(1) with national contact points in** other ~~national contact points~~**Member States through MyHealth@EU**. The exchange shall be based on the European electronic health record exchange format. **National contact point for digital health may enable the exchange of additional**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				categories of electronic health data referred to in Article 5(1A) insofar as Member State law has provided for these additional categories of personal electronic health to be accessed and exchanged, according to Article 5(1A).	
	Article 12(4)				
250	4. The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of		4. The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of	4. The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	MyHealth@EU, detailed rules concerning the security, confidentiality and protection of electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		MyHealth@EU, detailed rules concerning the security, confidentiality and protection of electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the ~~*advisory*~~***examination*** procedure referred to in Article ~~*68(2)*~~***68(2a). The implementing act shall include the target implementation dates, including for cross border***	MyHealth@EU, detailed rules concerning the security, confidentiality and protection of **personal** electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data interoperability, in consultation with the EHDS board. The European Union Agency for Cyber Security (ENISA) shall be consulted and closely involved in all steps of the examination procedure. Any measures adopted shall meet the highest technical standards in terms of security, confidentiality and protection of electronic health data.		
	Article 12(5)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
251	5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.		5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health and shall ensure that those connected are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.	5. Member States shall ensure connection of all healthcare providers to their national contact points for digital health**. Member States** ~~and~~ shall ensure that ~~those connected~~**connected healthcare providers** are enabled to perform two-way exchange of electronic health data with the national contact point for digital health.	
	Article 12(6)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
252	6. Member States shall ensure that pharmacies operating on their territories, including online pharmacies, are enabled to dispense electronic prescriptions issued by other Member States, under the conditions laid down in Article 11 of Directive 2011/24/EU. The pharmacies shall access and accept electronic prescriptions transmitted to them from other Member States through MyHealth@EU. Following dispensation of medicinal products based on an		6. Member States shall ensure that pharmacies operating on their territories, including online pharmacies, are enabled to dispense electronic prescriptions issued by other Member States, under the conditions laid down in Article 11 of Directive 2011/24/EU. The pharmacies shall access and accept electronic prescriptions transmitted to them from other Member States through MyHealth@EU***, provided that the requirements in Article 11 of Directive***	6. Member States shall ensure that pharmacies operating on their territories~~, including online pharmacies,~~ are enabled to dispense electronic prescriptions issued by other Member States, under the conditions laid down in Article 11 of Directive 2011/24/EU. The pharmacies shall access and accept electronic prescriptions transmitted to them from other Member States through MyHealth@EU. Following dispensation of medicinal products based on an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.		***2011/24/EU are fulfilled***. Following dispensation of medicinal products based on an electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.	electronic prescription from another Member State, pharmacies shall report the dispensation to the Member State that issued the prescription, through MyHealth@EU.	
		Article 12(7)			
253	7. The national contact points for digital health shall act as joint controllers of the electronic health data communicated through		7. The national contact points for digital health shall act as joint controllers of the electronic health data communicated through	7. The national contact points for digital health shall act as ~~joint~~ controllers of the **personal** electronic health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act as processor.		'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act as processor.	communicated through 'MyHealth@EU' for the processing operations in which they are involved. The Commission shall act as processor.	
		Article 12(8)			
254	8. The Commission shall, by means of implementing acts, allocate responsibilities among controllers and as regards the processor referred to in paragraph 7 of this Article, in accordance with Chapter IV of Regulation (EU)		8. The Commission shall, by means of implementing acts, allocate responsibilities among controllers and as regards the processor referred to in paragraph 7 of this Article, in accordance with Chapter IV of	8. **By means of implementing acts,** the Commission shall~~, by means of implementing acts, allocate responsibilities among controllers and as regards~~ **lay down the rules regarding the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2016/679. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		~~*Regulation*~~***Regulations*** (EU) 2016/679 ***and 2018/1725***. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	**requirements of cybersecurity, technical interoperability, semantic interoperability, operations and service management in relation to the processing by** the processor referred to in paragraph 7 of this Article **and its responsibilities towards the controllers**, in accordance with Chapter IV of Regulation (EU) 2016/679 **and of Regulation (EU) 2018/1725**. Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 12(9)				
255	9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be issued by the Joint Controllership group, based on the results of the compliance checks.		9. The approval for individual authorised participants to join MyHealth@EU for different services, or to disconnect a participant shall be issued by the Joint Controllership group, based on the results of the compliance checks.	9. **The national contact points referred to in paragraph 2 shall be authorised participants in MyHealth@EU, provided that they fulfil the conditions to join and to remain connected to MyHealth@EU as laid down pursuant to paragraph 4.** The approval for individual authorised participants to join MyHealth@EU for different services, or to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				disconnect a participant shall be issued by the ~~Joint Controllership group~~**Commission** , based on the results of the compliance checks **performed by the Commission**. **Subject to the outcome of the compliance check, the Commission shall, by means of implementing act, take decisions to connect individual authorised participants to join the infrastructure or to disconnect them. These implementing acts shall be adopted in accordance with the examination procedure referred to in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 68(2).	
	Article 13				
256	Article 13 Supplementary cross-border digital health services and infrastructures		Article 13 Supplementary cross-border digital health services and infrastructures	Article 13 Supplementary cross-border digital health services and infrastructures	
	Article 13(1)				
257	1. Member States may provide through MyHealth@EU		1. Member States may provide through MyHealth@EU	1. Member States may provide through MyHealth@EU	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	supplementary services that facilitate telemedicine, mobile health, access by natural persons to their translated health data, exchange or verification of health-related certificates, including vaccination card services supporting public health and public health monitoring or digital health systems, services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare. The Commission shall, by means of implementing		supplementary services that facilitate telemedicine, mobile health, access by natural persons to their translated health data, exchange or verification of health-related certificates, including vaccination card services supporting public health and public health monitoring or digital health systems, services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare. The Commission shall, by means of implementing	supplementary services that facilitate telemedicine, mobile health, access by natural persons to their translated health data, exchange or verification of health-related certificates, including vaccination card services supporting public health and public health monitoring or digital health systems, services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare. The Commission shall, by means of implementing	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	acts, set out the technical aspects of such provision. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		acts, set out the technical aspects of such provision. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	acts, set out the technical aspects of such ~~provision~~**services** . Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	
	Article 13(2)				
258	2. The Commission and Member States may facilitate the exchange of electronic health data with other infrastructures, such as the Clinical Patient Management System or		2. The Commission and Member States may facilitate the exchange of electronic health data with other infrastructures, such as the Clinical Patient Management System or	2. The Commission and Member States may facilitate the exchange of **personal** electronic health data with other infrastructures, such as the Clinical Patient	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	other services or infrastructures in the health, care or social security fields which may become authorised participants to MyHealth@EU. The Commission shall, by means of implementing acts, set out the technical aspects of such exchanges. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). The connection of another infrastructure to the central platform for digital health shall be subject to a decision of the joint controllership group for		other services or infrastructures in the health, care or social security fields which may become authorised participants to MyHealth@EU. The Commission shall, by means of implementing acts, set out the technical aspects of such exchanges. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). The connection of another infrastructure to the central platform for digital health shall be subject to a decision of the joint controllership group for	Management System or other services or infrastructures in the health, care or social security fields which may become authorised participants to MyHealth@EU. The Commission shall, by means of implementing acts, set out the technical aspects of such exchanges. Those implementing acts shall be adopted in accordance with the advisory **examination** procedure referred to in Article 68(2). The connection of another infrastructure to the central platform for digital health**, as well as its**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	MyHealth@EU referred to in Article 66.		MyHealth@EU referred to in Article 66.	**disconnection,** shall be subject to a decision**, by means of implementing acts,** of the ~~joint controllership group for MyHealth@EU~~**Commission, based on the result of the compliance checks of the technical aspects of such exchanges as referred to in subparagraph 1. Those implementing acts shall be adopted in accordance with the examination procedure** referred to in Article ~~66~~**68(2)**.	
		Article 13(3), first subparagraph			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
259	3. Member States and the Commission shall seek to ensure interoperability of MyHealth@EU with technological systems established at international level for the exchange of electronic health data. The Commission may adopt an implementing act establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of MyHealth@EU for the purposes of the electronic		*deleted*	3. ~~Member States and the Commission shall seek to ensure interoperability of MyHealth@EU with technological systems~~**A national contact point of a third country or a system** established at **an** international level ~~for the exchange of electronic health data. The Commission may adopt an implementing act establishing that a national contact point of a third country or a system established at an international level is compliant with~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data exchange. Before adopting such an implementing act, a compliance check of the national contact point of the third country or of the system established at an international level shall be performed under the control of the Commission.			~~requirements of MyHealth@EU for the purposes of the electronic health data exchange. Before adopting such an implementing act, a compliance check of the national contact point of the third country or of the system established at an international level~~**may become an authorised participant in MyHealth@EU provided that they fulfil the requirements of MyHealth@EU for the purposes of the personal electronic health data exchange as referred to in Article 12, that the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				transfer stemming from such connection complies with the rules in Chapter V of Regulation (EU) 2016/679, and that the requirements concerning legal, organizational, operational, semantic, technical and cybersecurity measures are equivalent to those applicable to Member States in the operation of MyHealth@EU services. The requirements in subparagraph 1 shall be ~~performed under the control of~~**verified through compliance check performed by** the Commission.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 13(3), second subparagraph			
260	The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the procedure referred to in Article 68. The connection of the national contact point of the third country or of the system established at an international level to the central platform for digital health, as well as the decision to be disconnected shall be subject to a		*deleted*	~~The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the procedure referred to in Article 68. The connection of~~**Based on the outcome of the compliance check, the Commission may, by means of implementing act, take the decision to connect as well as to disconnect** the national contact point of the third	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	decision of the joint controllership group for MyHealth@EU referred to in Article 66.			country or of the system established at an international level to ~~the central platform for digital health, as well as the decision to be disconnected~~**MyHealth@EU. Member States national security interests shall be taken into account. These implementing acts** shall be ~~subject to a decision of the joint controllership group for MyHealth@EU~~**adopted in accordance with the examination procedure** referred to in Article ~~66~~**68(2)**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 13(3), third subparagraph				
261	The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.		*deleted*	The Commission shall ~~make~~**maintain** the list of ~~implementing acts adopted~~ **national contact points of a third country or of systems established at an international level connected to MyHealth@EU** pursuant to this paragraph **and shall make it** publicly available.	
	CHAPTER III				
262					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	CHAPTER III EHR systems and wellness applications		CHAPTER III EHR systems and wellness applications	CHAPTER III EHR systems and wellness applications	
	Section 1				
263	Section 1 General provisions for EHR systems		Section 1 General provisions for EHR systems	Section 1 **Scope and** general provisions for EHR systems	
	Article 13A				
263a				**Article 13A**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				EHR harmonised components	
	Article 13a(1)				
263b				**1. EHR systems shall include a 'European interoperability component for EHR systems' and a 'European logging component for EHR systems' (the 'harmonised components'), in accordance with the provisions laid down in this Chapter.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 14(1)]	
	Article 13a(2)				
263c				**2. This Chapter shall not apply to general purpose software used in a healthcare environment.** [MOVED FROM ARTICLE 14(2)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 13B				
263d				**Article 13B** **Placing on the market and putting into service** [MOVED FROM ARTICLE 15]	
	Article 13b(1)				
263e				**1. EHR systems as referred to in Article 13A(1) may be placed on**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the market or put into service only if they comply with the provisions laid down in this Chapter. [MOVED FROM ARTICLE 15(1)]	
	Article 13b(2)				
263f				**2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				meaning of Article 1(1), point (b), of Directive (EU) 2015/1535 of the European Parliament and of the Council[1] to a natural or legal person established in the Union shall be considered as having been put into service. _____ **1. [1] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 15(2)]	
	Article 13b(3)				
263g				**3. Member States may not, for considerations relating to aspects concerning the harmonised components regulated by this Regulation, prohibit or restrict the placing on the market of EHR systems which comply with this**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Regulation.	
	Article 14				
264	Article 14 Interplay with legislation governing medical devices and AI systems		Article 14 Interplay with legislation governing medical devices and AI systems	Article 14 Interplay with legislation governing medical devices**, in vitro diagnostic medical devices** and AI systems	
	Article 14(1)				
265	1. EHR systems intended by their manufacturer for		1. EHR systems intended by their manufacturer for	~~1. EHR systems intended by their manufacturer for~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter.		primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter.	~~primary use of priority categories of electronic health data referred to in Article 5 shall be subject to the provisions laid down in this Chapter.~~ [MOVED TO THE NEW ARTICLE 13A(1)]	
		Article 14(2)			
266	2. This Chapter shall not apply to general software used in a healthcare environment.		2. This Chapter shall not apply to general software used in a healthcare environment ***that it is not***	~~2. This Chapter shall not apply to general software used in a healthcare environment.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			interoperable with EHR systems.	[MOVED TO THE NEW ARTICLE 13A(2)]	
	Article 14(3)				
267	3. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of		3. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 that claim interoperability of those medical devices with EHR systems shall prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of	~~3~~**1**. Manufacturers of medical devices as defined in Article 2(1) of Regulation (EU) 2017/745 **and manufacturers of in vitro diagnostic medical devices as defined in Article 2(2) of Regulation (EU) 2017/746** that claim interoperability of those medical devices with **the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.		this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.	**harmonised components of** EHR systems shall prove compliance with the essential requirements on **the European** interoperability **component for EHR systems and the European logging component for EHR systems,** laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those medical devices.	
	Article 14(4)				
268					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	4. Providers of high-risk AI systems as defined in Article 6 of Regulation […] [AI act COM/2021/206 final], which does not fall within the scope of Regulation (EU) 2017/745, that claim interoperability of those AI systems with EHR systems will need to prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk AI systems.		4. ***Notwithstanding the obligations laid down in Regulation [AI act COM/2021/206 final],*** providers of high-risk AI systems as defined in Article 6 of Regulation […] [AI act COM/2021/206 final], which ~~*does*~~***do*** not fall within the scope of Regulation (EU) 2017/745, that claim interoperability of those AI systems with EHR systems will need to prove compliance with the essential requirements on interoperability laid down in Section 2 of Annex II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk	**42**. Providers of high-risk AI systems as defined in Article 6 of Regulation […] [AI act COM/2021/206 final], which does not fall within the scope of Regulation (EU) 2017/745, that claim interoperability of those AI systems with **the harmonised components of** EHR systems will need to prove compliance with the essential requirements on **the European** interoperability **component for EHR systems and the European logging component for EHR systems, as further** laid down in Section 2 of Annex	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			AI systems.	II of this Regulation. Article 23 of this Chapter shall be applicable to those high-risk AI systems.	
	Article 14(5)				
269	5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.		5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.	~~5. Member States may maintain or define specific rules for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services.~~ [MOVED TO A NEW	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				ARTICLE 16A]	
	Article 15				
270	Article 15 Placing on the market and putting into service		Article 15 Placing on the market and putting into service	~~Article 15~~ ~~Placing on the market and putting into service~~ [MOVED TO ARTICLE 13B(1)]	
	Article 15(1)				
271					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in this Chapter.		1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in ***Section 3 of*** this Chapter ***and in Annex II***.	~~1. EHR systems may be placed on the market or put into service only if they comply with the provisions laid down in this Chapter.~~	
		Article 15(2)			
272	2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the meaning of Article 1(1), point (b), of Directive (EU)		2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the meaning of Article 1(1), point (b), of Directive (EU) 2015/1535	~~2. EHR systems that are manufactured and used within health institutions established in the Union and EHR systems offered as a service within the meaning of Article 1(1), point (b), of Directive (EU) 2015/1535~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2015/1535 of the European Parliament and of the Council[1] to a natural or legal person established in the Union shall be considered as having been put into service. _____ 1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).		of the European Parliament and of the Council[1] to a natural or legal person established in the Union shall be considered as having been put into service. _____ 1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).	~~of the European Parliament and of the Council[1] to a natural or legal person established in the Union shall be considered as having been put into service.~~ _____ ~~1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).~~ [MOVED TO ARTICLE 13B(2)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 16				
273	Article 16 Claims		Article 16 Claims	Article 16 Claims	
	Article 16, first paragraph				
274	In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be		In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be	In the information sheet, instructions for use or other information accompanying EHR systems, and in the advertising of EHR systems, it shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user with regard to its intended purpose, interoperability and security by:		prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the ***professional user as defined under Regulation (EU) 2018/1807*** ~~*user*~~ with regard to its intended purpose, interoperability and security by:	prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user with regard to its intended purpose, interoperability and security by:	
	Article 16, first paragraph, point (a)				
275	(a) ascribing functions and properties to the EHR system which it does not have;		(a) ascribing functions and properties to the EHR system which it does not have;	(a) ascribing functions and properties to the EHR system which it does not have;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 16, first paragraph, point (b)				
276	(b) failing to inform the user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose;		(b) failing to inform the ***professional*** user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose;	(b) failing to inform the user of likely limitations related to interoperability or security features of the EHR system in relation to its intended purpose;	
	Article 16, first paragraph, point (c)				
277	(c) suggesting uses for the EHR system other than		(c) suggesting uses for the EHR system other than	(c) suggesting uses for the EHR system other than	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	those stated in the technical documentation to form part of the intended purpose.		those stated in the technical documentation to form part of the intended purpose.	those stated in the technical documentation to form part of the intended purpose.	
	Article 16A				
277a				**Article 16A** **Procurement, reimbursement and financing of EHR systems**	
	Article 16a, first paragraph				
277b				**Member States may**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				maintain or define requirements for the procurement, reimbursement or financing of EHR systems in the context of the organisation, delivery or financing of healthcare services provided that such requirements are compliant with Union law and do not affect the harmonised components. [MOVED FROM ARTICLE 14(5)]	
	Section 2				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
278	Section 2 Obligations of economic operators with regard to EHR systems		Section 2 Obligations of economic operators with regard to EHR systems	Section 2 Obligations of economic operators with regard to EHR systems	
	Article 17				
279	Article 17 Obligations of manufacturers of EHR systems		Article 17 Obligations of manufacturers of EHR systems	Article 17 Obligations of manufacturers of EHR systems	
	Article 17(1)				
280					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. Manufacturers of EHR systems shall:		1. Manufacturers of EHR systems shall:	1. Manufacturers of EHR systems shall **with regard to the harmonised components referred to in Article 13A(1)**:	
	Article 17(1), point (a)				
281	(a) ensure that their EHR systems are in conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 23;		(a) ~~*ensure that*~~***obtain for*** their EHR systems ~~*are in*~~***a certificate of compliance from an independent third-party body to attest their*** conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article	(a) ensure that **these harmonised components of** their EHR systems are in conformity with the essential requirements laid down in Annex II and with the common specifications in accordance with Article 23;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			23;		
	Article 17(1), point (ab)				
281a				**(ab) ensure that these components of their EHR systems are not impeded or negatively affected by other components of the same EHR system;**	
	Article 17(1), point (b)				
282	(b) draw up the technical documentation of their		(b) draw up the technical documentation of their EHR	(b) draw up the technical documentation of their EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	EHR systems in accordance with Article 24;		systems in accordance with Article 24 ***before placing their systems on the market, and subsequently keep them up to date***;	systems **for these harmonised components** in accordance with Article 24;	
		Article 17(1), point (c)			
283	(c) ensure that their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use;		(c) ensure that their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use ***including in accessible formats for vulnerable groups and persons with***	(c) ensure that **these harmonised components of** their EHR systems are accompanied, free of charge for the user, by the information sheet provided for in Article 25 and clear and complete instructions for use;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			disabilities;		
	Article 17(1), point (d)				
284	(d) draw up an EU declaration of conformity as referred to in Article 26;		(d) ~~*draw up an EU declaration of conformity*~~***carry out the relevant conformity assessment procedures*** as referred to in Article ~~*26*~~***27a and Annex IVa***;	(d) draw up an EU declaration of conformity as referred to in Article 26;	
	Article 17(1), point (da)				
284a			***(da) draw up the EU***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			declaration of conformity in accordance with Article 26;		
	Article 17(1), point (e)				
285	(e) affix the CE marking in accordance with Article 27;		(e) affix the CE marking in accordance with Article 27 ***after the conformity assessment procedure has been completed***;	(e) affix the CE marking **for those harmonised components** in accordance with Article 27;	
	Article 17(1), point (ea)				
285a			***(ea) indicate the name,***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			registered trade name or registered trade mark, and the postal address and website, e-mail address or other digital contact at which they can be contacted, on the front office of the EHR system; the address shall indicate a single point at which the manufacturer can be contacted and. the contact details shall be in a language that is easily understood by users and market surveillance authorities;		
	Article 17(1), point (f)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
286	(f) comply with the registration obligations in Article 32;		(f) comply with the registration obligations in Article 32;	(f) comply with the registration obligations **for these harmonised components** in Article 32;	
	Article 17(1), point (g)				
287	(g) take without undue delay any necessary corrective action in respect of their EHR systems which are not in conformity with the essential requirements laid down in Annex II, or recall or withdraw such systems;		(g) take ~~*without undue delay*~~ any necessary corrective action in respect of their EHR systems ~~*which*~~***immediately, where manufacturers consider or have reasons to believe that such systems*** are not ***or no longer*** in conformity with	(g) take without undue delay any necessary corrective action in respect of **these harmonised components of** their EHR systems which are not in conformity with the essential requirements laid down in Annex II, or recall	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the essential requirements laid down in Annex II, or recall or withdraw such systems; ***the manufacturers shall then inform the national authorities of the Member States in which they made their EHR systems available or put them into service of the non-conformity and of any corrective action taken;***	or withdraw such systems;	
		Article 17(1), point (h)			
288	(h) inform the distributors of their EHR systems and, where applicable, the		(h) ***immediately*** inform the distributors of their EHR systems and, where	(h) inform the distributors of their EHR systems and, where applicable, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	authorised representative and importers of any corrective action, recall or withdrawal;		applicable, the authorised representative and importers of ***the non-conformity and of*** any corrective action, recall or withdrawal ***of that system***;	authorised representative**, importers and the users** ~~and importers~~ of any **mandatory preventive maintenance and its frequency,** corrective action, recall or withdrawal **in relation to these harmonised components**;	
	Article 17(1), point (i)				
289	(i) inform the market surveillance authorities of the Member States in which they made their EHR systems available or put them into service of the		*deleted*	(i) inform the market surveillance authorities of the Member States in which they made their EHR systems available or put them into service of the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	non-conformity and of any corrective action taken;			non-conformity and of any corrective action taken**, including the timetable for implementation, when those harmonised components of their EHR system have been brought into conformity and been recalled or withdrawn**;	
		Article 17(1), point (j)			
290	(j) upon request of a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity		(j) upon request ~~of~~ ~~a~~***provide*** market surveillance ~~authority, provide it~~***authorities in the Member States*** with all the information and	(j) upon request of a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of their EHR system with the essential requirements laid down in Annex II.		documentation ***in paper or digital format,*** necessary to demonstrate the conformity of ~~their~~***the*** EHR system ***which they have placed on the market or put into service*** with the essential requirements laid down in Annex II ***and Article 27a in the official language of the Member State***.	of **these harmonised components of** their EHR system with the essential requirements laid down in Annex II.	
		Article 17(1), point (k)			
291	(k) cooperate with market surveillance authorities, at their request, on any action taken to bring their EHR		(k) cooperate with market surveillance authorities, at their request, on any action taken to bring their EHR	(k) cooperate with market surveillance authorities, at their request, on any action taken to bring **these**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	systems in conformity with the essential requirements laid down in Annex II.		systems ***which they have placed on the market or put into service*** in conformity with the essential requirements laid down in Annex II ***and Article 27a in the official language of the Member State***.	**harmonised components of** their EHR systems in conformity with the essential requirements laid down in Annex II.	
	Article 17(1), point (ka)				
291a			***(ka) establish channels of complaint and keep a register of complaints, of non-conforming EHR systems, and keep distributors informed of any such monitoring.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 17(2)			
292	2. Manufacturers of EHR systems shall ensure that procedures are in place to ensure that the design, development and deployment of an EHR system continues to comply with the essential requirements laid down in Annex II and the common specifications referred to in Article 23. Changes in EHR system design or characteristics shall be adequately taken into		2. Manufacturers of EHR systems shall ensure that procedures are in place to ensure that the design, development and deployment of an EHR system continues to comply with the essential requirements laid down in Annex II and the common specifications referred to in Article 23 ***for EHR systems to remain in conformity with this Regulation***. Changes in EHR system	2. Manufacturers of EHR systems shall ensure that procedures are in place to ensure that the design, development and deployment of **the components of** an EHR system **defined in Article 2(2)(nc)-(nd)** continues to comply with the essential requirements laid down in Annex II and the common specifications referred to in Article 23.~~.~~ Changes in EHR system design or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	account and reflected in the technical documentation.		design or characteristics ***and changes in the technical standards and the technical specifications referred to in Annex II and III by reference to which the conformity of the EHR system is declared*** shall be adequately taken into account and reflected in the technical documentation. ***Manufacturers shall establish reporting channels and ensure their accessibility to allow users to submit complaints, and shall keep a register of complaints, of non-conforming EHR systems***	characteristics **with regard to these harmonised components** shall be adequately taken into account and reflected in the technical documentation.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and EHR system recalls.		
	Article 17(3)				
293	3. Manufacturers of EHR systems shall keep the technical documentation and the EU declaration of conformity for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market.		3. Manufacturers of EHR systems shall keep the technical documentation and the EU declaration of conformity ***at the disposal of the market surveillance authorities for at least*** ~~*for*~~ 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market. ***The source code or the programming logic included in the technical***	3. Manufacturers of EHR systems shall keep the technical documentation and the EU declaration of conformity for 10 years after the last **components of the** EHR system **defined in Article 2(2)(nc)-(nd)** covered by the EU declaration of conformity ~~has~~**have** been placed on the market.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			documentation shall, upon a reasoned request, be made available to the competent national authorities, if that source code or programming logic is necessary in order for them to be able to check compliance with the essential requirements set out in Annex II. The personnel of competent national authorities shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment activities in accordance with Annexes IVa, except in relation to the competent authorities		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of the Member State in which their activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected. Manufacturers shall establish reporting channels and ensure their accessibility to allow users to submit complaints, keep a register of complaints, of non-conforming EHR systems and EHR systems recalls.		
	Article 17(3a)				
293a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			3a. A manufacturer of EHR systems established outside the Union shall ensure that its authorised representative has the necessary documentation readily available in order to fulfil the tasks referred to in Article 18(2).		
	Article 17(3b)				
293b			***3b. Manufacturers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			documentation, in paper or electronic form, necessary to demonstrate the conformity of the EHR system with the essential requirements set out in Annex II and the common specifications referred to in Article 23, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks posed by the EHR system, which they have placed on the market or put into service.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 17(3c)				
293c			***3c. Liability rules under Directive 85/374/EEC, shall apply to manufacturers of EHR systems without prejudice to more protective measures under national law.***		
	Article 18				
294	Article 18 Authorised representatives		Article 18 Authorised representatives	Article 18 Authorised representatives	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 18(1)				
295	1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.		1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	1. Prior to making an EHR system available on the Union market, a manufacturer of an EHR system established outside of the Union shall, by written mandate, appoint an authorised representative which is established in the Union.	
	Article 18(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
296	2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:		2. An authorised representative shall perform the tasks specified in the mandate ~~*received from*~~***agreed with*** the manufacturer. The mandate shall allow the authorised representative to do at least the following:	2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:	
		Article 18(2), point (a)			
297	(a) keep the EU declaration of conformity and the technical documentation at the disposal of market		(a) keep the EU declaration of conformity and the technical documentation at the disposal of ***the Member***	(a) keep the EU declaration of conformity and the technical documentation at the disposal of market	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	surveillance authorities for the period referred to in Article 17(3);		***State*** market surveillance authorities for the period referred to in Article 17(3);	surveillance authorities for the period referred to in Article 17(3);	
		Article 18(2), point (b)			
298	(b) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EHR system with the essential requirements laid down in Annex II;		(b) further to a reasoned request from a market surveillance ~~*authority, provide that authority*~~***provide authorities of the Member States concerned a copy of the mandate*** with all the information and documentation necessary to demonstrate the conformity of an EHR system with the	(b) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EHR system with ~~the~~ essential requirements laid down in Annex II **as well as the common specifications in accordance with Article**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			essential requirements laid down in Annex II;	**23**;	
	Article 18(2), point (ba)				
298a			***(ba) immediately inform the manufacturer if the authorised representative has a reason to believe that an EHR system is no longer in conformity with the essential requirements laid down in Annex II;***		
	Article 18(2), point (bb)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
298b			***(bb) immediately inform the manufacturer about complaints received by consumers and professional users;***		
	Article 18(2), point (c)				
299	(c) cooperate with the market surveillance authorities, at their request, on any corrective action taken in relation to the EHR systems covered by their mandate.		(c) cooperate with the market surveillance authorities ***in the Member State***, at their request, on any corrective action taken in relation to the EHR systems covered by their mandate.	(c) cooperate with the market surveillance authorities, at their request, on any corrective action taken in relation to the **components of the** EHR systems **defined in Article 2(2)(nc)-(nd)** covered by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				their mandate.	
	Article 18(2), point (d)				
299a				**(d) terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation.**	
	Article 18(2), point (e)				
299b				**(e) ensure that the technical documentation can be made available to**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				those authorities, upon request. [[MOVED FROM ARTICLE 19(6)]]	
	Article 18(2a)				
299c			***2a. In the event of a change of the authorised representative, the detailed arrangements for the change shall address at least the following aspects:*** ***(a) the date of termination of the mandate of the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			outgoing authorised representative and the date of the beginning of the mandate of the incoming authorised representative;(b) the transfer of documents, including confidentiality aspects and property rights.		
	Article 19				
300	Article 19 Obligations of importers		Article 19 Obligations of importers	Article 19 Obligations of importers	
	Article 19(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
301	1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements laid down in Annex II.		1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements laid down in Annex II.	1. Importers shall place on the Union market only EHR systems which are in conformity with the essential requirements **in relation to the harmonised components of EHR systems as** laid down in Annex II **as well as the common specifications in accordance with Article 23**.	
		Article 19(2)			
302	2. Before making an EHR		2. Before making an EHR	2. Before making an EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	system available on the market, importers shall ensure that:		system available on the market, importers shall ensure that:	system available on the market, importers shall ensure that:	
		Article 19(2), point (a)			
303	(a) the manufacturer has drawn up the technical documentation and the EU declaration of conformity;		(a) the manufacturer has ~~*drawn up the technical documentation and*~~ ***obtained a certificate of compliance from an independent third body to attest to the relevant conformity assessment procedure referred to in Article 27a and drawn up*** the EU declaration of conformity ***in accordance***	(a) the manufacturer has drawn up the technical documentation and the EU declaration of conformity;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			with Article 26; and drawn up the technical documentation, in accordance with Article 24, before placing their system on the market;		
	Article 19(2), point (aa)				
303a			***(aa) the manufacturer is identified and an authorised representative in accordance with Article 18 has been appointed;***		
	Article 19(2), point (b)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
304	(b) the EHR system bears the CE marking of conformity;		(b) the EHR system bears the CE marking of conformity ***referred to in Article 27 after the conformity assessment procedure has been completed***;	(b) the EHR system bears the CE marking of conformity;	
	Article 19(2), point (c)				
305	(c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use.		(c) the EHR system is accompanied by the information sheet referred to in Article 25 ***with clear and complete*** ~~*and appropriate*~~ instructions for	(c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use**, including**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			use ***including in accessible formats***.	**maintenance actions**.	
	Article 19(3)				
306	3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted in a document accompanying the EHR system.		3. Importers shall indicate their name, registered trade name or registered trade mark and the ***postal*** address ***and website, e-mail address or other digital contact*** at which they can be contacted in a document accompanying the EHR system. ***The address shall indicate a single point at which the manufacturer can be contacted. The***	3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted in a document accompanying the EHR system.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			contact details shall be in a language easily understood by users and the market surveillance authorities. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.		
		Article 19(4)			
307	4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the		4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the	4. Importers shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	essential requirements laid down in Annex II is jeopardised.		essential requirements laid down in Annex II ***and Article 27a*** is jeopardised.	essential requirements laid down in Annex II is jeopardised.	
	Article 19(5)				
308	5. Where an importer considers or has reason to believe that an EHR system is not in conformity with the essential requirements in Annex II, it shall not make that system available on the market until that system has been brought into conformity. The importer shall inform without undue delay the		5. Where an importer considers or has reason to believe that an EHR system is not ***or no longer*** in conformity with the essential requirements in Annex II ***and Article 27a***, it shall not make that system available on the market***, or shall recall it or withdraw it if was already available on the market,*** until that	5. Where an importer considers or has reason to believe that an EHR system is not in conformity with the essential requirements in Annex II, it shall not make that system available on the market until that system has been brought into conformity. The importer shall inform without undue delay the manufacturer of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	manufacturer of such EHR system and the market surveillance authorities of the Member State in which it made the EHR system available, to that effect.		system has been brought into conformity. The importer shall inform ~~*without undue delay*~~***immediately*** the manufacturer of such EHR system and the market surveillance authorities of the Member State in which it made the EHR system available, to that effect***, giving details, in particular, of the non-conformity and of any corrective measures, recall or withdrawal of that system taken. Where an importer considers or has reason to believe that an EHR system presents a risk to the health or safety of***	such EHR system**, the users** and the market surveillance authorities of the Member State in which it made the EHR system available **on the market where this situation occurs**, to that effect.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural persons, it shall immediately inform the market surveillance authority of the Member State in which the importer is established, as well as the manufacturer and where applicable, the authorised representative.		
	Article 19(6)				
309	6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in		6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in	6. Importers shall keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities for the period referred to in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 17(3) and ensure that the technical documentation can be made available to those authorities, upon request.		Article 17(3) and ensure that the technical documentation can be made available to those authorities, upon request.	Article 17(3) ~~and ensure that the technical documentation can be made available to those authorities, upon request~~. [[MOVED TO ARTICLE 18(2)(e)]]	
		Article 19(7)			
310	7. Importers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and		7. Importers shall, further to a reasoned request from a market surveillance ~~authority~~ ***authorities of Member States concerned***	7. Importers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	documentation necessary to demonstrate the conformity of an EHR system in the official language of the Member State where the market surveillance authority is located. They shall cooperate with that authority, at its request, on any action taken to bring their EHR systems in conformity with the essential requirements laid down in Annex II.		provide it with all the information and documentation ***in paper or digital format*** necessary to demonstrate the conformity of an EHR system***. They shall cooperate with that authority, at its request, and with the manufacturer and, where applicable, with the manufacturer's authorised representative*** ~~*in the official language of the Member State where the market surveillance authority is located. They shall cooperate with that authority, at its request,*~~ on any action taken to bring their EHR systems in conformity with the	documentation necessary to demonstrate the conformity of **harmonised components of** an EHR system in the official language of the Member State where the market surveillance authority is located. They shall cooperate with that authority, at its request, on any action taken to bring their EHR systems in conformity with the essential requirements **in relation to those components as** laid down in Annex II.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			essential requirements laid down in Annex II***, and Article 27a, or to ensure that their EHR systems are withdrawn or recalled***.		
		Article 19(7a)			
310a			***7a. Manufacturers shall establish reporting channels and ensure their accessibility to allow users to submit complaints, keep a register of complaints, of non-conforming EHR systems and EHR systems recalls. Importers shall verify whether the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			established channels of complaint referred to in Article 17(2) are publicly available allowing them to submit complaints and communicate any risk related to their health and safety or to other aspects of public interest protection and of any serious incident involving an EHR system. If such channels are not available, the importer shall provide for them, taking into account the accessibility needs of vulnerable groups and persons with disabilities.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 19(7b)				
310b			***7b. Importers shall investigate complaints and information on incidents involving an EHR system they made available on the market and file those complaints, as well as of system recalls and any corrective measures taken to bring the EHR system into conformity, in the register referred to in Article 17(3d) or in their own internal register. Importers shall keep the manufacturer, distributors and, where relevant,***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			authorised representatives informed in a timely manner of the investigation performed and of the results of the investigation.		
	Article 20				
311	Article 20 Obligations of distributors		Article 20 Obligations of distributors	Article 20 Obligations of distributors	
	Article 20(1)				
312	1. Before making an EHR		1. Before making an EHR	1. Before making an EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	system available on the market, distributors shall verify that:		system available on the market, distributors shall verify that:	system available on the market, distributors shall verify that~~:~~ **with regard to the harmonised components of EHR systems**	
		Article 20(1), point (a)			
313	(a) the manufacturer has drawn up the EU declaration of conformity;		(a) the manufacturer has ***obtained a certificate of compliance from an independent third body to attest to the relevant conformity assessment procedure referred to in Article 27a and has*** drawn up the EU declaration of	(a) the manufacturer has drawn up the EU declaration of conformity;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			conformity***, in accordance with Article 26, and the technical documentation, in accordance with Article 24, before placing their system on the market***;		
		Article 20(1), point (b)			
314	(b) the EHR system bears the CE marking of conformity;		(b) the EHR system bears the CE marking of conformity ***referred to in Article 27 after the conformity assessment procedure has been completed***;	(b) the EHR system bears the CE marking of conformity;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 20(1), point (c)				
315	(c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use;		(c) the EHR system is accompanied by the information sheet referred to in Article 25 ***with clear and complete*** ~~*and appropriate*~~ instructions for use ***in accessible formats***;	(c) the EHR system is accompanied by the information sheet referred to in Article 25 and appropriate instructions for use;	
	Article 20(1), point (d)				
316	(d) where applicable, the importer has complied with the requirements set out in Article 19(3).		(d) where applicable, the importer has complied with the requirements set out in Article 19(3).	(d) where applicable, the importer has complied with the requirements set out in Article 19(3).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 20(2)				
317	2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements laid down in Annex II is jeopardised.		2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements laid down in Annex II ***and Article 27a*** is jeopardised.	2. Distributors shall ensure that, while an EHR system is under their responsibility, the EHR system is not altered in such a way that its conformity with the essential requirements **with regards to the EHR harmonised components** laid down in Annex II is jeopardised.	
	Article 20(3)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
318	3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II, it shall not make the EHR system available on the market until it has been brought into conformity. Furthermore, the distributor shall inform without undue delay the manufacturer or the importer, as well as the market surveillance authorities of the Member states where the EHR system has been made available on the market, to		3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II ***and Article 27a***, it shall not make the EHR system available on the market***, or shall recall it or withdraw it if was already available on the market,*** until it has been brought into conformity. Furthermore, the distributor shall inform ~~*without undue delay*~~***immediately*** the manufacturer or the importer, as well as the	3. Where a distributor considers or has reason to believe that an EHR system is not in conformity with the essential requirements laid down in Annex II, it shall not make the EHR system available on the market until it has been brought into conformity **with the harmonised components of EHR systems**. Furthermore, the distributor shall inform without undue delay the manufacturer or the importer **and the users**, as well as the market surveillance authorities of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	that effect.		market surveillance authorities of the Member states where the EHR system has been made available on the market, to that effect. ***Where a distributor considers or has reason to believe that an EHR system presents a risk to the health or safety of natural persons, it shall immediately inform the market surveillance authority of the Member State in which the distributor is established, as well as the manufacturer, the importer and where applicable, the authorised representative.***	the Member states where the EHR system has been made available on the market, to that effect.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 20(4)				
319	4. Distributors shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EHR system. They shall cooperate with that authority, at its request, on any action taken to bring their EHR systems in conformity with the essential requirements laid		4. Distributors shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EHR system. They shall cooperate with that authority, at its request, ***and with the manufacturer, the importer and, where applicable, with the manufacturer's authorised representative*** on any action	4. Distributors shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation necessary to demonstrate the conformity of an EHR system **with regard to the harmonised components of EHR systems**. They shall cooperate with that authority, at its request, on any action taken to bring their EHR systems in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	down in Annex II.		taken to bring ~~*their*~~***the*** EHR systems in conformity with the essential requirements laid down in Annex II ***or to withdraw or recall it***.	conformity with the essential requirements laid down in Annex II **in relation to those two components**.	
		Article 21			
320	Article 21 Cases in which obligations of manufacturers of an EHR system apply to importers and distributors		Article 21 Cases in which obligations of manufacturers of an EHR system apply to ~~*importers and distributors*~~ ***economic operators***	Article 21 Cases in which obligations of manufacturers of an EHR system apply to importers and distributors	
		Article 21, first paragraph			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
321	An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations laid down in Article 17, where they made an EHR system available on the market under their own name or trademark or modify an EHR system already placed on the market in such a way that conformity with the applicable requirements may be affected.		~~*An importer or distributor shall be considered a manufacturer*~~***If any economic operator other than the manufacturer makes modifications to the EHR system whilst deploying or using it, which lead to changes in the intended purpose and deployment recommendations*** for the ~~*purposes of this Regulation and shall be subject*~~***EHR system as declared by the manufacturer, in any case of any malfunctioning or deterioration in performance quality due*** to	An importer or **a** distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations laid down in Article 17, where they made an EHR system available on the market under their own name or trademark or modify an EHR system already placed on the market in such a way that conformity with the applicable requirements may be affected.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the ~~*obligations laid down in Article 17, where they made an*~~***changes made by the economic operator during deployment or use of the*** EHR system ~~*available on the market under their own name or trademark or modify an EHR system already placed on the market in such a way that conformity with the applicable requirements may be affected*~~***contrary to the manufacturer's recommendations for technical deployment of the system or purpose of its use, the economic operator shall be considered a manufacturer for the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			purposes of this Regulation and shall be subject to the obligations laid down in Article 17.		
	Article 22				
322	Article 22 Identification of economic operators		Article 22 Identification of economic operators	Article 22 Identification of economic operators	
	Article 22, first paragraph				
323	Economic operators shall,		Economic operators shall,	Economic operators shall,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:		on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:	on request, identify the following to the market surveillance authorities, for 10 years after the last EHR system covered by the EU declaration of conformity has been placed on the market:	
	Article 22, first paragraph, point (a)				
324	(a) any economic operator who has supplied them with an EHR system;		(a) any economic operator who has supplied them with an EHR system;	(a) any economic operator who has supplied them with an EHR system;	
	Article 22, first paragraph, point (b)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
325	(b) any economic operator to whom they have supplied an EHR system.		(b) any economic operator to whom they have supplied an EHR system.	(b) any economic operator to whom they have supplied an EHR system.	
	Section 3				
326	Section 3 Conformity of the EHR system		Section 3 Conformity ~~of the EHR system~~***Assessment***	Section 3 Conformity of the EHR system	
	Article 23				
327	Article 23		Article 23	Article 23	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Common specifications		Common specifications	Common specifications	
	Article 23(1), first subparagraph				
328	1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities of medical devices and high risk AI		1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a ***common template document and a*** time limit for implementing those common specifications. Where relevant, the common specifications shall take into account the specificities ***and***	1. The Commission shall, by means of implementing acts, adopt common specifications in respect of the essential requirements set out in Annex II, including a time limit for implementing those common specifications. **Those common specifications shall be based on existing harmonised standards for the harmonised**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	systems referred to in paragraphs 3 and 4 of Article 14.		***verify compatibility with sectoral legislation and harmonised standards*** of medical devices and high risk AI systems referred to in paragraphs 3 and 4 of Article 14***, including the state-of-the art standards for health informatics and the European electronic health record exchange format***.	**components of EHR systems, where applicable.** Where relevant, the common specifications shall take into account the specificities **and verify compatibility with sectorial legislation and harmonised standards** of medical devices and high risk AI systems referred to in paragraphs ~~3 and 4~~**1 and 2** of Article 14**, including the state-of-the-art standards for health informatics and the European electronic health record exchange format**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 23(1), second subparagraph				
329	Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2) ***after consultation with the EHDS board and the Advisory Forum***.	Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	
	Article 23(2)				
330	2. The common specifications referred to in paragraph 1 shall include		2. The common specifications referred to in paragraph 1 shall include	2. The common specifications referred to in paragraph 1 shall include	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the following elements:		the following elements:	the following elements:	
	Article 23(2), point (a)				
331	(a) scope;		(a) scope;	(a) scope;	
	Article 23(2), point (b)				
332	(b) applicability to different categories of EHR systems or functions included in them;		(b) applicability to different categories of EHR systems or functions included in them;	(b) applicability to different categories of EHR systems or functions included in them;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 23(2), point (c)				
333	(c) version;		(c) version;	(c) version;	
	Article 23(2), point (d)				
334	(d) validity period;		(d) validity period;	(d) validity period;	
	Article 23(2), point (e)				
335	(e) normative part;		(e) normative part;	(e) normative part;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 23(2), point (f)				
336	(f) explanatory part, including any relevant implementation guidelines.		(f) explanatory part, including any relevant implementation guidelines.	(f) explanatory part, including any relevant implementation guidelines.	
	Article 23(3)				
337	3. The common specifications may include elements related to the following:		3. The common specifications may include elements related to the following:	3. The common specifications may include elements related to the following:	
	Article 23(3), point (a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
338	(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;		(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;	(a) datasets containing electronic health data and defining structures, such as data fields and data groups for the representation of clinical content and other parts of the electronic health data;	
	Article 23(3), point (b)				
339	(b) coding systems and values to be used in datasets containing electronic health data;		(b) coding systems and values to be used in datasets containing electronic health data;	(b) coding systems and values to be used in datasets containing electronic health data**, taking due account of both the future**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				harmonisation of terminologies and their compatibility with existing national terminologies;	
	Article 23(3), point (c)				
340	(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;		(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;	(c) other requirements related to data quality, such as the completeness and accuracy of electronic health data;	
	Article 23(3), point (d)				
341					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(d) technical specifications, standards and profiles for the exchange of electronic health data;		(d) technical specifications, standards and profiles for the exchange of electronic health data;	(d) technical specifications, standards and profiles for the exchange of electronic health data;	
	Article 23(3), point (e)				
342	(e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;		(e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;	(e) requirements and principles related to security, confidentiality, integrity, patient safety and protection of electronic health data;	
	Article 23(3), point (f)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
343	(f) specifications and requirements related to identification management and the use of electronic identification.		(f) specifications and requirements related to identification management and the use of electronic identification.	(f) specifications and requirements related to identification management and the use of electronic identification.	
	Article 23(4)				
344	4. EHR systems, medical devices and high risk AI systems referred to in Article 14 that are in conformity with the common specifications referred to in paragraph 1 shall be considered to be in		4. EHR systems, medical devices and high risk AI systems referred to in Article 14 that are in conformity with the common specifications referred to in paragraph 1 shall be considered to be in	4. EHR systems, medical devices**, in vitro diagnostic medical devices** and high risk AI systems referred to in ~~Article~~**Articles 13A and** 14 that are in conformity with the common specifications referred to in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.		conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.	paragraph 1 shall be considered to be in conformity with the essential requirements covered by those specifications or parts thereof, set out in Annex II covered by those common specifications or the relevant parts of those common specifications.	
		Article 23(4a)			
344a			***4a. Where common specifications have an impact on data protection requirements for EHR***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			systems, they shall be subject to consultation with the European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) before their adoption, pursuant to Article 42(2) of Regulation (EU) 2018/1725.		
	Article 23(5)				
345	5. Where common specifications covering interoperability and security requirements of EHR systems affect medical		5. Where common specifications covering interoperability and security requirements of EHR systems affect medical	5. Where common specifications covering interoperability and security requirements of EHR systems affect medical	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	devices or high-risk AI systems falling under other acts, such as Regulations (EU) 2017/745 or […] [AI Act COM/2021/206 final], the adoption of those common specifications may be preceded by a consultation with the Medical Devices Coordination Group (MDCG) referred to in Article 103 of Regulation (EU) 2017/745 or the European Artificial Intelligence Board referred to in Article 56 of Regulation […] [AI Act COM/2021/206 final], as applicable.		devices or high-risk AI systems falling under other acts, such as Regulations (EU) 2017/745 or […] [AI Act COM/2021/206 final], the adoption of those common specifications ~~may~~***shall*** be preceded by a consultation with the Medical Devices Coordination Group (MDCG) referred to in Article 103 of Regulation (EU) 2017/745 or the European Artificial Intelligence Board referred to in Article 56 of Regulation […] [AI Act COM/2021/206 final], as applicable***, as well as the EDPB referred to in Article***	devices**, in vitro diagnostic medical devices** or high-risk AI systems falling under other acts, such as Regulations (EU) 2017/745 **and (EU) 2017/746** or […] [AI Act COM/2021/206 final], the **Commission shall ensure that the** adoption of those common specifications **shall have been** ~~may be~~ preceded by a consultation with the Medical Devices Coordination Group (MDCG) referred to in Article 103 of Regulation (EU) 2017/745 or the European Artificial Intelligence Board referred to in Article 56 of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			68 of Regulation (EU) 2016/679.	Regulation […] [AI Act COM/2021/206 final], as applicable.	
	Article 23(6)				
346	6. Where common specifications covering interoperability and security requirements of medical devices or high-risk AI systems falling under other acts such as Regulation (EU) 2017/745 or Regulation […] [AI Act COM/2021/206 final], impact EHR systems, the adoption of those common		6. Where common specifications covering interoperability and security requirements of medical devices or high-risk AI systems falling under other acts such as Regulation (EU) 2017/745 or Regulation […] [AI Act COM/2021/206 final], impact EHR systems, the adoption of those common	6. Where common specifications covering interoperability and security requirements of medical devices**, in vitro diagnostic medical devices** or high-risk AI systems falling under other acts such as ~~Regulation~~**Regulations** (EU) 2017/745 **and (EU) 2017/746** or Regulation […] [AI Act	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	specifications shall be preceded by a consultation with the EHDS Board, especially its subgroup for Chapters II and III of this Regulation.		specifications shall be preceded by a consultation with the EHDS Board, especially its subgroup for Chapters II and III of this Regulation***, and, where applicable, the EDPB referred to in Article 68 of Regulation (EU) 2016/679***.	COM/2021/206 final], impact EHR systems, the **Commission shall ensure that the** adoption of those common specifications shall ~~be~~**have been** preceded by a consultation with the EHDS Board~~, especially its subgroup for Chapters II and III of this Regulation~~.	
	Article 24				
347	Article 24 Technical documentation		Article 24 Technical documentation	Article 24 Technical documentation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 24(1)			
348	1. The technical documentation shall be drawn up before the EHR system is placed on the market or put into service and shall be kept up-to-date.		1. ~~*The technical documentation*~~***Manufacturers*** shall ~~*be drawn up*~~***draw up technical documentation*** before the EHR system is placed on the market or put into service and shall be kept up-to-date.	1. The technical documentation shall be drawn up before the EHR system is placed on the market or put into service and shall be kept up-to-date.	
		Article 24(2)			
349	2. The technical documentation shall be		2. The technical documentation shall be	2. The technical documentation shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	drawn up in such a way as to demonstrate that the EHR system complies with the essential requirements laid down in Annex II and provide market surveillance authorities with all the necessary information to assess the conformity of the EHR system with those requirements. It shall contain, at a minimum, the elements set out in Annex III.		drawn up in such a way as to demonstrate that the EHR system complies with the essential requirements laid down in Annex II and provide market surveillance authorities with all the necessary information to assess the conformity of the EHR system with those requirements. It shall contain, at a minimum, the elements set out in Annex III. ***Where the system or any part of it complies with European standards or common specifications, the list of the relevant European standards and common specifications shall also be indicated.***	drawn up in such a way as to demonstrate that the EHR system complies with the essential requirements laid down in Annex II and provide market surveillance authorities with all the necessary information to assess the conformity of the EHR system with those requirements. It shall contain, at a minimum, the elements set out in Annex III.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 24(2a)				
349a			***2a. To ensure conformity, a single unified template for technical documentation shall be provided by the Commission.***		
	Article 24(3)				
350	3. The technical documentation shall be drawn up in one of the		3. The technical documentation shall be drawn up in ~~one of~~ the	3. The technical documentation shall be drawn up in one of the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	official languages of the Union. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.		official ~~*languages*~~***language*** of the ~~*Union*~~***Member State concerned***. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.	official languages of the Union. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the official language of that Member State.	
		Article 24(4)			
351	4. When a market surveillance authority requests the technical		4. When a market surveillance authority requests the technical	4. When a market surveillance authority requests the technical	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	documentation or a translation of parts thereof from a manufacturer, it shall set a deadline of 30 days for receipt of such documentation or translation, unless a shorter deadline is justified because of a serious and immediate risk. If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by an independent body at its own expense within a specified period in order to verify the conformity with the essential requirements laid		documentation or a translation of parts thereof from a manufacturer, it shall set a deadline of 30 days for receipt of such documentation or translation, unless a shorter deadline is justified because of a serious and immediate risk. If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by an independent body at its own expense within a specified period in order to verify the conformity with the essential requirements laid	documentation or a translation of parts thereof from a manufacturer, it shall set a deadline of 30 days for receipt of such documentation or translation, unless a shorter deadline is justified because of a serious and immediate risk. If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by an independent body at its own expense within a specified period in order to verify the conformity with the essential requirements laid	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	down in Annex II and the common specifications referred to in Article 23.		down in Annex II and the common specifications referred to in Article 23.	down in Annex II and the common specifications referred to in Article 23.	
	Article 25				
352	Article 25 Information sheet accompanying the EHR system		Article 25 Information sheet accompanying the EHR system	Article 25 Information sheet accompanying the EHR system	
	Article 25(1)				
353	1. EHR systems shall be		1. EHR systems shall be	1. **The harmonised**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.		accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to ***professional*** users.	**components of** EHR systems shall be accompanied by an information sheet that includes concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.	
		Article 25(2)			
354	2. The information sheet referred to in paragraph 1 shall specify:		2. The information sheet referred to in paragraph 1 shall specify:	2. The information sheet referred to in paragraph 1 shall specify:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 25(2), point (a)				
355	(a) the identity, registered trade name or registered trademark, and the contact details of the manufacturer and, where applicable, of its authorised representative;		(a) the identity, registered trade name or registered trademark, and the contact details of the manufacturer ***including the postal and e-mail address and the telephone number*** and, where applicable, of its authorised representative;	(a) the identity, registered trade name or registered trademark, and the contact details of the manufacturer and, where applicable, of its authorised representative;	
	Article 25(2), point (aa)				
355a			***(aa) If the EHR system is not accompanied by the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			information sheet referred to in this Article and by clear and complete instructions for use in accessible formats for persons with disabilities, the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators shall be required to add to the EHR system that information sheet and those instructions for use .		
		Article 25(2), point (b)			
356					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(b) the name and version of the EHR system and date of its release;		(b) the name and version of the EHR system and date of its release;	(b) the name and version of the EHR system and date of its release;	
	Article 25(2), point (c)				
357	(c) its intended purpose;		(c) its intended purpose;	(c) its intended purpose;	
	Article 25(2), point (d)				
358	(d) the categories of electronic health data that the EHR system has been designed to process;		(d) the categories of electronic health data that the EHR system has been designed to process;	(d) the categories of electronic health data that the EHR system has been designed to process;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 25(2), point (e)				
359	(e) the standards, formats and specifications and versions thereof supported by the EHR system.		(e) the standards, formats and specifications and versions thereof supported by the EHR system.	(e) the standards, formats and specifications and versions thereof supported by the EHR system.	
	Article 25(3)				
360	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this		3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation	3. ~~The Commission is empowered to adopt delegated acts in accordance with Article 67 to supplement this Regulation~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation by allowing manufacturers to enter the information referred to in paragraph 2 into the EU database of EHR systems and wellness applications referred to in Article 32, as an alternative to supplying the information sheet referred to in paragraph 1 with the EHR system.		by allowing manufacturers to enter the information referred to in paragraph 2 into the EU database of EHR systems and wellness applications referred to in Article 32, as an alternative to supplying the information sheet referred to in paragraph 1 with the EHR system.	~~by allowing~~**As an alternative to supplying the information sheet referred to in paragraph 1 with the EHR system,** manufacturers ~~to~~**may** enter the information referred to in paragraph 2 into the EU database ~~of EHR systems and wellness applications~~ referred to in Article 32~~, as an alternative to supplying the information sheet referred to in paragraph 1 with the EHR system.~~**.**	
		Article 26			
361					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 26 EU declaration of conformity		Article 26 EU declaration of conformity	Article 26 EU declaration of conformity	
	Article 26(1)				
362	1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.		1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.	1. The EU declaration of conformity shall state that the manufacturer of the EHR system has demonstrated that the essential requirements laid down in Annex II have been fulfilled.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 26(2)				
363	2. Where EHR systems are subject to other Union legislation in respect of aspects not covered by this Regulation, which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the EHR system. The declaration shall contain all the information required for		~~2~~ *1a*. Where EHR systems are subject to other Union legislation in respect of aspects not covered by this Regulation, which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the EHR system. The declaration shall contain all the information required for	2. Where EHR systems are subject to other Union legislation in respect of aspects not covered by this Regulation, which also requires an EU declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the EHR system. The declaration shall contain all the information required for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the identification of the Union legislation to which the declaration relates.		the identification of the Union legislation to which the declaration relates.	the identification of the Union legislation to which the declaration relates.	
	Article 26(3)				
364	3. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available.		3. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available. ***Manufacturers shall provide a translation of the***	3. The EU declaration of conformity shall~~, as a minimum,~~ contain the information set out in Annex IV and shall be translated into one or more official Union languages determined by the Member State(s) in which the EHR system is made available.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			relevant parts of the technical documentation into the official language of the Member States where they have placed products on the market.		
		Article 26(3a)			
364a			***3a. Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the EHR system and in any event for at least 10 years after the placing on the market or the putting into service of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the EHR system.		
	Article 26(4)				
365	4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the conformity of the EHR system.		4. By drawing up the EU declaration of conformity~~,~~ the manufacturer***)*** shall assume responsibility for the ~~*conformity*~~***compliance*** of the EHR system ***with the requirements laid down in this Regulation***.	4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the conformity of the EHR system **when it is placed on the market or put into service**.	
	Article 26(4a)				
365a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			4a. The Commission is empowered to adopt delegated acts in accordance with Article 67 in order to amend the minimum content of the EU declaration of conformity set out in Annex IV.		
	Article 26(4b)				
365b			***4b. The Commission shall publish a standard uniformed template for the EU declaration of conformity and make it available in a digital***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			format in all the official Union languages.		
	Article 26A				
365c				**Article 26A** **European digital testing environment**	
	Article 26a(1)				
365d				**1. The Commission shall set up and operate a European digital testing**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				environment to support the assessment of harmonised components of EHR systems	
	Article 26a(2)				
365e				**2. Member States may set up digital testing environment to support the assessment of harmonised components of EHR systems. Such environments shall comply with the common specifications for digital testing environments laid down pursuant paragraph**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				4 and shall be communicated to the Commission.	
	Article 26a(3)				
365f				**3. Manufacturers shall use the testing environments mentioned in paragraphs 1 and 2 as a supporting element for the assessment of harmonised components of EHR systems. The results of the test shall be included in the documentation referred to in Article 24. The conformity to this**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				regulation shall be presumed in respect of the elements tested with positive results.	
	Article 26a(4)				
365g				**4. The Commission shall, by means of implementing acts, lay down the common specifications for digital testing environments. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27				
366	Article 27 CE marking		Article 27 CE marking	Article 27 CE marking	
	Article 27(1)				
367	1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the		1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the	1. The CE marking shall be affixed visibly, legibly and indelibly to the accompanying documents of the EHR system and, where applicable, to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	packaging.		packaging.	packaging.	
	Article 27(1a)				
367a			***1a. The CE marking shall be affixed before making the EHR system available on the market.***		
	Article 27(2)				
368	2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC)		2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC)	2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	765/2008 of the European Parliament and of the Council[1]. _____ 1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).		765/2008 of the European Parliament and of the Council[1]. _____ 1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).	765/2008 of the European Parliament and of the Council[1]. _____ 1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).	
		Article 27(2a)			
368a			***2a. Where EHR systems are subject to other Union***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			law in respect of aspects not covered by this Regulation, which also requires the affixing of the CE marking, the CE marking shall indicate that the systems also fulfil the requirements of that other law.		
	Article 27(2b)				
368b			***2b. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			appropriate action in the event of improper use of that marking.		
	Article 27a				
368c			***Article 27a*** ***Conformity assessment for EHR systems***		
	Article 27a(1)				
368d			***1. In order to certify the conformity of an EHR***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			system with this Regulation, prior to placing an EHR system on the market, the manufacturer, its authorised representative, or any economic operator referred to in Article 21 shall apply for a conformity assessment procedure.		
	Article 27a(2)				
368e			***2. Notified bodies shall take into account the specific interests and needs of SMEs when setting the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			fees for conformity assessment and reduce those fees proportionately to their specific interests and needs.		
		Article 27a(3), first subparagraph			
368f			***2. The conformity assessment procedure shall require the notified body to assess:***		
		Article 27a(3), first subparagraph, point (a)			
368g					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(a) whether the EHR system is in conformity with the requirements laid down in Annex II;		
	Article 27a(3), first subparagraph, point (b)				
368h			***(b) whether the EHR system is in conformity with the requirements laid down in Regulation (EU) .../... [.. (Cyber Resilience Act COM/2022/457];***		
	Article 27a(3), first subparagraph, point (c)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368i			***(c) whether the technical documentation is available and complete;***		
	Article 27a(3), first subparagraph, point (d)				
368j			***(d) whether the technical design of an EHR system meets the applicable requirements of this Regulation as provided for in an EU type examination procedure laid down in Annex IVa;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27a(3), second subparagraph				
368k			***The EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an EHR system and verifies and attests that the technical design of the EHR system meets the applicable requirements of this Regulation.***		
	Article 27a(3), third subparagraph				
368l					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Only after an Union wide approval has been issued, may the CE marking be affixed, together with an identification number.		
	Article 27A				
368 m				**Article 27A** **National requirements and reporting to the Commission**	
	Article 27a(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368n				**1. Member States may introduce national requirements for EHR systems and provisions on their conformity assessment in relation to aspects other than the harmonised components of EHR systems.**	
	Article 27a(2)				
368o				**2. National requirements or provisions on assessment referred to in paragraph 1 shall not**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				impede or adversely interact with the harmonised components of EHR systems.	
	Article 27a(3)				
368p				**3. When Member States adopt regulations in accordance with paragraph 1, they shall inform thereabout the Commission.**	
	Article 27aa				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368q			***Article 27aa*** ***General principles of the CE marking***		
	Article 27aa, first subparagraph				
368r			***The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.***		
	Article 27b				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368s			***Article 27b*** ***Notification***		
		Article 27b, first subparagraph			
368t			***Member States shall notify the Commission and the other Member States of conformity assessment bodies authorised to carry out conformity assessments in accordance with this Regulation.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27c				
368u			***Article 27c*** ***Notifying authorities***		
	Article 27c(1)				
368v			***1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			monitoring of notified bodies, including compliance with Article 27h.		
	Article 27c(2)				
368 w			***2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27c(3)				
368x			***3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 27e. In addition, that body shall have arrangements to cover***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			liabilities arising out of its activities.		
	Article 27c(4)				
368y			***4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3***		
	Article 27d				
368z			***Article 27d***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Requirements relating to notifying authorities		
	Article 27d(1)				
368aa			***1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.***		
	Article 27d(2)				
368ab			***2. A notifying authority***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.		
	Article 27d(3)				
368ac			***3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons other than those who carried out the assessment of the EHR system.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27d(4)				
368ad			***4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.***		
	Article 27d(5)				
368ae			***5. A notifying authority***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			shall safeguard the confidentiality of the information it obtains.		
	Article 27d(6)				
368af			***6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.***		
	Article 27e				
368a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
g			***Article 27e*** ***Information obligation on notifying authorities***		
	Article 27e(1)				
368a h			***Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto. The Commission shall make that information publicly available.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27f				
368a i			***Article 27f*** ***Requirements relating to notified bodies***		
	Article 27f(1)				
368a j			***1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27f(2)				
368ak			***2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.***		
	Article 27f(3)				
368al			***3. A conformity assessment body shall be a third-party body***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			independent of the organisation or the EHR system it assesses.		
	Article 27f(4)				
368am			***4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of an EHR system, that they assess, or the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			representative of any of those parties. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, installation, use or maintenance of EHR systems, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			particular apply to consultancy services. A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.		
	Article 27f(5)				
368an			***5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.		
	Article 27g(6)				
368a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
o			***6. The personnel responsible for carrying out conformity assessment tasks shall have the following:***		
		Article 27g(6), point (a)			
368ap			***(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27g(6), point (b)				
368aq			***(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;***		
	Article 27g(6), point (c)				
368ar			***(c) appropriate knowledge and understanding of the applicable harmonised standards and common specifications referred to in***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			this Regulation, and of the relevant provisions of Union harmonisation legislation and of national legislation;		
		Article 27g(6), point (d)			
368as			***(d) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.***		
		Article 27g(7)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368at			***7. A conformity assessment body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.***		
	Article 27g(8)				
368au			***8. The personnel of a conformity assessment body shall observe***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			professional secrecy with regard to all information obtained in carrying out the conformity assessment activities in accordance with Annexes IVa, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.		
	Article 27g(9)				
368av			***9. A conformity assessment body shall***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			participate in, or ensure that its personnel responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 27r and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.		
	Article 27f(6), first subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368aw			***6. A conformity assessment body shall be capable of carrying out all the conformity assessment activities mentioned in Annexes IVa in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. At all times, and for each conformity assessment procedure and each kind of a EHR system for which it has been notified, a conformity assessment body shall have***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			at its disposal the necessary:		
	Article 27f(6), first subparagraph, point (a)				
368ax			***(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;***		
	Article 27f(6), first subparagraph, point (b)				
368ay			***(b) descriptions of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;		
		Article 27f(6), first subparagraph, point (c)			
368az			***(c) appropriate policies and procedures to distinguish between activities that it carries out as a notified body and other activities;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27f(6), first subparagraph, point (d)				
368ba			***(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure and the degree of complexity of the technology in question.***		
	Article 27f(6), second subparagraph				
368bb			***A conformity assessment body shall have the means***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.		
	Article 27f(8), first subparagraph				
368bc			***8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			assessment activities shall be guaranteed.		
	Article 27f(8), second subparagraph				
368bd			***The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment activities shall not depend on the number of conformity assessments carried out or on the results of those assessments.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27g				
368be			***Article 27g*** ***Presumption of conformity of notified bodies***		
	Article 27g(1)				
368bf			***Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards the references of which have been published in the Official Journal of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the European Union, it shall be presumed to comply with the requirements set out in Article 27g in so far as the applicable harmonised standards cover those requirements.		
	Article 27h				
368bg			***Article 27h*** ***Use of subcontractors and subsidiaries by notified bodies***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 27h(1)			
368bh			***1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 27fand shall inform the notifying authority accordingly.***		
		Article 27h(2)			
368b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
i			***2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established.***		
	Article 27h(3)				
368bj			***3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.***		
	Article 27h(4)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368bk			***4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex IVa.***		
	Article 27i				
368bl			***Article 27i*** ***Application for notification***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27i(1)				
368bm			***1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.***		
	Article 27i(2)				
368bn			***2. The application for notification shall be***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annex IVa as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 27f.		
	Article 27i(3)				
368bo			***3. Where the conformity***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 27f.		
	Article 27j				
368bp			***Article 27j***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Notification procedure		
	Article 27j(1)				
368bq			***1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 27f.***		
	Article 27j(2)				
368br			***2. The notifying authority***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			shall send a notification to the Commission and the other Member States of each conformity assessment body referred to in paragraph 1, using the electronic notification tool developed and managed by the Commission.		
	Article 27j(3)				
368bs			***3. The notification referred to in paragraph 2 shall include the following:***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27j(3), point (a)				
368bt			***(a) full details of the conformity assessment activities to be performed;***		
	Article 27j(3), point (b)				
368bu			***(b) the relevant attestation of competence.***		
	Article 27j(4)				
368b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
v			***4. Where a notification is not based on an accreditation certificate referred to in Article 27i(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 27f.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 27j(5), first subparagraph			
368bw			***5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 27i(2), or within two months of the notification where it includes documentary evidence referred to in***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			paragraph 4 of this Article.		
		Article 27j(5), second subparagraph			
368bx			***Only such a body shall be considered a notified body for the purposes of this Regulation.***		
		Article 27j(6)			
368by			***6. The notifying authority shall notify the Commission and the other Member States of any***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			subsequent relevant changes to the notification referred to in paragraph 2.		
	Article 27k				
368bz			***Article 27k*** ***Identification numbers and lists of notified bodies***		
	Article 27k(1)				
368ca			***1. The Commission shall assign an identification***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			number to a notified body. It shall assign a single such number even where the body is notified under several Union acts.		
	Article 27k(2)				
368cb			***2. The Commission shall make publicly available the list of notified bodies including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified. The Commission shall ensure***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			that the list is kept up to date.		
	Article 27l				
368cc			***Article 27l*** ***Changes to notification***		
	Article 27l(1)				
368cd			***1. Where a notifying authority has ascertained or has been informed that a notified body no longer***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			meets the requirements laid down in Article 27f, or that it is failing to fulfil its obligations as set out in Article 27n, the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.		
	Article 27l(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368ce			***2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.***		
	Article 27m				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
368cf			***Article 27m*** ***Challenge of the competence of notified bodies***		
	Article 27m(1)				
368cg			***1. The Commission shall investigate all cases where it has doubts, or a doubt is brought to its attention, regarding the competence of a notified body or the continued fulfilment by a notified body of the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			requirements and responsibilities to which it is subject.		
	Article 27m(2)				
368ch			***2. The notifying authority shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27m(3)				
368ci			***3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.***		
	Article 27m(4), first subparagraph				
368cj			***4. Where the Commission ascertains that a notified body does not meet or no longer meetsthe requirements for its notification, it shall adopt***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			an implementing act requesting the notifying authority to take the necessary corrective measures, including the withdrawal of the notification if necessary.		
		Article 27m(4), second subparagraph			
368ck			***That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 68(2).***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27n				
368cl			***Article 27n*** ***Operational obligations of notified bodies***		
	Article 27n(1)				
368cm			***1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Article 27a.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27n(2)				
368cn			***2. A notified body shall perform its activities in a proportionate manner, avoiding an unnecessary burden for economic operators, and taking due account of the size of an undertaking, the structure of the undertaking, the degree of complexity of the EHR system in question. In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the EHR***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			system with the requirements of this Regulation.		
	Article 27n(3)				
368co			***3. Where a notified body finds that the harmonised standards or common specifications referred in this Regulation have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective actions and shall not issue an EU type-examination certificate.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27n(4), first subparagraph				
368cp			***4. Where, in the course of the monitoring of conformity following the issuance of a certificate of conformity or the adoption of an approval decision, a notified body finds that a EHR system no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate of conformity or the approval decision, if***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			necessary.		
	Article 27n(4), second subparagraph				
368cq			***Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates of conformity or approval decisions, as appropriate.***		
	Article 27o				
368c					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
r			***Article 27o*** ***Appeals against decisions of notified bodies***		
	Article 27o, first subparagraph				
368cs			***A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available.***		
	Article 27p				
368c					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
t			***Article 27p*** ***Information obligation on notified bodies***		
	Article 27p(1)				
368cu			***1. A notified body shall inform the notifying authority of the following:***		
	Article 27p(1), point (a)				
368cv			***(a) any refusal, restriction, suspension or withdrawal***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of a certificate of conformity or approval decision;		
	Article 27p(1), point (b)				
368cw			***(b) any circumstances affecting the scope of, or the conditions for, its notification;***		
	Article 27p(1), point (c)				
368cx			***(c) any request for information which it has***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			received from market surveillance authorities regarding its conformity assessment activities;		
		Article 27p(1), point (d)			
368cy			***(d) upon request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 27q			
368cz			***Article 27q*** ***Coordination of notified bodies***		
		Article 27q, first subparagraph			
368da			***The Commission shall ensure that appropriate coordination and cooperation between notified bodies are put in place and properly operated in the form of a sectoral group of notified***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			bodies.		
	Article 27q, second subparagraph				
368db			***Notified bodies shall participate in the work of that group, directly or by means of designated representatives.***		
	Article 27r				
368dc			***Article 27r*** ***Exchange of experience***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 27r, first subparagraph				
368dd			***The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.***		
	Section 4				
369	Section 4 Market surveillance of EHR		Section 4 Market surveillance of EHR	Section 4 Market surveillance of EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	systems		systems	systems	
	Article 28				
370	Article 28 Market surveillance authorities		Article 28 Market surveillance authorities	Article 28 Market surveillance authorities	
	Article 28(1)				
371	1. Regulation (EU) 2019/1020 shall apply to EHR systems covered by Chapter III of this		1. Regulation (EU) 2019/1020 shall apply to EHR systems covered by Chapter III of this	1. Regulation (EU) 2019/1020 shall apply to EHR systems **in relation to the harmonised**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation.		Regulation.	**components of EHR systems** covered by Chapter III of this Regulation.	
		Article 28(2)			
372	2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this		2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the ***necessary*** powers, ***financial*** resources, equipment, ***technical expertise, adequate staffing,*** and	2. Member States shall designate the market surveillance authority or authorities responsible for the implementation of this Chapter. They shall entrust their market surveillance authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation. Member States shall communicate the identity of the market surveillance authorities to the Commission which shall publish a list of those authorities.		knowledge necessary for the proper performance of their tasks pursuant to this Regulation. Member States shall communicate the identity of the market surveillance authorities to the Commission which shall publish a list of those authorities.	Regulation. **Market surveillance authorities shall take the measures referred to in Article 16 of Regulation (EU) 2019/1020 to enforce this Chapter.** Member States shall communicate the identity of the market surveillance authorities to the Commission ~~which shall publish a list of those authorities~~**The Commission and the Member States shall make this information publicly available**.	
		Article 28(2a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
372a			***2a. Staff of market surveillance authorities shall have no direct or indirect economic, financial or personal conflicts of interest that might be considered prejudicial to their independence and, in particular, they shall not be in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.***		
	Article 28(2b)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
372b			***2b. Pursuant to paragraph 2 of this Article, Member States shall determine and publish the selection procedure for market surveillance authorities. They shall ensure that the procedure is transparent and does not allow for conflicts of interest.***		
	Article 28(3)				
373	3. Market surveillance authorities designated pursuant to this Article may		3. Market surveillance authorities designated pursuant to this Article may	3. Market surveillance authorities designated pursuant to this Article may	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, any conflict of interest shall be avoided.		be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, any conflict of interest shall be avoided.	be the digital health authorities designated pursuant to Article 10. Where a digital health authority carries out tasks of market surveillance authority, **Member States shall ensure that** any conflict of interest ~~shall be~~ **is** avoided.	
		Article 28(4)			
374	4. Market surveillance authorities shall report to the Commission on a regular basis the outcomes of relevant market		4. Market surveillance authorities shall report to the Commission on a regular basis the outcomes of relevant market	4. Market surveillance authorities shall report to the Commission on a ~~regular~~ **yearly** basis the outcomes of relevant market	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	surveillance activities.		surveillance activities.	surveillance activities.	
	Article 28(4a)				
374a			***4a. Market surveillance authorities shall immediately inform notified bodies about manufacturers of EHR systems that no longer comply with the requirements on the declaration of conformity.***		
	Article 28(4b)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
374b			***4b. When a manufacturer or, pursuant to Article 21, another economic operator fails to cooperate with market surveillance authorities or if the information and documentation provided is incomplete or incorrect, market surveillance authorities shall take all appropriate measures to prohibit or restrict the relevant EHR system from being available on the market until the manufacturer cooperates or provides complete and correct information, or to***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			withdraw it from the market or to recall.		
	Article 28(5)				
375	5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.		5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.	5. The market surveillance authorities of the Member States shall cooperate with each other and with the Commission. The Commission shall provide for the organisation of exchanges of information necessary to that effect.	
	Article 28(6)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
376	6. For medical devices or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745 or Article 59 of Regulation […] [AI act COM/2021/206 final], as applicable.		6. For medical devices or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745 or Article 59 of Regulation […] [AI act COM/2021/206 final], as applicable.	6. For medical devices**, in vitro diagnostic medical devices** or high-risk AI systems referred to in Article 14 (3) and (4), the responsible authorities for market surveillance shall be those referred to in Article 93 of Regulation (EU) 2017/745**, Article 88 of Regulation (EU) 2017/746** or Article 59 of Regulation […] [AI act COM/2021/206 final], as applicable.	
	Article 29				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
377	Article 29 Handling of risks posed by EHR systems and of serious incidents		Article 29 Handling of risks posed by EHR systems and of serious incidents	Article 29 Handling of risks posed by EHR systems and of serious incidents	
	Article 29(1)				
378	1. Where a market surveillance authority finds that an EHR system presents a risk to the health or safety of natural persons or to other aspects of public interest protection, it shall require the manufacturer of		1. Where a market surveillance authority ~~finds~~***of one Member State has a reason to believe*** that an EHR system presents a risk to the health***, safety or rights*** ~~or safety~~ of natural persons ~~or to other aspects~~	1. Where a market surveillance authority finds that an **any of the harmonised components of EHR systems**~~EHR system~~ presents a risk to the health or safety of natural persons**, to the security of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the EHR system concerned, its authorised representative and all other relevant economic operators to take all appropriate measures to ensure that the EHR system concerned no longer presents that risk when placed on the market to withdraw the EHR system from the market or to recall it within a reasonable period.		~~*of public interest protection,*~~ ***, to the protection of personal data*** it shall ~~*require the manufacturer of*~~***carry out an evaluation in relation to*** the EHR system concerned~~.~~ ***covering all relevant requirements laid down in this regulation.*** Its authorised ~~*representative*~~***representatives*** and all other relevant economic operators ~~*to*~~***shall cooperate as necessary with the market surveillance authorities for that purpose and*** take all appropriate measures to ensure that the EHR system concerned no longer	**the EHR system** or to other aspects of public interest protection, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to take all appropriate measures to ensure that the EHR system concerned no longer presents that risk when placed on the market**. The measures may include withdrawal of** ~~to withdraw~~ the EHR system from the market or to recall it within a reasonable period.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			presents that risk when placed on the market to withdraw the EHR system from the market or to recall it within a reasonable period. ***The market surveillance authorities shall inform the relevant notified body accordingly.***		
	Article 29(1a)				
378a			***1a. Where the market surveillance authorities consider that non-***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.		
	Article 29(1b)				
378b			***1b. Where a market surveillance authority considers or has reason to believe that an EHR system has caused damage to the health or safety of natural***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			persons or to other aspects of public interest protection, it shall immediately provide information and documentation, as applicable, to the affected person or user and, as appropriate, other third parties affected by the damage caused to the person or user, without prejudice to data protection rules.		
	Article 29(2)				
379	2. The economic operator		2. The economic operator	2. The economic operator	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems concerned that it has placed on market throughout the Union.		referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems concerned that it has placed on market throughout the Union.	referred to in paragraph 1 shall ensure that corrective action is taken in respect of all the EHR systems **with regard to the harmonised components** concerned that it has placed on market throughout the Union.	
	Article 29(3)				
380	3. The market surveillance authority shall immediately inform the Commission and the market surveillance authorities of other Member States of the measures ordered pursuant to		3. The market surveillance authority***, or, where applicable, the supervisory authority under Regulation (EU) 2016/679,*** shall immediately inform the Commission and the market	3. The market surveillance authority shall immediately inform the Commission and the market surveillance authorities of other Member States of the measures ordered pursuant to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the EHR system concerned, the origin and the supply chain of the EHR system, the nature of the risk involved and the nature and duration of the national measures taken.		surveillance authorities***, or, if applicable, the supervisory authorities under Regulation (EU) 2016/679,*** of other Member States of the measures ordered pursuant to paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the EHR system concerned, the origin and the supply chain of the EHR system, the nature of the risk involved and the nature and duration of the national measures taken.	paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the EHR system concerned, the origin and the supply chain of the EHR system, the nature of the risk involved and the nature and duration of the national measures taken.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 29(3a)			
380a			***3a. Where a finding of a market surveillance authority, or a serious incident it is informed of, concerns personal data protection, the market surveillance authority shall immediately inform and cooperate with the relevant supervisory authorities under Regulation (EU) 2016/679.***		
		Article 29(4), first subparagraph			
381					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	4. Manufacturers of EHR systems placed on the market shall report any serious incident involving an EHR system to the market surveillance authorities of the Member States where such serious incident occurred and the corrective actions taken or envisaged by the manufacturer.		4. Manufacturers of EHR systems placed on the market shall report any serious incident involving an EHR system to the market surveillance authorities***, or, in cases involving personal data, the supervisory authorities under Regulation (EU) 2016/679*** of the Member States where such serious incident occurred and the corrective actions taken or envisaged by the manufacturer.	4. Manufacturers of EHR systems placed on the market **or put into service** shall report any serious incident involving an EHR system to the market surveillance authorities of the Member States where such serious incident occurred and **to the market surveillance authorities of the Member States where such EHR systems is placed on the market or put into service. The report shall also contain a description of** the corrective actions taken or envisaged by the manufacturer. **Member States may provide for**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				users of EHR systems placed on the market or put into service to report such incidents.	
	Article 29(4), second subparagraph				
382	Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of		Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) 2016/1148, immediately after the manufacturer has established a causal link between the EHR system and the serious incident or the reasonable likelihood of	Such notification shall be made, without prejudice to incident notification requirements under Directive (EU) ~~2016/1148~~**2022/2555** , immediately after the manufacturer has established a causal link between the EHR system and the serious incident or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	such a link, and, in any event, not later than 15 days after the manufacturer becomes aware of the serious incident involving the EHR system.		such a link, and, in any event, not later than ~~15~~7 days after the manufacturer becomes aware of the serious incident involving the EHR system.	the reasonable likelihood of such a link, and, in any event, not later than ~~15~~**3** days after the manufacturer becomes aware of the serious incident involving the EHR system.	
		Article 29(5)			
383	5. The market surveillance authorities referred to in paragraph 4 shall inform the other market surveillance authorities, without delay, of the serious incident and the corrective action taken or envisaged by the		5. The ~~*market surveillance*~~ authorities referred to in paragraph 4 shall inform the other ~~*market surveillance*~~ authorities, without delay, of the serious incident and the corrective action taken or envisaged by the	5. The market surveillance authorities referred to in paragraph 4 shall inform the other market surveillance authorities, without delay, of the serious incident and the corrective action taken or envisaged by the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	manufacturer or required of it to minimise the risk of recurrence of the serious incident.		manufacturer or required of it to minimise the risk of recurrence of the serious incident.	manufacturer or required of it to minimise the risk of recurrence of the serious incident.	
		Article 29(6)			
384	6. Where the tasks of the market surveillance authority are not performed by the digital health authority, it shall cooperate with the digital health authority. It shall inform the digital health authority of any serious incidents and of EHR systems presenting a risk, including risks related		6. Where the tasks of the market surveillance authority are not performed by the digital health authority, it shall cooperate with the digital health authority. It shall inform the digital health authority of any serious incidents and of EHR systems presenting a risk, including risks related	6. Where the tasks of the market surveillance authority are not performed by the digital health authority, it shall cooperate with the digital health authority. It shall inform the digital health authority of any serious incidents and of EHR systems **in relation to the harmonised**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.		to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.	**components of EHR systems** presenting a risk, including risks related to interoperability, security and patient safety, and of any corrective action, recall or withdrawal of such EHR systems.	
	Article 29(7)				
384a				**7. Where the market surveillance authority becomes aware that the risk or the incident can entail a personal data breach, as defined in Article 4(12) of Regulation**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(EU) 2016/679 which is to be notified pursuant to Article 33 of that Regulation, they shall, without undue delay, inform the supervisory authorities as referred to in Article 55 or 56 of that Regulation.	
	Article 29(8)				
384b				**8. For incidents putting at risk patient safety or information security, the market surveillance authorities may take immediate actions and**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				require immediate corrective actions.	
	Article 30				
385	Article 30 Handling of non-compliance			Article 30 Handling of non-compliance	
	Article 30(1)				
386	1. Where a market surveillance authority makes one of the following		1. Where a market surveillance authority makes one***, inter alia,*** of the	1. Where a market surveillance authority makes one of the following	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to put an end to the non-compliance concerned:		following findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators to ~~*put an end to the non-compliance concerned*~~***bring the EHR system into conformity***:	findings, it shall require the manufacturer of the EHR system concerned, its authorised representative and all other relevant economic operators**, within a deadline it establishes, to take appropriate measures** to put an end to the non-compliance concerned:	
		Article 30(1), point (a)			
387	(a) the EHR system is not in conformity with essential requirements laid down in Annex II;		(a) the EHR system is not in conformity with essential requirements laid down in Annex II ***and with the***	(a) the **harmonised components of EHR systems**~~EHR system~~ is not in conformity with **the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			common specifications in accordance with Article 23;	essential requirements laid down in Annex II;	
	Article 30(1), point (b)				
388	(b) the technical documentation is either not available or not complete;		(b) the technical documentation is ~~*either not available*~~***not available, not complete*** or not ~~*complete*~~***in accordance with Article 24***;	(b) the technical documentation is either not available or not complete;	
	Article 30(1), point (c)				
389	(c) the EU declaration of conformity has not been		(c) the EU declaration of conformity has not been	(c) the EU declaration of conformity has not been	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	drawn up or has not been drawn up correctly;		drawn up or has not been drawn up correctly ***as referred to in Article 26***;	drawn up **with regard to the harmonised components of EHR systems** or has not been drawn up correctly;	
		Article 30(1), point (d)			
390	(d) the CE marking has been affixed in violation of Article 27 or has not been affixed.		(d) the CE marking has been affixed in violation of Article 27 or has not been affixed.	(d) the CE marking has been affixed in violation of Article 27 or has not been affixed.	
		Article 30(1), point (da)			
390a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(da) the registration obligations of Article 32 have not been fulfilled.		
	Article 30(1a)				
390b			***1a. Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the EHR system does not comply with the requirements laid down in this Regulation, they shall require without delay the relevant economic operator to take all appropriate***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			corrective action to bring the EHR system into compliance with those requirements, to withdraw the EHR system from the market, or to recall it within a reasonable period.		
		Article 30(1b), first subparagraph			
390c			***1b. Where the relevant economic operator does not take adequate corrective action within the period referred to in Article 29(1), second subparagraph, the market surveillance authorities shall take all***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			appropriate provisional measures to prohibit or restrict the EHR system being made available on their national market, to withdraw the EHR system from that market or to recall it.		
	Article 30(1b), second subparagraph				
390d			***The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 30(1c)				
390e			***1c. The information referred to in paragraph 1b, second subparagraph, shall include all available details, in particular the data necessary for the identification of the noncompliant EHR system, the origin of that EHR system, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			particular, the market surveillance authorities shall indicate whether the noncompliance is due to any of the following:		
		Article 30(1c), point (a)			
390f			***(a) failure of the EHR system to meet the requirements relating to the essential requirements set out in Annex II;***		
		Article 30(1c), point (b)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
390g			***(b) shortcomings in the harmonised standards referred to in Article 23;***		
	Article 30(1c), point (c)				
390h			***(c) shortcomings in the technical specifications referred to in Article 23.***		
	Article 30(1d)				
390i			***1d. Member States other***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the EHR system concerned, and, in the event of disagreement with the adopted national measure, of their objections.		
	Article 30(1e)				
390j					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			1e. Where, within three months of receipt of the information referred to in paragraph 1b, second subparagraph, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.		
	Article 30(2)				
391	2. Where the non-compliance referred to in paragraph 1 persists, the		2. Where the non-compliance referred to in paragraph 1 persists, the	2. Where the non-compliance referred to in paragraph 1 persists, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Member State concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.		Member State concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.	~~Member State~~ **market surveillance authority** concerned shall take all appropriate measures to restrict or prohibit the EHR system being placed on the market or ensure that it is recalled or withdrawn from the market.	
	Article 30a				
391a			***Article 30a*** ***Union safeguard procedure***		
	Article 30a(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
391b			***1. Where, on completion of the procedure set out in Article 29(2) and Article 30(1a), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union law, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 68(2a).		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 30a(2)				
391c			***2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant EHR system is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure. Where the national measure is considered justified and the non-***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			compliance of the EHR system is attributed to shortcomings in the harmonised standards or technical specifications referred to in this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.		
	Section 5				
392	Section 5 Other provisions on interoperability		Section 5 Other provisions on interoperability	Section 5 Other provisions on interoperability	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 31				
393	Article 31 Voluntary labelling of wellness applications		Article 31 ~~*Voluntary*~~ Labelling of wellness applications	Article 31 ~~Voluntary~~ Labelling of wellness applications	
	Article 31(1)				
394	1. Where a manufacturer of a wellness application claims interoperability with an EHR system and therefore compliance with the essential requirements laid down in Annex II and common specifications in		1. Where a manufacturer of a wellness application claims interoperability with an EHR system and therefore compliance with the essential requirements laid down in Annex II and common specifications in	1. Where a manufacturer of a wellness application claims interoperability with an EHR system **in relation to the harmonised components of EHR systems** and therefore compliance with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 23, such wellness application may be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application.		Article 23, such wellness application ~~*may*~~***shall*** be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application ***and the competent market surveillance authority shall be informed***.	essential requirements laid down in Annex II and common specifications in Article 23, such wellness application ~~may~~**shall** be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application.	
		Article 31(2)			
395	2. The label shall indicate the following information:		2. The label shall indicate the following information:	2. The label shall indicate the following information:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 31(2), point (a)				
396	(a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;		(a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;	(a) categories of electronic health data for which compliance with essential requirements laid down in Annex II has been confirmed;	
	Article 31(2), point (b)				
397	(b) reference to common specifications to demonstrate compliance;		(b) reference to common specifications to demonstrate compliance;	(b) reference to common specifications to demonstrate compliance;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 31(2), point (c)				
398	(c) validity period of the label.		(c) validity period of the label.	(c) validity period of the label.	
	Article 31(3)				
399	3. The Commission may, by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with the		3. The Commission ~~*may*~~***shall***, by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with	3. The Commission may, by means of implementing acts, determine the format and content of the label. Those implementing acts shall be adopted in accordance with the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	advisory procedure referred to in Article 68(2).		the advisory procedure referred to in Article 68(2).	~~advisory~~**examination** procedure referred to in Article 68(2).	
		Article 31(4)			
400	4. The label shall be drawn-up in one or more official languages of the Union or languages determined by the Member State(s) in which the in which the wellness application is placed on the market.		4. The label shall be drawn-up in one or more official languages of the Union***, and in the language of*** ~~*or languages determined by*~~ the Member State(s) ~~*in which the*~~ in which the wellness application is placed on the market.	4. The label shall be drawn-up in one or more official languages of the Union or languages determined by the Member State(s) in which the ~~in which the~~ wellness application is placed on the market **or put into service**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 31(5)				
401	5. The validity of the label shall not exceed 5 years.		5. The validity of the label shall not exceed 5 years.	5. The validity of the label shall not exceed ~~5~~**3** years.	
	Article 31(6)				
402	6. If the wellness application is embedded in a device, the accompanying label shall be placed on the device. 2D barcodes may also be used to display the label.		6. If the wellness application is ***an integral part of a device or*** embedded in a device ***after its putting into service***, the accompanying label shall be ***shown in the application itself or*** placed on the device ***and in the case of***	6. If the wellness application is embedded in a device, the accompanying label shall be placed on the device. **Two-dimensional, 2D,**~~2D~~ barcodes may also be used to display the label.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			software a digital label. 2D barcodes may also be used to display the label.		
	Article 31(7)				
403	7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II.		7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II.	7. The market surveillance authorities shall check the compliance of wellness applications with the essential requirements laid down in Annex II.	
	Article 31(8)				
404					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	8. Each supplier of a wellness application, for which a label has been issued, shall ensure that the wellness application that is placed on the market or put into service is accompanied with the label for each individual unit, free of charge.		8. Each supplier of a wellness application, for which a label has been issued, shall ensure that the wellness application that is placed on the market or put into service is accompanied with the label for each individual unit, free of charge.	8. Each supplier of a wellness application, for which a label has been issued, shall ensure that the wellness application that is placed on the market or put into service is accompanied with the label for each individual unit, free of charge.	
		Article 31(9)			
405	9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at		9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at the	9. Each distributor of a wellness application for which a label has been issued shall make the label available to customers at the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the point of sale in electronic form or, upon request, in physical form.		point of sale in electronic form ~~*or, upon request, in physical form*~~.	point of sale in electronic form or, upon request, in physical form.	
		Article 31(10)			
406	10. The requirements of this Article shall not apply to wellness applications which are high-risk AI systems as defined under Regulation […] [AI Act COM/2021/206 final].		*deleted*	*10.* The requirements of this Article shall not apply to wellness applications which are high-risk AI systems as defined under Regulation […] [AI Act COM/2021/206 final].	
		Article 31a			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
406a			***Article 31a*** ***Interoperability of wellness applications with EHR systems***		
		Article 31a(1)			
406b			***1. Manufacturers of wellness applications may claim interoperability with an EHR system, after relevant conditions are met. When this is the case, the users of such wellness applications shall be duly***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			informed about such interoperability and its effects.		
	Article 31a(2)				
406c			***2. The interoperability of wellness applications with EHR systems shall not mean automatic sharing or transmission of all or part of the health data from the wellness application with the EHR system. The sharing or transmission of such data shall only be possible following the consent of the natural***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			person and in accordance with Article 3(6) of this Regulation and interoperability shall be limited exclusively to this end. The manufacturers of wellness applications claiming interoperability with an EHR system shall ensure that the user is able to choose which categories of health data from the wellness application they want to insert in the EHR system and the circumstance for that sharing or transmission.		
	Article 31a(3)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
406d			***3. Wellness applications shall not be permitted to access the information in EHRs or extract or process information from it.***		
	Section 6				
406e				**Section 6 Registration of EHR system and wellness application**	
	Article 32				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
407	Article 32 Registration of EHR systems and wellness applications		Article 32 Registration of EHR systems and wellness applications	Article 32 **EU database for** registration of EHR systems and wellness applications	
	Article 32(1)				
408	1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 and wellness		1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 ~~*and*~~ wellness	1. The Commission shall establish and maintain a publicly available database with information on EHR systems for which an EU declaration of conformity has been issued pursuant to Article 26 and wellness	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	applications for which a label has been issued pursuant to Article 31.		applications for which a label has been issued pursuant to Article ~~31~~34.	applications for which a label has been issued pursuant to Article 31.	
		Article 32(2)			
409	2. Before placing on the market or putting into service an EHR system referred to in Article 14 or a wellness application referred to in Article 31, the manufacturer of such EHR system or wellness application or, where applicable, its authorised representative shall register the required data into the		2. Before placing on the market or putting into service an EHR system referred to in Article 14 or a wellness application referred to in Article 31, the manufacturer of such EHR system or wellness application or, where applicable, its authorised representative shall register the required data into the	2. Before placing on the market or putting into service an EHR system referred to in Article 14 or a wellness application referred to in Article 31, the manufacturer of such EHR system or wellness application or, where applicable, its authorised representative shall register the required data into the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	EU database referred to in paragraph 1.		EU database referred to in paragraph 1.	EU database referred to in paragraph 1.	
	Article 32(3)				
410	3. Medical devices or high-risk AI systems referred to in paragraphs 3 and 4 of Article 14 of this Regulation shall be registered in the database established pursuant to Regulations (EU) 2017/745 or […] [AI Act COM/2021/206 final], as applicable.		3. Medical devices or high-risk AI systems referred to in paragraphs 3 and 4 of Article 14 of this Regulation shall ***also*** be registered in the database established pursuant to Regulations (EU) 2017/745 or […] [AI Act COM/2021/206 final], as applicable.	3. **Medical devices, in vitro diagnostic** medical devices or high-risk AI systems referred to in paragraphs ~~3 and 4~~**1 and 2** of Article 14 of this Regulation shall be registered in the database established pursuant to Regulations (EU) 2017/745**, (EU) 2017/746** or […] [AI Act COM/2021/206 final], as applicable. **In such**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				cases, the information shall also be forwarded to the EU database referred to in paragraph 1.	
	Article 32(4)				
411	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2.		4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2.	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to determine the list of required data to be registered by the manufacturers of EHR systems and wellness applications pursuant to paragraph 2.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	CHAPTER IV				
412	CHAPTER IV Secondary use of electronic health data		CHAPTER IV Secondary use of electronic health data	CHAPTER IV Secondary use of electronic health data	
	Section 1				
413	Section 1 General conditions with regard to the secondary use of electronic health data		Section 1 General conditions with regard to the secondary use of electronic health data	Section 1 General conditions with regard to the secondary use of electronic health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 32A				
413a				**Article 32A** **Applicability to health data holders**	
	Article 32, (1)				
413b				**1. The following categories of health data holders shall be exempted from the obligations incumbent on health data holders laid down in this Chapter:**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 32, (1a)				
413c				**(a) individual researchers and natural persons;**	
	Article 32, (1b)				
413d				**(b) legal persons that qualify as micro-enterprises as defined in Article 2 of the Annex to Commission Recommendation**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2003/361/EC.	
	Article 32, (2)				
413e				**2. Member States may, by virtue of national legislation, provide that the obligations of health data holders laid down in this Chapter shall apply to the health data holders referred to in paragraph 1 which fall under their jurisdiction.**	
	Article 32, (3)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
413f				**3. Member States may provide, by virtue of national legislation, that the obligations of health data holders laid down in this Chapter shall not apply to health data holders in the care sector, which fall under their jurisdiction, in order to avoid a disproportionate burden on the entities pertaining to this sector.**	
	Article 32, (4)				
413g					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				4. Member States may, by virtue of national legislation, provide that the duties of certain categories of data holders shall be fulfilled by health data intermediation entities.	
	Article 32, (5)				
413h				**5. National legislation defined under paragraphs 2, 3 and 4 of this Article shall be notified to the Commission by [date of applicability of chapter IV]. Any subsequent law**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				or amendment affecting them shall be notified to the Commission without delay.	
	Article 33				
414	Article 33 Minimum categories of electronic data for secondary use		Article 33 ~~*Minimum*~~ Categories of electronic ***health*** data for secondary use	Article 33 Minimum categories of electronic data for secondary use	
	Article 33(1)				
415					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. Data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter:		1. ~~*Data holders*~~***This chapter*** shall ~~*make*~~***apply to*** the following categories of electronic ***health*** data available for secondary use ~~*in accordance with the provisions of this Chapter*~~:	1. **Health** data holders shall make the following categories of electronic data available for secondary use in accordance with the provisions of this Chapter:	
		Article 33(1), point (a)			
416	(a) EHRs;		(a) ***electronic health data from*** EHRs;	(a) **health data from EHRs processed in a structured form**~~EHRs~~;	
		Article 33(1), point (b)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
417	(b) data impacting on health, including social, environmental behavioural determinants of health;		(b) data ***on factors*** impacting on health, including ~~*social*~~***socio-economic***, environmental ***and*** behavioural determinants of health;	(b) data ~~impacting on health, including~~ **on** social, environmental **and** behavioural determinants of health~~;~~	
	Article 33(1), point (ba)				
417a				**(ba) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				financing;	
	Article 33(1), point (c)				
418	(c) relevant pathogen genomic data, impacting on human health;		(c) relevant pathogen ~~*genomic*~~ data, impacting on human health;	(c) ~~relevant~~ pathogen ~~genomic~~ data, impacting on human health;	
	Article 33(1), point (d)				
419	(d) health-related administrative data, including claims and reimbursement data;		(d) ~~*health-related*~~***healthcare-related*** administrative data, including claims and	(d) ~~health-related~~**healthcare-related** administrative data, including **insurance status,** claims and reimbursement	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			reimbursement data;	data **and other administrative data relating to an individual's socioeconomic status, in a structured form**;	
	Article 33(1), point (e)				
420	(e) human genetic, genomic and proteomic data;		(e) ***extracts from*** human genetic, genomic and proteomic data***, such as genetic markers***;	(e) human genetic~~, genomic and proteomic~~ **and genomic** data;	
	Article 33(1), point (ea)				
420a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(ea) other human molecular data such as proteomic transcriptomic, epigenomic, metabolomic, lipidomic and other omic data;	
	Article 33(1), point (f)				
421	(f) person generated electronic health data, including medical devices, wellness applications or other digital health applications;		(f) ~~*person*~~***automatically*** generated electronic health data, ~~*including*~~***via*** medical devices~~*, wellness applications or other digital health applications*~~;	(f) person generated ~~electronic~~ health data~~,~~ ~~including~~ **through** medical devices, wellness applications or other digital health applications;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 33(1), point (fa)				
421a			***(fa) data from wellness applications;***		
	Article 33(1), point (g)				
422	(g) identification data related to health professionals involved in the treatment of a natural person;		(g) identification data related to ***healthcare providers and categories of*** health professionals involved in the treatment of a natural person ***or in research***;	(g) ~~identification data related to~~ **data on professional status, specialisation and institution of** health professionals involved in the treatment of a natural person;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 33(1), point (h)				
423	(h) population wide health data registries (public health registries);		(h) population wide health data registries (public health registries);	(h) ~~population-wide~~ **population-based** health data registries (public health registries);	
	Article 33(1), point (i)				
424	(i) electronic health data from medical registries for specific diseases;		(i) electronic health data from medical registries for specific diseases;	(i) ~~electronic health~~ data from medical registries ~~for specific diseases~~**and mortality registries** ;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 33(1), point (j)				
425	(j) electronic health data from clinical trials;		(j) electronic health data from clinical trials ***subject to transparency provisions under Union law***;	(j) ~~electronic health data from~~ **data from clinical trials and** clinical ~~trials~~**investigations that have ended in accordance with Article 37(4) of Regulation (EU) 536/2014 and Article 77(5) of Regulation (EU) 2017/745, respectively**;	
	Article 33(1), point (k)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
426	(k) electronic health data from medical devices and from registries for medicinal products and medical devices;		(k) electronic health data from medical devices and from registries for medicinal products and medical devices;	(k) ~~electronic~~ health data from medical devices ~~and from registries for medicinal products and medical devices;~~	
	Article 33(1), point (ka)				
426a				**(ka) data from registries for medicinal products and medical devices;**	
	Article 33(1), point (l)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
427	(l) research cohorts, questionnaires and surveys related to health;		(l) ***data from*** research cohorts, questionnaires and surveys related to health;	(l) **data from** research cohorts, questionnaires and surveys related to health**, after the first publication of results**;	
	Article 33(1), point (m)				
428	(m) electronic health data from biobanks and dedicated databases;		(m) electronic health data from biobanks and dedicated databases;	(m) ~~electronic~~ health data from biobanks and ~~dedicated~~ **associated** databases;	
	Article 33(1), point (n)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
429	(n) electronic data related to insurance status, professional status, education, lifestyle, wellness and behaviour data relevant to health;		*deleted*	(n) ~~electronic~~ data related to ~~insurance status,~~ professional status, education~~, lifestyle, wellness~~ and behaviour data relevant to health;	
	Article 33(1), point (o)				
430	(o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data		(o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data	~~(o) electronic health data containing various improvements such as correction, annotation, enrichment received by the data holder following a processing based on a data~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	permit.		permit.	~~permit.~~ SEE PARA 9 IN THIS ARTICLE]	
		Article 33(2)			
431	2. The requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[1].		2. The ~~*requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC*~~[1] ***Commission, after consulting the EDPB,***	~~2. The requirement in the first subparagraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC[1].~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	_____ 1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).		***EDPS and the Member States, shall adopt guidelines on measures to protect the personal data of health professionals involved in the treatment of natural persons***. _____ ~~*1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).*~~	_____ ~~1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).~~ [MOVED TO ARTICLE 35B(5) AND AMENDED]	
		Article 33(3)			
432	3. The electronic health data referred to in		3. The electronic health data referred to in paragraph	~~3. The electronic health data referred to in paragraph~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	paragraph 1 shall cover data processed for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, collected by entities and bodies in the health or care sectors, including public and private providers of health or care, entities or bodies performing research in relation to these sectors, and Union institutions, bodies, offices and agencies.		1 shall cover data processed for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, collected by entities and bodies in the health or care sectors, including public and private providers of health or care, entities or bodies performing research in relation to these sectors, and Union institutions, bodies, offices and agencies.	~~1 shall cover data processed for the provision of health or care or for public health, research, innovation, policy making, official statistics, patient safety or regulatory purposes, collected by entities and bodies in the health or care sectors, including public and private providers of health or care, entities or bodies performing research in relation to these sectors, and Union institutions, bodies, offices and agencies.~~ [INTEGRATED IN ARTICLE 2(2)(y)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 33(4)				
433	4. Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken.		*deleted*	~~4. Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use. Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken.~~ [SEE ARTICLES 35B(1)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				AND 35A(1)]	
	Article 33(5)				
434	5. Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.		5. ~~*Where the consent*~~***Natural persons shall have the right to opt-out*** of the ~~*natural person is required by national law, health data access bodies*~~***processing of their electronic health data for secondary use. Member States*** shall ~~*rely on the obligations laid down in this Chapter to provide access to*~~ ***provide for an accessible and easily***	~~5. Where the consent of the natural person is required by national law, health data access bodies shall rely on the obligations laid down in this Chapter to provide access to electronic health data.~~ [MOVED TO ARTICLE 37(5)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			understandable opt-out mechanism, whereby natural persons shall be offered the possibility to explicitly express their wish not to have all or part of their personal electronic health data ***processed for some or all secondary use purposes. The exercise of this right to opt-out shall not affect the lawfulness of the processing that took place under Chapter IV before the individual opted-out***.		
	Article 33(5a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
434a			***5a. Without prejudice to paragraph 5, electronic health data referred to under paragraph 1, points (e), (fa) and (m), shall only be made available for secondary use after obtaining the consent of the natural person. Such an opt-in mechanism shall be easily understandable and accessible and provided in a user-friendly format whereby data subjects are made aware of the sensitive nature of the data.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 33(6)				
435	6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation […] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combing it with other data for joint analysis.		6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation […] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combing it with other data for joint analysis.	~~6. Where a public sector body obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation […] [Data Act COM/2022/68 final], in accordance with the rules laid down in that Regulation, it may be supported by a health data access body to provide technical support to process the data or combing it with other data for joint analysis.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO ARTICLE 37(3B)]	
	Article 33(7)				
436	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list in paragraph 1 to adapt it to the evolution of available electronic health data.		*deleted*	~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list in paragraph 1 to adapt it to the evolution of available electronic health data.~~	
	Article 33(8)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
437	8. Health data access bodies may provide access to additional categories of electronic health data that they have been entrusted with pursuant to national law or based on voluntary cooperation with the relevant data holders at national level, in particular to electronic health data held by private entities in the health sector.		*deleted*	~~8~~**3**. ~~Health data access bodies~~**Member States** may provide ~~access to additional categories of electronic health data that they have been entrusted with pursuant to~~ **by virtue of** national law ~~or based on voluntary cooperation with the relevant data holders at national level, in particular to electronic health data held by private entities in the health sector~~**that additional categories of electronic health data shall be made available for secondary use pursuant to this**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Regulation.	
	Article 33(9)				
437a				**4. Member States may establish rules for the processing and use of electronic health data containing various improvements related to processing of electronic health data based on a data permit pursuant to Article 46, such as correction, annotation and enrichment.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[DELETED IN ARTICLE 33(1)(o) AND AMENDED]	
	Article 33(5)				
437b				**5. Member States may introduce stricter measures at a national level aimed at safeguarding the sensitivity and value of the data referred to in Article 33 (1) points (e) and (ea). Member States shall notify the Commission of those rules and measures and shall notify the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Commission without delay of any subsequent amendment affecting them.	
	Article 33a				
437c			***Article 33a*** ***IP rights and trade secrets in secondary use***		
	Article 33a, first subparagraph				
437d			***Electronic health data***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			entailing content protected by intellectual property rights, trade secrets or data covered by regulatory data protection shall be made available for secondary use. In those cases, the following procedure shall apply:		
		Article 33a, first subparagraph, point (a)			
437e			***(a) health data access bodies shall take measures necessary to preserve the confidentiality of such data and to ensure such rights are not infringed;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 33a, first subparagraph, point (b)			
437f			***(b) the Commission shall, after consultation with the EHDS Board, issue guidelines on the identification of commercially confidential information. The guidelines shall outline procedural steps and measures the health data access bodies may undertake to identify and preserve the confidentiality of such information before providing data access to the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data users. The guidance shall be made publicly available;		
	Article 33a, first subparagraph, point (c)				
437g			***(c) health data holders may, when requested to make available to health data access bodies relevant electronic health data pursuant to Article 41(1) which it considers to contain content protected by intellectual property rights, trade secrets or data covered by regulatory data protection, inform the data***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			access body that this is the case and indicate which parts of the datasets are concerned. The determination of which data contains intellectual property, trade secrets or data covered by regulatory data protection shall nevertheless rest with the health data access body;		
		Article 33a, first subparagraph, point (d)			
437h			***(d) health data holders and the health data users may conclude data sharing agreements, in order to***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			share additional data containing protected content protected by intellectual property rights, trade secrets or data covered by regulatory data protection, that would otherwise be made available under point (a). Such agreements shall set out the relevant conditions for the use of such data. The health data holder or the health data user shall inform the health data access body of the conclusion of such an agreement. The Commission shall, by implementing acts draw up templates with standard		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			clauses for such agreements. The implementing acts shall be adopted in accordance with the advisory procedure;		
		Article 33a, first subparagraph, point (e)			
437i			***(e) should the health data access body deem any measures under point (a) to be insufficient to ensure the protection of IP rights, the confidentiality of trade secrets or the data covered by regulatory data protection for regulatory approval, it shall refuse the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			granting of the relevant health data access permit to the health data user;		
		Article 33a, first subparagraph, point (f)			
437j			***(f) the decision of health data access bodies on the measures in point (a) or the refusal of the data in point (e) shall be binding. Health data holders and health data users shall have the right to lodge a complaint in accordance with Article 38a and to a judicial remedy in accordance with Article***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			38b regarding such decisions.		
	Article 34				
438	Article 34 Purposes for which electronic health data can be processed for secondary use		Article 34 Purposes for which electronic health data can be processed for secondary use	Article 34 Purposes for which electronic health data can be processed for secondary use	
	Article 34(1)				
439	1. Health data access		1. Health data access	1. Health data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies shall only provide access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant complies with:		bodies shall only provide access to electronic health data referred to in Article 33 ***to a health data user*** where the ~~*intended purpose of processing pursued*~~***processing of the data*** by the ~~*applicant complies with*~~***data user is necessary for one of the following purposes, and in accordance with Article 6(1), point (c), and Article 9(2), points (g) to (j), of Regulation (EU) 2016/679***:	bodies shall only ~~provide~~**grant** access **for secondary use** to electronic health data referred to in Article 33 ~~where the intended purpose of processing pursued by the applicant complies with~~**to a health data user for the following categories of purposes** :	
		Article 34(1), point (a)			
440					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(a) activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;		(a) activities for reasons of public interest in the area of public ~~*and occupational*~~ health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;	(a) ~~activities for reasons of~~ public interest in the area of public and occupational health, such as **activities for** protection against serious cross-border threats to health~~,~~ **and** public health surveillance or **activities** ensuring high levels of quality and safety of healthcare**, including patient safety,** and of medicinal products or medical devices;	
		Article 34(1), point (b)			
441	(b) to support public sector		(b) to support public sector	(b) **policy making and**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;		bodies ~~*or*~~***and*** Union institutions, agencies and bodies ~~*including regulatory authorities*~~, in the health or care sector to carry out their tasks defined in their mandates ***where processing is necessary for reasons of substantial public interest in the area of public health***;	**regulatory activities** to support public sector bodies or Union institutions, agencies and bodies**,** including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;	
		Article 34(1), point (c)			
442	(c) to produce national, multi-national and Union level official statistics related to health or care		(c) to produce national, multi-national and Union level official statistics ***defined in Regulation (EU)***	(c) ~~to produce~~ **statistics, such as** national, multi-national and Union level official statistics related to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	sectors;		***No 223/2009[1]*** related to health or care sectors; _____ ***1. Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).***	health or care sectors;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 34(1), point (d)				
443	(d) education or teaching activities in health or care sectors;		*deleted*	(d) education or teaching activities in health or care sectors **at the level of vocational or higher education**;	
	Article 34(1), point (e)				
444	(e) scientific research related to health or care sectors;		(e) scientific research related to health or care sectors***, contributing to public health or health***	(e) scientific research related to health or care sectors;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			technology assessment, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices, with the aim of benefitting the end-users, such as patients, health professionals and health administrators, including: ***(i) development and innovation activities for products or services***; ***(ii) training, testing and evaluating of algorithms, including in medical devices, in-vitro diagnostic***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			medical devices, AI systems and digital health applications; ***(iii) university and post-university teaching activities related to scientific research.***		
	Article 34(1), point (f)				
445	(f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of		*deleted*	(f) development and innovation activities ~~for products or services~~ contributing to **the** public health or social security, or **aimed at** ensuring high	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	quality and safety of health care, of medicinal products or of medical devices;			levels of quality and safety of ~~health care~~**healthcare**, of medicinal products or of medical devices~~;~~**, in particular:**	
	Article 34(1), point (i)				
445a				**(i) activities for the development of medicinal products or services of medical devices;**	
	Article 34(1), point (ii)				
445b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(ii) training, testing and evaluating activities of algorithms, including in medical devices, AI systems and digital health applications;	
	Article 34(1), point (g)				
446	(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health		*deleted*	~~(g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	care, of medicinal products or of medical devices;			~~care, of medicinal products or of medical devices;~~ moved to f(ii)	
		Article 34(1), point (h)			
447	(h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.		(h) ~~*providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons*~~***improving delivery of care, treatment optimisation and providing***	(h) providing ~~personalised~~ healthcare ~~consisting in assessing, maintaining or restoring the state of health of natural persons~~, based on the **electronic** health data of other natural persons.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			personalised healthcare.		
	Article 34(2)				
448	2. Access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant fulfils one of the purposes referred to in points (a) to (c) of paragraph 1 shall only be granted to public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks conferred to		2. ~~*Access to electronic health data referred to in Article 33 where the intended purpose of processing pursued by the applicant fulfils one of*~~ The purposes referred to in points (a) to (c) of paragraph 1 shall ~~*only be granted to*~~***be reserved for*** public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks	2. Access to electronic health data ~~referred to in Article 33 where the intended purpose of processing pursued by the applicant fulfils one of~~**for** the purposes referred- to in points (a) to (c) of paragraph ~~1 shall only be granted to~~ **1is reserved for** public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.		conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.	conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.	
		Article 34(3)			
449	3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in		3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in	~~3. The access to privately held data for the purpose of preventing, responding to or assisting in the recovery from public emergencies shall be ensured in~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accordance with Article 15 of the Regulation […] [Data Act COM/2022/68 final].		accordance with Article 15 of the Regulation […] [Data Act COM/2022/68 final].	~~accordance with Article 15 of the Regulation […] [Data Act COM/2022/68 final].~~	
	Article 34(4)				
450	4. Public sector bodies or Union institutions, agencies and bodies that obtain access to electronic health data entailing IP rights and trade secrets in the exercise of the tasks conferred to them by Union law or national law, shall take all specific measures necessary to preserve the confidentiality of such data.		*deleted*	~~4. Public sector bodies or Union institutions, agencies and bodies that obtain access to electronic health data entailing IP rights and trade secrets in the exercise of the tasks conferred to them by Union law or national law, shall take all specific measures necessary to preserve the confidentiality of such data.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO ARTICLE 35A(1) AND AMENDED]	
	Article 35				
451	Article 35 Prohibited secondary use of electronic health data		Article 35 Prohibited secondary use of electronic health data	Article 35 Prohibited secondary use of electronic health data	
	Article 35, first paragraph -1				
451a			***-1. Secondary use of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			electronic health data that is not covered by the data permit pursuant to Article 46 or data requests pursuant to Article 47 shall be prohibited.		
	Article 35, - first paragraph a				
451b			***-1a. Any secondary use of electronic health data for purposes other than those referred to in Article 34 shall be prohibited.***		
	Article 35, first paragraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
452	Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 for the following purposes shall be prohibited:		***1.*** Seeking access to and processing electronic health data obtained via a data permit issued pursuant to Article 46 ***or a data request granted pursuant to Article 47*** for the following purposes shall be prohibited:	~~Seeking access to and processing~~**Health data users shall be prohibited to access, processor use** electronic health data ~~obtained via a~~**outside the scope of the** data permit ~~issued~~**pursuant to Article 46 or data request** pursuant to Article ~~46 for~~**47. In particular,** the following ~~purposes~~**processing and using the electronic health data** shall be prohibited:	
		Article 35, first paragraph, point (a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
453	(a) taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as "decisions", they must produce legal effects or similarly significantly affect those natural persons;		(a) taking decisions detrimental to a natural person ***or group of natural persons*** based on their electronic health data; in order to qualify as "decisions", they must produce legal***, economic or social*** effects or similarly significantly affect those natural persons;	(a) taking decisions detrimental to a natural person **or a group of natural persons** based on their electronic health data; in order to qualify as "decisions", they must produce legal**, social or economical,** effects or similarly significantly affect those natural persons;	
		Article 35, first paragraph, point (b)			
454	(b) taking decisions in relation to a natural person		(b) taking decisions in relation to a natural person	(b) taking decisions in relation to a natural person	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums;		or groups of natural persons ***in relation to job offers or offering less favourable terms in the provision of goods or services, including*** to exclude them from the benefit of an insurance ***or credit*** contract or to modify their contributions and insurance premiums ***or conditions of loans, or taking any other decisions in relation to a natural person or groups of natural persons having the effect of discriminating on the basis of the health data obtained***;	or groups of natural persons to exclude them from the benefit of an insurance contract**, such as life assurance contract or a policy of health insurance or health-related insurance, or to modify their contributions or premiums contract** or to modify their contributions and insurance premiums;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35, first paragraph, point (ba)				
454a				**(ba) activities potentially detrimental to natural persons related to employment, pension and banking, including mortgaging of properties;**	
	Article 35, first paragraph, point (c)				
455	(c) advertising or marketing activities towards health professionals, organisations in health or natural persons;		(c) advertising or marketing activities ~~*towards health professionals, organisations in health or natural persons*~~;	(c) advertising or marketing activities towards health professionals, organisations in health or natural persons**, with the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				exception of public health messaging by competent public sector bodies;	
	Article 35, first paragraph, point (d)				
456	(d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit;		(d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit;	~~(d) providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit;~~ [MOVE TO ARTICLE 35C(2)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35, first paragraph, point (e)				
457	(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality.		(e) developing products or services that may harm individuals***, public health or*** ~~*and*~~ societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco ***and nicotine*** products, ***weaponry or products*** ~~*or goods*~~ or services which are designed or modified in such a way that they ***create addiction or that they*** contravene public order or morality~~.~~***;***	(e) developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services**, services, included those for automated processing,** which are designed or modified in such a way that they contravene public order or ~~morality.~~**cause a risk for human health;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35, 1., point (ea)				
457a			***(ea) automated individual decision-making, including profiling, in accordance with Article 22 of the Regulation (EU) 2016/679, whether solely on the basis of the datasets shared under this Regulation or in combination with other data.***		
	Article 35, first paragraph, point (f)				
457b				**(f) activities in conflict**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				with ethical provisions pursuant to national law;	
	Article 35A				
457c				**Article 35A** **Intellectual property rights and trade secrets**	
	Article 35a, first paragraph				
457d				**1. Where the health data access body or the Union data access service obtain**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				access to electronic health data from health data holders entailing intellectual property rights and/or trade secrets in the exercise of the tasks conferred to them by this Regulation, they shall take all specific measures, including legal, organisational, and technical ones, necessary to preserve the confidentiality of such data. If the health data access body, by itself or in cooperation with other entities, is unable to preserve the confidentiality of intellectual property	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				rights or trade secrets, it shall refuse access to the health data user in that respect. The health data access body shall inform the health data user of this refusal and explain why it is not possible to provide access. [MOVED FROM ARTICLE 34(4) AND AMENDED, SEE ALSO ARTICLE 37(1)(ii)]	
	Article 35a, second paragraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
457e				**2. The health data access body or the Union data access service shall make the legal, organisational and technical measures taken to preserve the confidentiality of electronic health data entailing intellectual property rights or trade secrets referred to in paragraph 1 available to the data holder. Generic information about these measures may be made publicly available.**	
	Article 35b				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
457f				**Article 35B** **Duties of health data holders** Old Article 41	
	Article 35b, first paragraph				
457g				**1. A health data holder is obliged to make the electronic health data under Article 33 they hold available upon request to the health data access**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				body according to a data permit pursuant to Article 46 or data request pursuant to Article 47.	
	Article 35b, (1aa)				
457h				**1aa. Where such electronic health data entail intellectual property rights or trade secrets the health data holder shall inform the health data access body of such intellectual property rights and trade secrets when communicating to the health data access**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				body the dataset descriptions pursuant to Article 35B(2) for the datasets it holds, or at the latest following a request received from the health data access body. If the requested electronic health data is protected by intellectual property rights and/or trade secrets, the health data holder shall justify to the health access body why the data needs specific protection. [MOVED FROM ARTICLES 41(1) AND 33(4) AND	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				AMENDED]	
	Article 35b, (1a)				
457i				**1a. The health data holder shall put the requested electronic health data referred to in paragraph 1 at the disposal of the health data access body within a reasonable time of up to 3 months determined by the health data access body. In justified cases, such as in complex and burdensome request, the health data access body**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				may extend this period by up to 3 additional months. [MOVED FROM ARTICLE 41(4) AND AMENDED]	
	Article 35b, (1b)				
457j				**1b. The health data holder shall fulfil its obligations towards natural persons laid down in Article 35D.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35b, (2)				
457k				**2. The health data holder shall communicate to the health data access body a description of the dataset it holds in accordance with Article 55. The health data holder shall, at a minimum, on an annual basis check that its dataset description in the national datasets catalogue is accurate and up to date.** [MOVED FROM ARTICLE 41(2) AND AMENDED]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35b, (3.)				
457l				**3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the health data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.** [MOVED FROM ARTICLE 41(3)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35b, (4)				
457 m				**4. A health data holder shall cooperate with the health data access body when the body is carrying out its tasks.** [SOME PARTS MOVED FROM ARTICLE 41(1)]	
	Article 35b, (5)				
457n					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Old Art. 41(5) - [MOVED FROM ARTICLE 33(2)] [[THEN MOVED TO ARTICLE 33A AND AMENDED]]	
	Article 35c				
457o				**Article 35C** **Duties of health data users**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35c, first paragraph				
457p				**1. Health data users shall only access and process the electronic health data in accordance with a data permit pursuant to Article 46 or a data request pursuant to Article 47 . This includes a prohibition for health data users to try to re-identify the natural persons in the dataset made available to them or to process and use electronic health data outside the scope of the respectively data permit**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				pursuant to Article 46 or data request pursuant to Article 47, in particular the prohibited purposes pursuant to Article 35 or any other misuse of electronic health data. [MOVED FROM ARTICLE 46(7) AND ARTICLE 44(3)]	
		Article 35c, second paragraph			
457q				**2. When processing electronic health data within the secure**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				processing environments referred to in Article 50, the health data users are prohibited to provide access to or otherwise making the electronic health data available to third parties not mentioned in the data permit. [MOVED FROM ARTICLE 35(d)]	
	Article 35c, third paragraph				
457r					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				3. Health data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, within 18 months after the completion of the electronic health data processing in the secure environment or after having received the answer to the data request referred to in Article 47. This period may in justified cases related to the permitted purposes of the processing of electronic health data be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				extended by the health data access body, in particular in cases where the result is published in a scientific journal or other scientific publication. Those results or output shall only contain anonymous data. The health data users shall inform the health data access bodies from which a data permit was obtained and support them to also make the information related to the results or output provided by the health data users public on health data access bodies' websites. Such publication on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				health data access bodies website shall be without prejudice to publication rights in a scientific journal or other scientific publication. Whenever the health data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the context of the EHDS. [MOVED FROM ARTICLE 46(11) AND AMENDED]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35c, fourth paragraph				
457s				**4. Where required by Member State's law, the health data users shall inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset as referred to in Article 35G.** [MOVED FROM ARTICLE	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				46(12) AND AMENDED]	
	Article 35c, fifth paragraph				
457t				**5. The health data users shall cooperate with the health data access body when the health data access body is carrying out its tasks.**	
	Article 35d				
457u				***Article 35D***	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Information from the health data holder to natural persons	
		Article 35d, first paragraph			
457v				**1. Where Member State law provides that health data holders, in addition to their information obligations under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, health data holders shall inform natural persons about their processing of personal electronic health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data pursuant to this Chapter, the information shall in particular include the following:	
	Article 35d, first paragraph, point (a)				
457 w				**(a) the health data holder's obligation to make personal electronic health data available for secondary use to the health data access body upon request or, in situations referred to in Article 49, the health data holder's role pursuant to that Article;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35d, first paragraph, point (b)				
457x				**(b) the categories of personal electronic health data it holds that may be made available and the purposes for which those data may be processed pursuant to Article 34;**	
	Article 35d, second paragraph				
457y				**2. The information referred to in paragraph 1**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				shall be provided to the natural persons in an easily accessible, intelligible and clearly legible manner and within the timeframe set out respectively in Articles 13(1) and 14(3) of Regulation (EU) 2016/679 or, where applicable Articles 15(1) and 16(3) of Regulation (EU) 2018/1725. Where the health data holder has not obtained the personal electronic health data from the natural person concerned and if the provision of information to each person concerned proves impossible or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				would involve a disproportionate effort in the meaning of Article 14(5)(b) of Regulation (EU) 2016/679 or Article 16(5)(b) of Regulation (EU) 2018/1725 respectively, the health data holder shall take appropriate measures and at the minimum make the information referred to in paragraph 1 publicly available.	
	Article 35d, third paragraph				
457z				**3. The information**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				referred to in paragraph 1 shall also be made publicly available.	
	Article 35d, fourth paragraph				
457aa					
	Article 35d, fifth paragraph				
457ab				**4. Where a Member State has provided for the right to object pursuant to Article 35F,**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35d, fifth paragraph, point (a)				
457ac				**(a) if this right is to be exercised with the data holder, the data holder shall inform the data subject about the procedure to object.**	
	Article 35d, fifth paragraph, point (b)				
457ad				**(b) if this right is to be exercised with the health data access bodies or with**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				the health data intermediation entities, national legislation may define an obligation for the data holder or the health data intermediation entities to inform the data subject about the procedure to object.	
	Article 35e				
457ae				**Article 35E** **Obligations of health data access bodies towards natural persons**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 35e, first paragraph				
457af				**1. Health data access bodies shall make publicly available and easily searchable through electronic means the conditions under which electronic health data is made available for secondary use. This shall include information concerning:**	
	Article 35e, first paragraph, point (a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
457ag				**(a) the legal basis under which access is granted;**	
	Article 35e, first paragraph, point (b)				
457ah				**(b) the technical and organisational measures taken to protect the rights of natural persons;**	
	Article 35e, first paragraph, point (c)				
457ai				**(c) the applicable rights**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				of natural persons in relation to secondary use of electronic health data;	
	Article 35e, first paragraph, point (d)				
457aj				**(d) the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;**	
	Article 35e, first paragraph, point (e)				
457a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
k				**(e) the results or outcomes of the projects for which the electronic health data were used.**	
	Article 35e, second paragraph				
457a l					
	Article 35e, third paragraph				
457a m				**2. If a Member State has provided for the right to object pursuant to Article**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				35F to be exercised at the health data access bodies, the relevant health data access bodies shall provide public information about the procedure to object and facilitate the exercise of this right. Paras 3 and 4 deleted in ST 14216/23	
	Article 35f				
457an				**Article 35F** **Right to object to the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				processing of personal electronic health data for secondary use	
	Article 35f, first paragraph				
457ao				**1. Member States may provide, by way of national legislation, that natural persons falling under their jurisdiction shall have a specific right to object to the processing of their personal electronic health data for the purposes laid down in Article 34(1) under the conditions set out in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				paragraph 2.	
	Article 35f, second paragraph				
457ap				**2. Where Member State law provides for the right to object referred to in paragraph 1, it shall lay down at least the following rules and specific safeguards:**	
	Article 35f, second paragraph, point (a)				
457aq				**(a) Natural persons may**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				exercise this right to object, at any time and without stating reasons, in a simple and accessible manner, including by electronic means;	
		Article 35f, second paragraph, point (b)			
457ar				**(b) Member State law shall lay down whether the right to object is to be exercised with either the health data access bodies, the health data intermediation entities, the health data holders or with more than one of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				them;	
		Article 35f, second paragraph, point (c)			
457as				**(c) After a natural person has exercised the right to object referred to in paragraph 1, the personal electronic health data related to the natural person shall not be made available for secondary use under a data permits pursuant to Article 46 or be processed for secondary use following a data request for electronic health data in a statistical**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				format pursuant to Article 47;	
	Article 35f, second paragraph, point (d)				
457at				**(d) Member State law shall lay down the mechanisms to inform the applicant of, a data permit pursuant to Article 46 or a data request pursuant to Article 47 at the latest prior to the payment of any fees, about the anonymous statistics of natural persons who have exercised the right to object pursuant to this**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				article.	
		Article 35f, third paragraph			
457a u				**3. Member States may restrict the right to object referred to in paragraph 1 under the conditions set out in Article 23 of Regulation (EU) 2016/679, especially for purposes related to public interest in the area of public and occupational health, such as activities for protection against serious cross-border threats to health, and public health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices. In such case, Member States shall implement appropriate and effective measures to inform data subjects about restrictions to the right to object.	
	Article 35g				
457a v				**Article 35G**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Information of findings related to a natural person's health status	
		Article 35g, first paragraph			
457a w				**Where Member States' law to which the health data access body is subject requires health data users to inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset pursuant to a**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data permit the health data access body may, under the conditions laid down in national law, inform the natural person or his or her treating health professional about that finding. [FIRST SENTENCE MOVED FROM ARTICLE 46(12) AND SECOND SENTENCE MOVED FROM ARTICLE 38(3)]	
	Section 2				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
458	Section 2 Governance and mechanisms for the secondary use of electronic health data		Section 2 Governance and mechanisms for the secondary use of electronic health data	Section 2 Governance and mechanisms for the secondary use of electronic health data	
	Article 36				
459	Article 36 Health data access bodies		Article 36 Health data access bodies	Article 36 Health data access bodies	
	Article 36(1)				
460					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. Member States shall designate one or more health data access bodies responsible for granting access to electronic health data for secondary use. Member States may either establish one or more new public sector bodies or rely on existing public sector bodies or on internal services of public sector bodies that fulfil the conditions set out in this Article. Where a Member State designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for		1. Member States shall designate one or more health data access bodies responsible for ~~*granting access to electronic health data for secondary use*~~***the tasks and obligations referred to in Articles 37, 38 and 39 of this Regulation***. Member States may either establish one or more new public sector bodies or rely on existing public sector bodies or on internal services of public sector bodies that fulfil the conditions set out in this Article. Where a Member State	1. Member States shall designate one or more health data access bodies responsible for ~~granting access to electronic health data for secondary use~~**carrying out the tasks set out in Articles 37 and 39** . Member States may either establish one or more new public sector bodies or rely on existing public sector bodies or on internal services of public sector bodies that fulfil the conditions set out in this Article. **The tasks laid down in Article 37 may be divided between different health data access bodies.** Where a Member State	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	coordinating requests with the other health data access bodies.		designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for coordinating ***data access applications and*** requests with the other health data access bodies. ***Each health data access body shall contribute to the consistent application of this Regulation throughout the Union. For that purpose, the health data access bodies shall cooperate with each other and with the Commission,***	designates several health data access bodies, it shall designate one health data access body to act as coordinator, with responsibility for coordinating ~~requests~~ **tasks** with the other health data access bodies **both within the Member State and towards health data access bodies in other Member States**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and, for concerns regarding data protection, with the supervisory authorities under Regulation (EU) 2016/679 as well as with the EDPB and the EDPS.		
		Article 36(2)			
461	2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and		2. Member States shall ensure that each health data access body is provided with the human ***and financial resources, including necessary expertise, and ethics bodies, to support their***	2. Member States shall ensure that each health data access body is provided with the human, technical and financial resources, premises and infrastructure necessary for the effective performance of its tasks and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the exercise of its powers.		***tasks as provided for in Article 37(1), points (a) and (aa), and shall guarantee that all rights of natural persons under this Chapter are respected.*** ***Member States shall also ensure technical*** ~~*, technical and financial*~~ resources, premises and infrastructure necessary for the effective performance of its tasks and the exercise of its powers, ***in a timely manner***.	the exercise of its powers.	
		Article 36(2a)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
461a			***2a. Member States shall ensure that designated separate structures are set up within health data access bodies for the authorisation of the data permit, on the one hand, and for the reception and preparation of the data set, including anonymisation, pseudonymisation of the electronic health data and possible re-identification of natural persons for the purposes of Article 33(5) and 38(3), on the other hand.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 36(3)				
462	3. In the performance of their tasks, health data access bodies shall actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users. Staff of health data access bodies shall avoid any conflicts of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.		3. In the performance of their tasks, health data access bodies shall actively cooperate with ***relevant*** stakeholders' representatives, especially with representatives of patients, ***consumers,*** data holders and data users. ~~*Staff of health data access bodies shall avoid any conflicts of interest. Health data access bodies shall not be bound by any instructions, when making their decisions.*~~	3. In the performance of their tasks, health data access bodies shall ~~actively cooperate with stakeholders' representatives, especially with representatives of patients, data holders and data users. Staff of health data access bodies shall~~ avoid any ~~conflicts~~**conflict** of interest. ~~Health data access bodies shall not be bound by any instructions, when making their decisions~~.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 36(3a)				
462a			***3a. Each health data access body shall act with complete independence in performing its tasks and exercising its powers in accordance with this Regulation. The members of the governance and decision-making bodies and staff of each health data access body shall, in the performance of their tasks and exercise of their powers in accordance with this Regulation, remain free from external influence, whether direct***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			or indirect and shall neither seek nor take instructions from any natural or legal person. Members of the governance and decision-making bodies and staff of each health data access body shall refrain from any action incompatible with their duties and shall not, during their term of office, engage in any incompatible occupation, whether gainful or not.		
		Article 36(4)			
463					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	4. Member States shall communicate to the Commission the identity of the health data access bodies designated pursuant to paragraph 1 by the date of application of this Regulation. They shall also communicate to the Commission any subsequent modification of the identity of those bodies. The Commission and the Member States shall make this information publicly available.		4. Member States shall communicate to the Commission the identity of the health data access bodies designated pursuant to paragraph 1 by the date of application of this Regulation. They shall also communicate to the Commission any subsequent modification of the identity of those bodies. The Commission and the Member States shall make this information publicly available.	4. Member States shall ~~communicate to~~**inform** the Commission **of** the identity of the health data access bodies designated pursuant to paragraph 1 by the date of application of this Regulation. They shall also ~~communicate to~~**inform** the Commission **of** any subsequent modification of the identity of those bodies. The Commission and the Member States shall make this information publicly available.	
	Article 36a				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
463a				***Article 36A*** ***Union data access service***	
	Article 36a(1)				
463b				**1. The Commission shall exercise the tasks set out in Articles 37 and 39 concerning health data holders which are Union institutions, bodies, offices or agencies.**	
	Article 36a(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
463c				**2. The Commission shall ensure that the necessary human, technical and financial resources, premises and infrastructure are allocated to the effective performance of these tasks and the exercise of its duties.**	
	Article 36a(3)				
463d				**3. Unless there is an explicit exclusion, references to the tasks and**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				duties of health data access bodies in this regulation shall also apply to the Commission, where data holders which are Union institutions, bodies, offices, or agencies are concerned.	
	Article 37				
464	Article 37 Tasks of health data access bodies		Article 37 Tasks of health data access bodies	Article 37 Tasks of health data access bodies	
	Article 37(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
465	1. Health data access bodies shall carry out the following tasks:		1. Health data access bodies shall carry out the following tasks:	1. Health data access bodies shall carry out the following tasks:	
		Article 37(1), point (a)			
466	(a) decide on data access applications pursuant to Article 45, authorise and issue data permits pursuant to Article 46 to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II		(a) decide on data access applications pursuant to Article 45, ~~*authorise and issue data permits pursuant to Article 46 to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II*~~	(a) decide on data access applications pursuant to Article 45, authorise and issue data permits pursuant to Article 46 to access electronic health data falling within their national remit for secondary use and decide on data requests ~~in accordance with Chapter II~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of Regulation […] [Data Governance Act COM/2020/767 final] and this Chapter;		~~*of Regulation […] [Data Governance Act COM/2020/767 final] and this Chapter*~~***including deciding on whether the data shall be made accessible in anonymised or pseudonymised form, based on its own thorough assessment of any reasons provided by the health data applicant pursuant to Article 45(2), point (d)***;	~~of Regulation […] [Data Governance Act COM/2020/767 final] and this Chapter~~**pursuant to Article 47 in accordance with this Chapter and Chapter II of Regulation (EU) 2022/868 including**;	
	Article 37(1), point (a)(i)				
466a				**(i) process electronic health data referred to in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Article 33 such as the gathering, combination, preparation and compiling of necessary requested data from health data holders, the pseudonymisation or anonymisation of the data and the disclosure of those data for secondary use to health data users on the basis of a data permit or a data request; [MOVED FROM ARTICLE 37(1)(d)] [MOD.SU.12.rev1]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (a)(ii)				
466b				**(ii) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets of electronic health data before those data are made available for secondary use pursuant to a data permit or a data request taking into account the relevant rights of both the health data holder and health data user;** [MOVED FROM ARTICLE	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				37(1)(d)]	
	Article 37(1), point (a)(iii)				
466c				**(iii) provide access to electronic health data to health data users pursuant to a data permit in a secure processing environment in accordance with the requirements laid down in Article 50.**	
	Article 37(1), point (aa)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
466d			***(aa) assess and issue data permits pursuant to Article 46 of this Regulation and assess data request pursuant to Article 47 of this Regulation to access electronic health data falling within their national remit for secondary use and decide on data requests in accordance with Chapter II of Regulation (EU) .../... […] [Data Governance Act COM/2020/767 final] and this Chapter;***		
		Article 37(1), point (ab)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
466e			***(ab) request electronic health data referred to in Article 33 from relevant health data holders pursuant to a data permit or a data request granted;***		
		Article 37(1), point (ab)			
466f				**(ab) monitor and supervise compliance with the requirements laid down in this Regulation by health data users and health data holders.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM ARTICLE 43(1)]	
	Article 37(1), point (b)				
467	(b) support public sector bodies in carrying out the tasks enshrined in their mandate, based on national or Union law;		(b) support public sector bodies in carrying out the tasks enshrined in their mandate, based on national or Union law;	~~(b) support public sector bodies in carrying out the tasks enshrined in their mandate, based on national or Union law;~~	
	Article 37(1), point (c)				
468					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(c) support Union institutions, bodies, offices and agencies in carrying out tasks enshrined in the mandate of Union institutions, bodies, offices and agencies, based on national or Union law;		(c) support Union institutions, bodies, offices and agencies in carrying out tasks enshrined in the mandate of Union institutions, bodies, offices and agencies, based on national or Union law;	~~(c) support Union institutions, bodies, offices and agencies in carrying out tasks enshrined in the mandate of Union institutions, bodies, offices and agencies, based on national or Union law;~~	
		Article 37(1), point (d)			
469	(d) process electronic health data for the purposes set out in Article 34, including the collection, combination, preparation and disclosure of those data for secondary use on the		(d) process electronic health data for the purposes set out in Article 34, including the ~~*collection,*~~ ~~*combination,*~~ ~~*preparation*~~***combination,*** ***preparation,***	~~(d) process electronic health data for the purposes set out in Article 34, including the collection, combination, preparation and disclosure of those data for secondary use on the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	basis of a data permit;		***anonymisation and pseudonymisation*** and disclosure of those data for secondary use on the basis of a data permit***, while also ensuring proper security of that data***;	~~basis of a data permit;~~ [MOVED TO ARTICLE 37(1)(a)(i) AND AMENDED]	
		Article 37(1), point (e)			
470	(e) process electronic health data from other relevant data holders based on a data permit or a data request for a purposes laid down in Article 34;		*deleted*	~~(e) process electronic health data from other relevant data holders based on a data permit or a data request for a purposes laid down in Article 34;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (f)				
471	(f) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets;		(f) take all measures necessary to preserve the confidentiality of IP rights and ***regulatory data protection, and the confidentiality*** of trade secrets ***as provided for in Article 33a***;	~~(f) take all measures necessary to preserve the confidentiality of IP rights and of trade secrets;~~ [MOVED TO ARTICLE 37(1)(a)(ii) AND AMENDED]	
	Article 37(1), point (g)				
472	(g) gather and compile or provide access to the		(g) ~~*gather and compile or provide access to the*~~	~~(g) gather and compile or provide access to the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	necessary electronic health data from the various data holders whose electronic health data fall within the scope of this Regulation and put those data at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50;		~~necessary~~***based on a data permit, put the relevant*** electronic health data ~~*from the various data holders whose electronic health data fall within the scope of this Regulation and put those data*~~ at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50 ***and store the data for the period of the duration of the data permit***;	~~necessary electronic health data from the various data holders whose electronic health data fall within the scope of this Regulation and put those data at the disposal of data users in a secure processing environment in accordance with the requirements laid down in Article 50;~~ SEE ARTICLE 37(1)(a)(i)]	
		Article 37(1), point (h)			
473					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(h) contribute to data altruism activities in accordance with Article 40;		(h) contribute to data altruism activities in accordance with Article 40;	~~(h) contribute to data altruism activities in accordance with Article 40;~~	
	Article 37(1), point (i)				
474	(i) support the development of AI systems, the training, testing and validating of AI systems and the development of harmonised standards and guidelines under Regulation […] [AI Act COM/2021/206 final] for the training, testing and validation of AI systems in health;		*deleted*	~~(i) support the development of AI systems, the training, testing and validating of AI systems and the development of harmonised standards and guidelines under Regulation […] [AI Act COM/2021/206 final] for the training, testing and validation of AI systems in health;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (j)				
475	(j) cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;		(j) cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;	(j) cooperate with and supervise data holders to ensure the consistent and accurate implementation of the data quality and utility label set out in Article 56;	
	Article 37(1), point (ja)				
475a			***(ja) support data holders that are small enterprises in accordance with***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Commission Recommendation 2003/361/EC, in particular medical practioners and pharmacies, to comply with their obligations under Article 41;		
		Article 37(1), point (k)			
476	(k) maintain a management system to record and process data access applications, data requests and the data permits issued and data requests answered, providing at least information on the name of		(k) maintain a management system to record and process data access applications, data requests***, the decisions on those applications*** and the data permits issued and data requests answered,	(k) maintain a management system to record and process data access applications, data requests**, the decisions on these** and the data permits issued and data requests answered, providing at least	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request;		providing at least information on the name of the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request;	information on the name of the data applicant, the purpose of access the date of issuance, duration of the data permit and a description of the data application or the data request;	
	Article 37(1), point (l)				
477	(l) maintain a public information system to comply with the obligations laid down in Article 38;		(l) maintain a public information system to comply with the obligations laid down in Article 38;	~~(l) maintain a public information system to comply with the obligations laid down in Article 38;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO LETTER Q(V) AND AMENDED]	
	Article 37(1), point (m)				
478	(m) cooperate at Union and national level to lay down appropriate measures and requirements for accessing electronic health data in a secure processing environment;		(m) cooperate at Union and national level to lay down ~~*appropriate measures and requirements*~~***common standards, technical requirements and appropriate measures*** for accessing electronic health data in a secure processing environment;	(m) cooperate at Union and national level to lay down appropriate measures and requirements for accessing electronic health data in a secure processing environment;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (n)				
479	(n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for electronic health data use and management;		(n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for ~~*electronic health data*~~***the secondary*** use and management ***of electronic health data***;	(n) cooperate at Union and national level and provide advice to the Commission on techniques and best practices for **secondary use of** electronic health data ~~use~~ and management;	
	Article 37(1), point (o)				
480	(o) facilitate cross-border access to electronic health data for secondary use		(o) facilitate cross-border access to electronic health data for secondary use	(o) facilitate cross-border access to electronic health data for secondary use	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.		hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.	hosted in other Member States through HealthData@EU and cooperate closely with each other and with the Commission.	
	Article 37(1), point (p)				
481	(p) send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset;		(p) send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset;	~~(p) send to the data holder free of charge, by the expiry of the data permit, a copy of the corrected, annotated or enriched dataset, as applicable, and a description of the operations performed on the original dataset;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (q)				
482	(q) make public, through electronic means:		(q) make public, through electronic means:	(q) make public, through electronic means:	
	Article 37(1), point (q)(i)				
483	(i) a national dataset catalogue that shall include details about the source and nature of electronic health data, in accordance with Articles 56 and 58, and the conditions for making		(i) a national dataset catalogue that shall include details about the source and nature of electronic health data, in accordance with Articles **55,** 56 and 58, and the conditions for making	(i) a ~~national~~ dataset catalogue ~~that shall include details about the source and nature of electronic health data, in accordance with Articles 56 and 58, and the conditions for making~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data available. The national dataset catalogue shall also be made available to single information points under Article 8 of Regulation […] [Data Governance Act COM/2020/767 final];		electronic health data available. The national dataset catalogue shall also be made available to single information points under Article 8 of Regulation […] [Data Governance Act COM/2020/767 final];	~~electronic health data available. The national dataset catalogue shall also be made available to single information points under~~ **referred to in** Article ~~8 of Regulation […] [Data Governance Act COM/2020/767 final];~~**55** [DELETED PARTS MOVED TO ARTICLE 55]	
		Article 37(1), point (q)(ii)			
484	(ii) all data permits,		(ii) all ~~*data permits,*~~	(ii) ~~all~~**data access**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	requests and applications on their websites within 30 working days after issuance of the data permit or reply to a data request;		~~*requests and applications on their websites within 30 working days*~~***health data applications and requests without undue delay*** after ~~*issuance of the data permit or reply to a data request*~~***their reception***;	**applications and** data permits, requests and **answers, including the rejected** applications**,** on their websites within 30 working days after ~~issuance of the~~**deciding on a** data permit or ~~reply to~~ a data request;	
		Article 37(1), point (q)(iia)			
484a			***(iia) all health data permits or requests granted as well as denied, together with a justification, within 30 working days of their issuance;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (q)(iii)				
485	(iii) penalties applied pursuant to Article 43;		(iii) ~~*penalties*~~***enforcement measures*** applied pursuant to Article 43 ***and administrative fines applied pursuant to Article 43a***;	(iii) ~~penalties applied~~ **measures related to non-compliance** pursuant to Article 43;	
	Article 37(1), point (q)(iv)				
486	(iv) results communicated by data users pursuant to Article 46(11);		(iv) results communicated by data users pursuant to Article 46(11);	(iv) results communicated by **health** data users pursuant to Article ~~46(11)~~**35C(3)**;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (q)(v)				
486a				**(v) an information system to comply with the obligations laid down in Article 35E;** [MOVED FROM LETTER L AND AMENDED] [MOD.SU.12.rev1]	
	Article 37(1), point (q)(vi)				
486b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(vi) information of the connection of a national contact point of a third country or an international organisation, as soon as it becomes an authorised participant in HealthData@EU, through electronic means, at minimum on an easily accessible website or web portal.	
	Article 37(1), point (r)				
487	(r) fulfil obligations towards natural persons		(r) fulfil obligations towards natural persons	(r) fulfil obligations towards natural persons pursuant to ~~Article~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	pursuant to Article 38;		pursuant to Article 38;	~~38~~**Articles 35E to 35G**;	
		Article 37(1), point (ra)			
487a			***(ra) monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter; monitoring and supervision shall include regular audits on health data users regarding their processing of electronic health data in the secure processing environment;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 37(1), point (s)				
488	(s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;		(s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;	~~(s) request from data users and data holders all the relevant information to verify the implementation of this Chapter;~~ [SEE LETTER AB]	
	Article 37(1), point (t)				
489	(t) fulfil any other tasks related to making available the secondary use of		(t) fulfil any other tasks related to making available the secondary use of	(t) fulfil any other tasks related to making available the secondary use of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data in the context of this Regulation.		electronic health data in the context of this Regulation.	electronic health data in the context of this Regulation.	
	Article 37(2)				
490	2. In the exercise of their tasks, health data access bodies shall:			2. In the exercise of their tasks, health data access bodies shall:	
	Article 37(2), point (a)				
491	(a) cooperate with supervisory authorities under Regulation (EU) 2016/679 and Regulation		(a) cooperate with supervisory authorities under Regulation (EU) 2016/679 ~~*and Regulation*~~	(a) cooperate with supervisory authorities under Regulation (EU) 2016/679 and Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(EU) 2018/1725 in relation to personal electronic health data and the EHDS Board;		~~(EU) 2018/1725~~ in relation to personal electronic health data and the EHDS Board;	(EU) 2018/1725 in relation to personal electronic health data and the EHDS Board;	
		Article 37(2), point (aa)			
491a			***(aa) immediately notify the relevant supervisory authorities under Regulation (EU) 2016/679 of any potential issue related to the processing of personal electronic health data for secondary use, and exchange any relevant information at their disposal to ensure application and***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			enforcement of this Regulation and relevant provisions of Regulation (EU) 2016/679 and this Regulation, including penalties;		
		Article 37(2), point (b)			
492	(b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 where a health data access body has imposed penalties or other measures pursuant to Article 43 in relation to		(b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 ~~*and Regulation (EU) 2018/1725*~~ where a health data access body has imposed ~~*penalties or other measures*~~***enforcement measures pursuant to***	(b) inform the relevant supervisory authorities under Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 ~~where a health data access body has imposed penalties or other measures pursuant to Article 43 in relation to~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	processing personal electronic health data and where such processing refers to an attempt to re-identify an individual or unlawful processing of personal electronic health data;		***Article 43 or administrative fines*** pursuant to Article ~~43~~***43a*** in relation to processing personal electronic health data and where such processing refers to an attempt to re-identify an individual or unlawful processing of personal electronic health data;	~~processing personal electronic health data and where such processing refers to an attempt to re-identify an individual or~~**of any suspected** unlawful processing of personal electronic health data;	
		Article 37(2), point (c)			
493	(c) cooperate with stakeholders, including patient organisations, representatives from natural		(c) cooperate with ***all relevant*** stakeholders, including patient organisations,	(c) cooperate with stakeholders, including patient organisations, representatives from natural	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	persons, health professionals, researchers, and ethical committees, where applicable in accordance with Union and national law;		representatives from natural persons, health professionals, researchers, and ~~*ethical*~~***ethics*** committees, where applicable in accordance with Union and national law;	persons, health professionals, researchers, and ethical committees, where applicable in accordance with Union ~~and~~ **or** national law;	
		Article 37(2), point (d)			
494	(d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation […] [Data		(d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation […] [Data	(d) cooperate with other national competent bodies, including the national competent bodies supervising data altruism organisations under Regulation ~~[…] [Data~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Governance Act COM/2020/767 final], the competent authorities under Regulation […] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745 and Regulation […] [AI Act COM/2021/206 final] .		Governance Act COM/2020/767 final], the competent authorities under Regulation […] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745 and Regulation […] [AI Act COM/2021/206 final] .	~~Governance Act COM/2020/767 final]~~**(EU) 2022/868** , the competent authorities under Regulation […] [Data Act COM/2022/68 final] and the national competent authorities for Regulations (EU) 2017/745**, (EU) 2017/746** and Regulation […] [AI Act COM/2021/206 final]**, where relevant**~~-~~.	
		Article 37(3)			
495	3. The health data access bodies may provide		3. The health data access bodies may provide	3. The health data access bodies may provide	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation […] [Data Act COM/2022/68 final].		assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation […] [Data Act COM/2022/68 final].	assistance to public sector bodies where those public sector bodies access electronic health data on the basis of Article 14 of Regulation […] [Data Act COM/2022/68 final].	
	Article 37(3a)				
495a				**3a. The health data access body may provide support to a public sector body where it obtains data in emergency situations as defined in Article 15, point (a) or (b) of the Regulation […] [Data Act**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				COM/2022/68 final], in accordance with the rules laid down in that Regulation, by providing technical support to process the data or combining it with other data for joint analysis. [MOVED FROM ARTICLE 33(6)]	
	Article 37(4)				
496	4. The Commission is empowered to adopt			~~4. The Commission is empowered to adopt~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	delegated acts in accordance with Article 67 to amend the list of tasks in paragraph 1 of this Article, to reflect the evolution of activities performed by health data access bodies.		*deleted*	~~delegated acts in accordance with Article 67 to amend the list of tasks in paragraph 1 of this Article, to reflect the evolution of activities performed by health data access bodies.~~	
	Article 37(5)				
496a				**5. Notwithstanding national laws requesting the data subject's consent pursuant to Article 9(4) of Regulation (EU) 2016/679, health data access bodies shall rely on the obligations laid down in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this Chapter, when requesting and processing personal electronic health data from the health data holder and provide access to pseudonymised electronic health data to the health data user. [MOVED FROM ARTICLE 33(5)]	
	Article 38				
497	Article 38 Obligations of health data		Article 38 Obligations of health data	~~Article 38~~ ~~Obligations of health data~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access bodies towards natural persons		access bodies towards natural persons	~~access bodies towards natural persons~~	
	Article 38(1)				
498	1. Health data access bodies shall make publicly available and easily searchable the conditions under which electronic health data is made available for secondary use, with information concerning:		1. Health data access bodies shall make publicly available and easily searchable ***and accessible for natural persons*** the conditions under which electronic health data is made available for secondary use, with information concerning:	~~1. Health data access bodies shall make publicly available and easily searchable the conditions under which electronic health data is made available for secondary use, with information concerning:~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 38(1), point (a)				
499	(a) the legal basis under which access is granted;		(a) the legal basis under which access is granted ***to the health data user***;	~~(a) the legal basis under which access is granted;~~ [MOVED TO ARTICLE 35E(1) AND AMENDED]	
	Article 38(1), point (b)				
500	(b) the technical and organisational measures taken to protect the rights of natural persons;		(b) the technical and organisational measures taken to protect the rights of natural persons;	~~(b) the technical and organisational measures taken to protect the rights of natural persons;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO ARTICLE 35E(1) AND AMENDED]	
		Article 38(1), point (c)			
501	(c) the applicable rights of natural persons in relation to secondary use of electronic health data;		(c) the applicable rights of natural persons in relation to secondary use of electronic health data, ***including the right to opt-out pursuant to Article 33(5) and the right to opt-in pursuant to Article 33(5a), and detailed information on how to***	~~(c) the applicable rights of natural persons in relation to secondary use of electronic health data;~~ [MOVED TO ARTICLE 35E(1) AND AMENDED]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			exercise them;		
		Article 38(1), point (d)			
502	(d) the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;		(d) the ~~*arrangements*~~***modalities*** for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;	~~(d) the arrangements for natural persons to exercise their rights in accordance with Chapter III of Regulation (EU) 2016/679;~~ [MOVED TO ARTICLE 35E(1) AND AMENDED]	
		Article 38(1), point (da)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
502a			***(da) the identity and the contact details of the health data access body;***		
		Article 38(1), point (db)			
502b			***(db) the record on who has been granted access to which sets of electronic health data and a justification regarding the purposes for processing them as referred to in Article 34(1);***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 38(1), point (e)				
503	(e) the results or outcomes of the projects for which the electronic health data were used.		(e) the results or outcomes of the projects for which the electronic health data were used.	~~(e) the results or outcomes of the projects for which the electronic health data were used.~~ [MOVED TO ARTICLE 35E(1) AND AMENDED]	
	Article 38(2)				
504	2. Health data access bodies shall not be obliged to provide the specific		*deleted*	~~2. Health data access bodies shall not be obliged to provide the specific~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.			~~information under Article 14 of Regulation (EU) 2016/679 to each natural person concerning the use of their data for projects subject to a data permit and shall provide general public information on all the data permits issued pursuant to Article 46.~~ [SEE ARTICLE 35E]	
	Article 38(3)				
505	3. Where a health data access body is informed by		3. Where a health data access body is informed by	~~3. Where a health data access body is informed by~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	a data user of a finding that may impact on the health of a natural person, the health data access body may inform the natural person and his or her treating health professional about that finding.		a ***health*** data user of a ~~*finding that may impact on*~~***significant finding related to*** the health of a natural person***, as referred to in Article 41a(5) of this Regulation***, the health data access body ***shall inform the treating health professional with the relevant competence of the natural person and if that health professional cannot be found, and shall inform the natural person about that finding. Natural persons shall have the right to request not to be informed of such findings. In accordance with Article 23(1), point (i), of***	~~a data user of a finding that may impact on the health of a natural person, the health data access body may inform the natural person and his or her treating health professional about that finding.~~ [MOVED TO ARTICLE 35G AND AMENDED]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation (EU) 2016/679, Member States may restrict the scope of the obligation to ~~*may*~~ inform the natural ~~*person and his or her treating*~~***persons whenever necessary for the protection of the natural persons based on patient safety and ethics, by delaying the communication of their information until a*** health professional ~~*about that finding*~~***can communicate and explain to the natural persons information that potentially can have an impact on them***.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 38(4)				
506	4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies.		4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies.	~~4. Member States shall regularly inform the public at large about the role and benefits of health data access bodies.~~	
	Article 38a				
506a			***Article 38a*** ***Right to lodge a complaint with a health data access body***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 38a(1)				
506b			***1. Without prejudice to any other administrative or judicial remedy, natural and legal persons shall have the right to lodge a complaint, individually or, where relevant, collectively, with the health data access body, where their rights laid down in this Chapter are affected. Where the complaint concerns the rights of natural persons pursuant to Article 38(1), point (d), of this Regulation, the health data access body shall inform***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and send a copy of the complaint to the competent supervisory authorities under Regulation (EU) 2016/679.		
		Article 38a(2)			
506c			***2. The health data access body with which the complaint has been lodged shall inform the complainant of the progress of the proceedings and of the decision taken.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 38a(3)				
506d			***3. Health data access bodies shall cooperate to handle and resolve complaints, including by exchanging all relevant information by electronic means, without undue delay.***		
	Article 38a(4)				
506e			***4. Each health data access body shall facilitate submitting complaints, in***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			particular by providing a complaint submission form which can also be completed electronically, without excluding the possibility of using other means of communication.		
	Article 38b				
506f			***Article 38b*** ***Right to an effective judicial remedy against a health data access body***		
	Article 38b(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
506g			***1. Without prejudice to any other administrative or non-judicial remedy, each natural or legal person shall have the right to an effective judicial remedy against a legally binding decision of a health data access body concerning them.***		
	Article 38b(2)				
506h			***2. Without prejudice to any other administrative or non-judicial remedy, each***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural or legal person shall have the right to an effective judicial remedy where the health data access body which is competent pursuant to Article 37 does not handle a complaint or does not inform the natural or legal person within three months about the progress or outcome of the complaint lodged pursuant to Article 38a.		
	Article 38b(3)				
506i			***3. Proceedings against a***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data access body shall be brought before the courts of the Member States where the health data access body is established.		
	Article 39				
507	Article 39 Reporting by health data access bodies		Article 39 Reporting by health data access bodies	Article 39 Reporting by health data access bodies	
	Article 39(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
508	1. Each health data access body shall publish an annual activity report which shall contain at least the following:		1. Each health data access body shall publish an annual activity report ***and make it publicly available on its website,*** which shall contain at least the following ***categories of information***:	1. Each health data access body shall publish ~~an annual~~**a biennial** activity report**. If a Member States designates more than one health data access body, the coordinating body referred to in Article 37(1) shall be responsible for the report and request necessary information from the other health data access bodies. The activity report shall follow a structure agreed within EHDS Board. The activity report** ~~which~~ shall contain at least the following:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 39(1), point (a)				
509	(a) information relating to the data access applications for electronic health data access submitted, such as the types of applicants, number of data permits granted or refused, purposes of access and categories of electronic health data accessed, and a summary of the results of the electronic health data uses, where applicable;		(a) information relating to the data access applications ***and data requests*** for electronic health data access submitted, such as the types of applicants, number of data permits granted or refused, purposes of access and categories of electronic health data accessed, and a summary of the results of the electronic health data uses, where applicable;	(a) information relating to the data access applications for electronic health data access submitted, such as the types of applicants, number of data permits granted or refused, **categories of** purposes of access and categories of electronic health data accessed, and a summary of the results of the electronic health data uses, where applicable;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 39(1), point (b)				
510	(b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;		(b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;	~~(b) a list of data permits involving access to electronic health data processed by the health data access body based on data altruism and a summary description of the general interests purposes pursued, where applicable, including the outcomes of the data permits granted;~~	
	Article 39(1), point (c)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
511	(c) information on the fulfilment of regulatory and contractual commitments by data users and data holders, as well as penalties imposed;		(c) information on the fulfilment of regulatory and contractual commitments by data users and data holders, as well as ~~*penalties*~~***the number and amount of administrative fines*** imposed ***by health data access bodies***;	(c) information on the fulfilment of regulatory and contractual commitments by **health** data users and **health** data holders, as well as penalties imposed;	
		Article 39(1), point (d)			
512	(d) information on audits carried out on data users to ensure compliance of the processing with this		(d) information on audits carried out on data users to ensure compliance of the processing ~~*with*~~***within the***	(d) information on audits carried out on **health** data users to ensure compliance of the processing ~~with~~ **in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Regulation,		***secure processing environment as referred to in Article 50(3) of*** this Regulation~~,~~**;**	**the secure processing environment pursuant to Article 50(1)(e) of** this Regulation,	
		Article 39(1), point (e)			
513	(e) information on audits on compliance of secure processing environments with the defined standards, specifications and requirements;		(e) information on ***internal and third party*** audits on compliance of secure processing environments with the defined standards, specifications and requirements***, as referred to in Article 50(3) of this Regulation***;	(e) information on **third party** audits on compliance of secure processing environments with the defined standards, specifications and requirements **pursuant to Article 50(3) of this Regulation;**~~;~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 39(1), point (f)				
514	(f) information on the handling of requests from natural persons on the exercise of their data protection rights;		(f) information on the handling of requests from natural persons on the exercise of their data protection rights;	(f) information on the handling of requests from natural persons on the exercise of their data protection rights;	
	Article 39(1), point (g)				
515	(g) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural		(g) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural	~~(g) a description of its activities carried out in relation to engagement with and consultation of relevant stakeholders, including representatives of natural~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	persons, patient organisations, health professionals, researchers, and ethical committees;		persons, patient organisations, health professionals, researchers, and ethical committees;	~~persons, patient organisations, health professionals, researchers, and ethical committees;~~	
		Article 39(1), point (h)			
516	(h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence;		(h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence;	~~(h) information on cooperation with other competent bodies in particular in the area of data protection, cybersecurity, data altruism, and artificial intelligence;~~	
		Article 39(1), point (i)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
517	(i) revenues from data permits and data requests;		(i) revenues from data permits and data requests;	(i) revenues from data permits and data requests;	
	Article 39(1), point (j)				
518	(j) satisfaction from applicants requesting access to data;		*deleted*	~~(j) satisfaction from applicants requesting access to data;~~	
	Article 39(1), point (k)				
519	(k) average number of days between application and		(k) average number of days between application and	(k) average number of **working** days between	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access to data;		access to data;	application and access to data;	
	Article 39(1), point (l)				
520	(l) number of data quality labels issued, disaggregated per quality category;		(l) number of data quality labels issued ***by data holders***, disaggregated per quality category;	(l) number of data quality labels issued, disaggregated per quality category;	
	Article 39(1), point (m)				
521	(m) number of peer-reviewed research publications, policy		(m) number of peer-reviewed research publications, policy	~~(m) number of peer-reviewed research publications, policy~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	documents, regulatory procedures using data accessed via the EHDS;		documents, regulatory procedures using data accessed via the EHDS;	~~documents, regulatory procedures using data accessed via the EHDS;~~	
	Article 39(1), point (n)				
522	(n) number of digital health products and services, including AI applications, developed using data accessed via EHDS.		(n) number of digital health products and services, including AI applications, developed using data accessed via EHDS.	(n) number of digital health products and services, including AI applications, developed using data accessed via EHDS.	
	Article 39(2)				
523	2. The report shall be		2. The report shall be	2. The report shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	transmitted to the Commission.		transmitted to the Commission***, which shall make it publicly available on its website***.	~~transmitted~~ **sent** to the Commission **and the EHDS Board within 6 months after the end date of the 2 year reporting period**.	
		Article 39(3)			
524	3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to modify the content of the annual activity report.		3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to ~~*modify the content of the annual activity report*~~***amend paragraph 1 of this Article by adding categories to those listed in that***	~~3. The Commission is empowered to adopt delegated acts in accordance with Article 67 to modify the content of the annual activity report.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			paragraph.		
	Article 40				
525	Article 40 Data altruism in health		Article 40 Data altruism in health	~~Article 40~~ ~~Data altruism in health~~	
	Article 40(1)				
526	1. When processing personal electronic health data, data altruism organisations shall comply with the rules set out in		1. ~~*When processing personal electronic health data,*~~***In addition to rules regarding*** data altruism ~~*organisations shall comply*~~	~~1. When processing personal electronic health data, data altruism organisations shall comply with the rules set out in~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Chapter IV of Regulation […] [Data Governance Act COM/2020/767 final]. Where data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation.		~~with the rules set out in~~***established by Regulation (EU) 2022/868, where data altruism organisations recognised under*** Chapter IV of ~~*Regulation […] [Data Governance Act COM/2020/767 final]. Where data altruism organisations*~~***that Regulation*** process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation.	~~Chapter IV of Regulation […] [Data Governance Act COM/2020/767 final]. Where data altruism organisations process personal electronic health data using a secure processing environment, such environments shall also comply with the requirements set out in Article 50 of this Regulation.~~ MOVED TO ARTICLE 50(3A)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 40(2)				
527	2. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of Regulation […] [Data Governance Act COM/2020/767 final] in the monitoring of entities carrying out data altruism activities.		2. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of Regulation ~~*[…] [Data Governance Act COM/2020/767 final]*~~ ***(EU) 2022/868*** in the monitoring of entities carrying out data altruism activities***, where electronic health data are concerned***.	~~2. Health data access bodies shall support the competent authorities designated in accordance with Article 23 of Regulation […] [Data Governance Act COM/2020/767 final] in the monitoring of entities carrying out data altruism activities.~~	
	Article 41				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
528	Article 41 Duties of data holders		Article 41 Duties of ***health*** data holders	~~Article 41~~ ~~Duties of data holders~~	
	Article 41(1)				
529	1. Where a data holder is obliged to make electronic health data available under Article 33 or under other Union law or national legislation implementing Union law, it shall cooperate in good faith with the health data access		1. ~~*Where a data holder is obliged to make*~~***Health data holders shall make relevant*** electronic health data ~~*available*~~ under Article 33 ~~*or under other Union law or national legislation implementing Union law,*~~ ~~*it*~~***available upon request to***	~~1. Where a data holder is obliged to make electronic health data available under Article 33 or under other Union law or national legislation implementing Union law, it shall cooperate in good faith with the health data access~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies, where relevant.		***the health data access body pursuant to a data permit issued or data request granted by such a body. Health data holders*** shall cooperate in good faith with the health data access bodies, where relevant.	~~bodies, where relevant.~~ MOVED TO ARTICLE 35B(1)	
	Article 41(1a)				
529a			***1a. The requirement laid down in the first paragraph shall not apply to data holders that qualify as micro enterprises as defined in Article 2 of the Annex to Commission***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Recommendation 2003/361/EC.		
	Article 41(1b)				
529b			***1b. The health data holder shall put the electronic health data at the disposal of the health data access body within three months of receiving the request from the health data access body. In justified cases, after consultation with the health data holder concerned, that period may be extended by the health data access body for a***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			maximum of two months. The health data access body may decide that the extension is to be shorter than two months.		
	Article 41(1c)				
529c			***1c. Paragraphs 1 and 1a of this Article constitute a legal obligation pursuant to Article 6(1), point (c), of this Regulation in combination with Article 9(2), points (g) (to (j), of Regulation 2016/679 for the health data holder to disclose personal electronic***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data to the health data access body.		
	Article 41(2)				
530	2. The data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55.		2. The ***health*** data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55.	~~2. The data holder shall communicate to the health data access body a general description of the dataset it holds in accordance with Article 55.~~ MOVED TO ARTICLE 35B(2)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 41(3)				
531	3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.		3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the ***health*** data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.	~~3. Where a data quality and utility label accompanies the dataset pursuant to Article 56, the data holder shall provide sufficient documentation to the health data access body for that body to confirm the accuracy of the label.~~ MOVED TO ARTICLE 35B(3)	
	Article 41(4)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
532	4. The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months.		*deleted*	~~4. The data holder shall put the electronic health data at the disposal of the health data access body within 2 months from receiving the request from the health data access body. In exceptional cases, that period may be extended by the health data access body for an additional period of 2 months.~~ MOVED TO ARTICLE 35B(1A)	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 41(5)				
533	5. Where a data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.		5. Where a ***health*** data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.	~~5. Where a data holder has received enriched datasets following a processing based on a data permit, it shall make available the new dataset, unless it considers it unsuitable and notifies the health data access body in this respect.~~ SEE ARTICLE 33(9)	
	Article 41(6)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
534	6. Data holders of non-personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.		6. ***Health*** data holders of non-personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.	~~6. Data holders of non-personal electronic health data shall ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation. Trusted open public databases shall have in place a robust, transparent and sustainable governance and a transparent model of user access.~~	
		Article 41(7)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
535	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the duties of the data holders in this Article, to reflect the evolution of activities performed by data holders.		*deleted*	~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the duties of the data holders in this Article, to reflect the evolution of activities performed by data holders.~~	
	Article 41a				
535a			***Article 41a*** ***Duties of health data users***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 41a(1)				
535b			***1. Health data users may access and process the electronic health data for secondary use referred to in Article 33 only in accordance with the data permit issued by the health data access body in accordance with Article 46 of this Regulation.***		
	Article 41a(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
535c			***2. Health data users shall not re-identify or seek to re-identify the natural persons to whom the electronic health data which they obtained based on the data permit or data request belong. Such conduct shall be considered a serious breach of this Regulation.***		
	Article 41a(3)				
535d			***3. Health data users shall make public the results or***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those results or output shall not contain personal data. In justified cases, especially cases referred to in Article 34(1), point (e), that period may be extended by the relevant health data access body, after consultation with the health data user. The		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data users shall inform the health data access bodies from which a data permit was obtained about the results or output and provide them with necessary support in order to make them public also on health data access bodies' websites. The result shall also be made publicly available in lay summaries. Whenever the health data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health data has been obtained in the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			context of the EHDS.		
	Article 41a(4)				
535e			***4. Without prejudice to paragraph 2, health data users shall inform the health data access body of any significant findings related to the health of the natural person whose data are included in the dataset.***		
	Article 41a(5)				
535f					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			5. The ECDC and the EMA shall, in consultation and cooperation with relevant stakeholders, including representatives of patients, health professionals and researchers, create guidelines in order to help health data users to fulfil their obligation under paragraph 5, especially to determine whether their findings are clinically significant.		
	Article 41a(6)				
535g					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			6. The ECDC and the EMA shall, in consultation and cooperation with relevant stakeholders, including representatives of patients, health professionals and researchers, create guidelines in order to help health data users to fulfil their obligation under paragraph 5, especially to determine whether their findings are clinically significant.		
	Article 42				
536					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 42 Fees		Article 42 Fees	Article 42 Fees	
	Article 42(1)				
537	1. Health data access bodies and single data holders may charge fees for making electronic health data available for secondary use. Any fees shall include and be derived from the costs related to conducting the procedure for requests, including for assessing a data application or a data request, granting, refusing		1. Health data access bodies ~~*and single data holders may charge fees*~~***may charge fees to health data users*** for making electronic health data available for secondary use. Any fees shall include and be derived from the costs related to ***the set up, combination, preparation, anonymisation,***	1. Health data access bodies ~~and~~**or** single **health** data holders **referred to in Article 49** may charge fees for making electronic health data available for secondary use. ~~Any~~**Such** fees shall ~~include and be derived from the costs related to conducting the procedure for requests, including~~ **be in proportion to the cost of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	or amending a data permit pursuant to Articles 45 and 46 or providing an answer to a data request pursuant to Article 47, in accordance with Article 6 of Regulation […] [Data Governance Act COM/2020/767 final]		***pseudonymisation, maintenance, tasks under Article 33a, making available or updating of the dataset and*** conducting the procedure for requests, including for assessing a data application or a data request, granting, refusing or amending a data permit pursuant to Articles 45 and 46 or providing an answer to a data request pursuant to Article 47, in accordance with Article 6 of Regulation […] [Data Governance Act COM/2020/767 final]***. No fees shall be charged to public sector bodies and Union institutions, offices, agencies and bodies when***	**making the data available and not restrict competition. Such fees shall cover all or part of costs related to the procedure** for assessing a data **permit** application or a data request, granting, refusing or amending a data permit pursuant to ~~Articles~~**Article** 45 and 46 or providing an answer to a data request pursuant to Article 47, ~~in accordance with~~**as well as costs related to the gathering, preparation and provisioning of the electronic health data. This provision prevails over** Article 6 of Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			making data available for the purposes referred to in Article 34(1), points (a), (b) and(c). No fees shall be charged to public sector bodies or Union institutions, offices, agencies and bodies with a legal mandate in the field of public health.	~~[…] [Data Governance Act COM/2020/767 final]~~**(EU)2022/868 for health data holders and single data holders from the public sector. Reduced fees may be established by the Member States for certain types of data users located in the Union, such as university researchers or micro-enterprises.**	
		Article 42(2)			
538	2. Where the data in question are not held by the data access body or a public		2. ***In the case of health data holders,*** where the data in question are not held	2. Where the **electronic health** data in question are ~~not~~ held by ~~the data access~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	sector body, the fees may also include compensation for part of the costs for collecting the electronic health data specifically under this Regulation in addition to the fees that may be charged pursuant to paragraph 1. The part of the fees linked to the data holder's costs shall be paid to the data holder.		by the ***health*** data access body or a public sector body ***or a Union institution, office, agency and body***, the fees may ~~*also include compensation for part of*~~***be derived from*** the costs for ~~*collecting*~~***gathering, enriching, and preparing*** the electronic health data specifically under this Regulation in addition to the fees that may be charged pursuant to paragraph 1. The part of the fees linked to the ***health*** data holder's costs shall be paid to the ***health*** data holder.	~~body or a public sector~~**a health data holder or a data intermediation entity which is not a health data access** body, the fees **charged pursuant to paragraph 1** may also include compensation for ~~part of the costs for collecting~~ **costs incurred by the health data holder compiling and preparing** the electronic health data ~~specifically under this Regulation in addition to the fees that may be charged pursuant to paragraph 1~~**to be made available for secondary use. When the health data holder is a public sector body, Article**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				6 of Regulation (EU)2022/868 shall not apply. The part of the fees linked to the **health** data holder's costs shall be paid to the **health** data holder.	
		Article 42(3)			
539	3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the		3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the	~~3. The electronic health data referred to in Article 33(1), point (o), shall be made available to a new user free of charge or against a fee matching the compensation for the costs of the human and technical resources used to enrich the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data. That fee shall be paid to the entity that enriched the electronic health data.		electronic health data. That fee shall be paid to the entity that enriched the electronic health data.	~~electronic health data. That fee shall be paid to the entity that enriched the electronic health data.~~	
	Article 42(4)				
540	4. Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict		4. Any fees charged to ***health*** data users pursuant to this Article by the health data access bodies or ***health*** data holders shall be transparent***, non-discriminatory,*** and proportionate to the cost of ~~*collecting and*~~ making electronic health data available for secondary use,	~~4. Any fees charged to data users pursuant to this Article by the health data access bodies or data holders shall be transparent and proportionate to the cost of collecting and making electronic health data available for secondary use, objectively justified and shall not restrict~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update tat dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees proportionately to their size or budget.		objectively justified and shall not restrict competition. The support received by the ***health*** data holder from donations, public national or Union funds, to set up, develop or update ~~tat~~***that*** dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, ***academic and*** educational institutions, ***non-commercial entities*** and healthcare providers shall be taken into account when setting the fees, by	~~competition. The support received by the data holder from donations, public national or Union funds, to set up, develop or update tat dataset shall be excluded from this calculation. The specific interests and needs of SMEs, public bodies, Union institutions, bodies, offices and agencies involved in research, health policy or analysis, educational institutions and healthcare providers shall be taken into account when setting the fees, by reducing those fees proportionately to their size or budget.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			reducing those fees proportionately to their size or budget.		
	Article 42(5)				
541	5. Where data holders and data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the data holder or the data user disagree with the fee set out		5. Where ***health*** data holders and ***health*** data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the ***health*** data holder or the	~~5. Where data holders and data users do not agree on the level of the fees within 1 month of the data permit being granted, the health data access body may set the fees in proportion to the cost of making available electronic health data for secondary use. Where the data holder or the data user disagree with the fee set out~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation […] [Data Act COM/2022/68 final].		***health*** data user disagree with the fee set out by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation […] [Data Act COM/2022/68 final].	~~by the health data access body, they shall have access to dispute settlement bodies set out in accordance with Article 10 of the Regulation […] [Data Act COM/2022/68 final].~~	
	Article 42(5a)				
541a				**5a. Before issuing a data permit pursuant to Article 46 or providing an answer to a data request pursuant to Article 47, the health data access body shall**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				inform the applicant of the expected fees. The applicant shall be informed about the option to withdraw the application. If the applicant withdraw its application, the applicant shall only be charged the costs that have already been incurred.	
		Article 42(6)			
542	6. The Commission may, by means of implementing acts, lay down principles and rules for the fee		6. The Commission ~~*may*~~***shall***, by means of implementing acts, lay down principles and rules	6. The Commission may, ~~by means of implementing acts, lay down principles and rules for the~~**in close**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	policies and fee structures. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		for the fee policies and fee structures***, including deductions for the entities listed in paragraph 4, second sub-paragraph***. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	**cooperation with the EHDS Board, issue guidelines on** fee policies and fee structures~~. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2)~~ **in order to support consistency and transparency between Member States**.	
		Article 43			
543	Article 43 Penalties by health data		Article 43 ~~*Penalties*~~***Enforcement*** by	Article 43 ~~Penalties~~**Non-compliance**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access bodies		health data access bodies	by health data ~~access bodies~~**holder and health data user**	
	Article 43(1)				
544	1. Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter.		*deleted*	~~1. Health data access bodies shall monitor and supervise compliance by data users and data holders with the requirements laid down in this Chapter.~~ [MOVED TO ARTICLE 37(1)(ab)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 43(2)			
545	2. When requesting from data users and data holders the information that is necessary to verify compliance with this Chapter, the health data access bodies shall be proportionate to the performance of the compliance verification task.		2. When ~~*requesting from data users and data holders the information that is necessary*~~***carrying out its monitoring and supervisory tasks*** to verify compliance with this Chapter, ***as referred to in Article 37(1), point (ra),*** the health data access bodies shall ~~*be*~~***request information from health data holders and users that is*** proportionate ~~*to*~~***for*** the performance of the ~~*compliance verification*~~	2. When ~~requesting from data users and data holders the information that is necessary to verify compliance with this Chapter, the~~**health data access bodies perform their monitoring and supervising tasks the bodies have the right to request and receive from** health data ~~access bodies shall be proportionate to the performance of the~~**users and health data holders all**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			task.	**the necessary information to verify** compliance ~~verification task~~**with this Chapter**.	
	Article 43(3)				
546	3. Where health data access bodies find that a data user or data holder does not comply with the requirements of this Chapter, they shall immediately notify the data user or data holder of those findings and shall give it the opportunity to state its views within 2 months.		3. Where health data access bodies find that a ***health*** data user or ***health*** data holder does not comply with the requirements of this Chapter, they shall immediately notify the ***health*** data user or ***health*** data holder of those findings and shall give it the opportunity to state its	3. Where **a** health data access ~~bodies find~~**body finds** that a **health** data user or **a health** data holder does not comply with the requirements of this Chapter, ~~they~~ **it** shall immediately notify the **health** data user or **health** data holder of those findings and **take**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			views within ~~*2 months*~~*4 weeks.* *Where the finding of non-compliance concerns a possible breach of Regulation (EU) 2016/679, the health data access body shall immediately inform the supervisory authorities under Regulation (EU) 2016/679 and provide them with all relevant information at their disposal concerning this finding to ensure application and enforcement of the relevant provisions of that Regulation, including*	**appropriate measures. The health data access body** shall give ~~it~~**the concerned health data user or the health data holder** the opportunity to state its views within **a reasonable time** ~~2 months~~.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			penalties.		
	Article 43(4)				
547	4. Health data access bodies shall have the power to revoke the data permit issued pursuant to Article 46 and stop the affected electronic health data processing operation carried out by the data user in order to ensure the cessation of the non-compliance referred to in paragraph 3, immediately or within a reasonable time limit, and shall take appropriate and		4. Health data access bodies shall have the power to revoke the data permit issued pursuant to Article 46 and stop the affected electronic health data processing operation carried out by the ***health*** data user in order to ensure the cessation of the non-compliance referred to in paragraph 3, immediately or ~~*within a reasonable time limit*~~***without undue delay***,	4. **With regard to non-compliance by a health data user pursuant to a data permit,** health data access bodies shall have the power to revoke the data permit issued pursuant to Article 46 and stop the affected electronic health data processing operation carried out by the **health** data user ~~in order to ensure the cessation of the non-compliance referred to in~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	proportionate measures aimed at ensuring compliant processing by the data users. In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the data user from any access to electronic health data for a period of up to 5 years.		and shall take appropriate and proportionate measures aimed at ensuring compliant processing by the ***health*** data users. In this regard, the health data access bodies shall be able, where appropriate, to revoke the data permit and to exclude the ***health*** data user from any access to electronic health data for a period of up to 5 years.	~~paragraph 3,~~ immediately or within a reasonable time limit, and shall take appropriate and proportionate measures aimed at ensuring compliant processing by the **health** data users~~.~~ In this regard, the health data access bodies shall **also** be able, where appropriate, ~~to revoke the data permit and~~ **to exclude or initiate proceedings** to exclude **in accordance with national law the health**~~the~~ data user from any access to electronic health data **within the EHDS in the context of secondary use** for a period of up to 5 years.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43(4a)				
547a				**4a. Where a health data access body finds that a health data user is processing or using the electronic health data outside the scope of the data permit for the prohibited uses laid down in Article 35 or a health data user does not respect the health data access body's measures ensuring pseudonymisation, it shall immediately revoke the data permit issued.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43(5)				
548	5. Where data holders withhold the electronic health data from health data access bodies with the manifest intention of obstructing the use of electronic health data, or do not respect the deadlines set out in Article 41, the health data access body shall have the power to fine the data holder with fines for each day of delay, which shall be transparent and proportionate. The amount		5. Where ***health*** data holders withhold the electronic health data from health data access bodies with the manifest intention of obstructing the use of electronic health data, or do not respect the deadlines set out in Article 41, the health data access body shall have the power to fine the ***health*** data holder with fines for each day of delay, which shall be transparent and proportionate. The amount	5. **With regard to non-compliance by a health data holder,** where **health** data holders withhold the electronic health data from health data access bodies with the manifest intention of obstructing the use of electronic health data, or do not respect the deadlines set out in Article ~~41~~**35B(1a)**, the health data access body shall have the power to fine the **health** data holder with ~~fines~~**periodic penalty**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of the fines shall be established by the health data access body. In case of repeated breaches by the data holder of the obligation of loyal cooperation with the health data access body, that body can exclude the data holder from participation in the EHDS for a period of up to 5 years. Where a data holder has been excluded from the participation in the EHDS pursuant to this Article, following manifest intention of obstructing the secondary use of electronic health data, it shall not have the right to provide access to health data in accordance		of the fines shall be established by the health data access body. In case of repeated breaches by the ***health*** data holder of the obligation of loyal cooperation with the health data access body, that body can exclude the ***health*** data holder from ~~*participation in the EHDS*~~***submitting data access applications pursuant to Chapter IV*** for a period of up to 5 years~~.~~ ~~*Where a data holder has been excluded from the participation in the EHDS*~~**,** ***while still being obliged to make data accessible*** pursuant to ~~*this Article, following manifest intention*~~	**payment in accordance with national law** for each day of delay, which shall be transparent and proportionate. The amount of the fines shall be established by the health data access body. In case of repeated breaches by the **health** data holder of the obligation of ~~loyal~~ cooperation with the health data access body, that body ~~can~~ **may** exclude ~~the data holder from participation in the EHDS for a period of up to 5 years. Where a~~**or initiate proceedings to exclude in accordance with national law the health** data holder ~~has been~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with Article 49.		~~*of obstructing the secondary use of electronic health data, it shall not have the right to provide access to health data in accordance with Article 49*~~***Chapter IV, where applicable***.	~~excluded from the~~**from** participation in the EHDS ~~pursuant to this Article, following manifest intention of obstructing the~~ **in the context of** secondary use ~~of electronic health data, it shall not have the right to provide access to health data in accordance with Article 49.~~**for a period of up to 5 years.**	
		Article 43(6)			
549	6. The health data access body shall communicate the measures imposed pursuant		6. The health data access body shall communicate the measures imposed pursuant	6. The health data access body shall communicate the measures imposed pursuant	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to paragraph 4 and the reasons on which they are based to the data user or holder concerned, without delay, and shall lay down a reasonable period for the data user or holder to comply with those measures.		to ~~*paragraph*~~***paragraphs*** 4 and ***5 and*** the reasons on which they are based to the ***health*** data user or holder concerned, without delay, and shall lay down a reasonable period for the ***health*** data user or holder to comply with those measures.	to paragraph 4 and the reasons on which they are based to the **health** data user or holder concerned, without delay, and shall lay down a reasonable period for the **health** data user or holder to comply with those measures.	
		Article 43(7)			
550	7. Any penalties and measures imposed pursuant to paragraph 4 shall be made available to other health data access bodies.		7. Any ~~*penalties and*~~***enforcement*** measures imposed pursuant to paragraph 4 shall be ~~*made available*~~***notified*** to other	7. Any **measures imposed by the health data access body** ~~penalties and measures imposed~~ pursuant to paragraph 4 shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data access bodies ***and made publicly available on the website of the EHDS Board***.	~~made available~~ **notified** to other health data access bodies**, through the tool referred to in paragraph 8**.	
		Article 43(7a)			
550a			***7a. The health data access body shall ensure coherent enforcement based on the provisions of this Regulation and Regulation (EU) 2016/679 by taking into account any decision or investigation ongoing in supervisory authorities.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43(8)				
551	8. The Commission may, by means of implementing act, set out the architecture of an IT tool aimed to support and make transparent to other health data access bodies the activities referred to in this Article, especially penalties and exclusions. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		8. The Commission may, by means of implementing act, set out the architecture of an IT tool aimed to support and make transparent to other health data access bodies the activities referred to in this Article, especially penalties and exclusions. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	8. The Commission ~~may~~**shall** , by means of implementing act, set out the architecture of an IT tool aimed to support and make transparent to other health data access bodies the ~~activities~~ **measures related to non-compliance** referred to in this Article, especially ~~penalties~~**periodic penalty payments, revoking of data permits** and exclusions. Those implementing acts shall be	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	
	Article 43(9)				
552	9. Any natural or legal person affected by a decision of a health data access body shall have the right to an effective judicial remedy against such decision.		*deleted*	*9.* Any natural or legal person affected by a decision of a health data access body shall have the right to an effective judicial remedy against such decision.	
	Article 43(10)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
553	10. The Commission may issues guidelines on penalties to be applied by the health data access bodies.		10. The Commission ~~*may issues*~~***shall issue*** guidelines on ~~*penalties*~~***enforcement measures*** to be applied by the health data access bodies***, in accordance with the principles set out in Article 68a***.	10. The Commission may ~~issues~~**issue** guidelines**, in close cooperation with EHDS Board, on periodic penalty payments and other measures** ~~on penalties~~ to be applied by the health data access bodies.	
		Article 43a			
553a			***Article 43a*** ***General conditions for the imposition of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			administrative fines by health data access bodies		
	Article 43a(1)				
553b			***1. Each health data access body shall ensure that the imposition of administrative fines pursuant to this Article in respect of infringements referred to in paragraphs 4 and 5 shall in each individual case be effective, proportionate and dissuasive.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43a(2)				
553c			***2. Administrative fines shall, depending on the circumstances of each individual case, be imposed in addition to, or instead of, measures referred to in Article 43(4) and (5). When deciding whether to impose an administrative fine and deciding on the amount of the administrative fine in each individual case due regard shall be given to the following:***		
	Article 43a(2), point (a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
553d			***(a) the nature, gravity and duration of the infringement;***		
		Article 43a(2), point (b)			
553e			***(b) whether any penalties or administrative fines have already been applied by other competent authorities to the same infringing party for the same infringement;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43a(2), point (c)				
553f			***(c) the intentional or negligent character of the infringement;***		
	Article 43a(2), point (d)				
553g			***(d) any action taken by the health data holder or health data user to mitigate the damage suffered by natural persons;***		
	Article 43a(2), point (e)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
553h			***(e) the degree of responsibility of the health data user, taking into account technical and organisational measures implemented by them pursuant to Article 45(2), points (e) and (f),and Article 45(4);***		
	Article 43a(2), point (f)				
553i			***(f) any relevant previous infringements by the health data holder or health data user;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43a(2), point (g)				
553j			***(g) the degree of cooperation with the health data access body, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;***		
	Article 43a(2), point (h)				
553k			***(h) the manner in which the infringement became***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			known to the health data access body, in particular whether, and if so to what extent, the health data user notified the infringement;		
		Article 43a(2), point (i)			
553l			***(i) where measures referred to in Article 43(4) and (5) have previously been ordered against the controller or processor concerned with regard to the same subject-matter, compliance with those measures;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43a(2), point (j)				
553 m			***(j) any other aggravating or mitigating factor applicable to the circumstances of the case, such as financial benefits gained, or losses avoided, directly or indirectly, from the infringement.***		
	Article 43a(3)				
553n			***3. If a health data holder***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			or health data user intentionally or negligently, for the same or linked health data permits or health data requests, infringes several provisions of this Regulation, the total amount of the administrative fine shall not exceed the amount specified for the gravest infringement.		
	Article 43a(4)				
553o			***4. In accordance with paragraph 2, infringements of the obligations of the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data holder or health data user pursuant to Article 41 and Article 41a(1), (4), (5) and (7) shall be subject to administrative fines of up to 10 000 000 EUR, or in the case of an undertaking, up to 2 % of the total worldwide annual turnover of the preceding financial year, whichever is higher.		
	Article 43a(5)				
553p			***5. Infringements of the following provisions shall, in accordance with***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			paragraph 2, be subject to administrative fines of up to EUR 20 000 000, or in the case of an undertaking, of up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher;		
	Article 43a(5), point (a)				
553q			***(a) health data users processing electronic health data obtained via a data permit issued in line with Article 46 for the purposes referred to in Article 35;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 43a(5), point (b)				
553r			***(b) health data users extracting personal health data outside the secure processing environment provided by the health data access body pursuant to Article 50;***		
	Article 43a(5), point (c)				
553s			***(c) re-identifying or seeking to re-identify the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			natural persons to whom the electronic health data which they obtained based on the data permit or data request pursuant to Article 41a(3) belong;		
		Article 43a(5), point (d)			
553t			***(d) non-compliance with enforcement measures by the health data access body pursuant to Article 43.***		
		Article 43a(6)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
553u			***6. Without prejudice to the corrective powers of health data access bodies pursuant to Article 43, each Member State may lay down the rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.***		
	Article 43a(7)				
553v			***7. The exercise by the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data access body of its powers under this Article shall be subject to appropriate procedural safeguards in accordance with Union and Member State law, including effective judicial remedies and due process.		
		Article 43a(8)			
553 w			***8. Where the legal system of the Member State does not provide for administrative fines, this Article may be applied in such a manner that the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			fine is initiated by the competent health data access body and imposed by competent national courts, while ensuring that those legal remedies are effective and have an equivalent effect to the administrative fines imposed by health data access bodies. In any event, the fines imposed shall be effective, proportionate and dissuasive. Those Member States shall notify the Commission of the provisions of their laws which they adopt pursuant to this paragraph by ... [date of application of this Regulation] and, without		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			delay, any subsequent amendment law or amendment affecting them.		
	Article 43A				
553x				**Article 43A** **Relationship with data protection supervisory authorities**	
	Article 43a(1)				
553y				**The supervisory**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				authority or authorities responsible for monitoring and enforcement the application of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725 shall also be responsible for monitoring and enforcement the processing of personal electronic health data for secondary use, in accordance with the relevant provisions of Regulation (EU) 2016/679 or of Regulation (EU) 2018/1725 respectively. They shall be competent to impose administrative fines up to the amount referred to in Article 83	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and 52 respectively of those Regulations. Those supervisory authorities and the health data access bodies referred to in Article 36 of this Regulation shall, where relevant, cooperate in the enforcement of this Regulation, within the remit of their respective competences.	
	Section 3				
554	Section 3 Data permit for the secondary use of electronic health data		Section 3 Data permit for the secondary use of electronic health data	Section 3 ~~Data permit for the secondary use of~~**Access to** electronic health data **for**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				secondary use	
	Article 44				
555	Article 44 Data minimisation and purpose limitation		Article 44 Data minimisation and purpose limitation	Article 44 Data minimisation and purpose limitation	
	Article 44(1)				
556	1. The health data access body shall ensure that access is only provided to requested electronic health		1. The health data access body shall ensure that access is only provided to requested electronic health	1. The health data access body shall ensure that access is only provided to requested electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data relevant for the purpose of processing indicated in the data access application by the data user and in line with the data permit granted.		data ***that are adequate,*** relevant ~~*for*~~***and limited to what is necessary in relation to*** the purpose of processing indicated in the data access application by the data user and in line with the data permit granted.	data relevant for the purpose of processing indicated in the data ~~access~~ **permit** application by the **health** data user and in line with the data permit granted.	
		Article 44(2)			
557	2. The health data access bodies shall provide the electronic health data in an anonymised format, where the purpose of processing by the data user can be		2. The health data access bodies shall provide the electronic health data in an anonymised format, ***in any event*** where the purpose of processing by the ***health***	2. The health data access bodies shall provide ~~the~~ electronic health data in an anonymised **or anonymised statistical** format, where the purpose of processing by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	achieved with such data, taking into account the information provided by the data user.		data user can be achieved with such data, taking into account the information provided by the ***health*** data user.	the **health** data user can be achieved with such data, taking into account the information provided by the **health** data user.	
		Article 44(3)			
558	3. Where the purpose of the data user's processing cannot be achieved with anonymised data, taking into account the information provided by the data user, the health data access bodies shall provide access to electronic health data in pseudonymised		3. Where the ~~*purpose of the data user's*~~***health data user has sufficiently demonstrated that the purpose of*** processing cannot be achieved with anonymised data ***in line with Article 46(1c)***, taking into account the information provided by the ***health data***	3. Where the purpose of the **health** data user's processing cannot be achieved with anonymised data, taking into account the information provided by the **health** data user, the health data access bodies shall provide access to electronic health data in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	format. The information necessary to reverse the pseudonymisation shall be available only to the health data access body. Data users shall not re-identify the electronic health data provided to them in pseudonymised format. The data user's failure to respect the health data access body's measures ensuring pseudonymisation shall be subject to appropriate penalties.		***userthe*** ~~*data user; the*~~ health data access bodies shall provide access to electronic health data in pseudonymised format. The information necessary to reverse the pseudonymisation shall be available only to the health data access body. ***Health*** Data users shall not re-identify the electronic health data provided to them in ***anonymised or*** pseudonymised format. ~~*The data user's failure to respect the health data access body's measures ensuring pseudonymisation shall be subject to appropriate penalties.*~~	pseudonymised format. The information necessary to reverse the pseudonymisation shall be available only to the health data access body~~. Data users shall not re-identify the electronic health data provided to them in pseudonymised format. The data user's failure to respect the health data access body's measures ensuring pseudonymisation shall be subject to appropriate penalties.~~ **or a body that acts as trusted third party in accordance with national law.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[THIRD SENTENCE MOVED TO ARTICLE 35C(1). LAST SENTENCE SEE ARTICLE 43(4A)]	
	Article 44(3a)				
558a			***3a. The health data user's failure to respect the health data access body's measures ensuring anonymisation and pseudonymisation shall be considered a particularly serious breach of this Regulation and shall be subject to effective,***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			proportionate and dissuasive penalties.		
	Article 44(3b)				
558b			***3b. The Commission shall, by means of implementing acts, set out the procedures and requirements, and provide technical tools, for a unified procedure for anonymising and pseudonymising the electronic health data. Those implementing acts shall be adopted in accordance with the advisory procedure***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			referred to in Article 68(2).		
	Article 45				
559	Article 45 Data access applications		Article 45 Data access applications	Article 45 Data access applications	
	Article 45(1)				
560	1. Any natural or legal person may submit a data access application for the purposes referred to in Article 34.		1. ~~*Any natural or legal person*~~***Health data applicants*** may submit a data access application for the purposes referred to in	1. ~~Any~~**A** natural or legal person may submit a data access application for the purposes referred to in Article 34 **to the health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Article 34.	**data access body**.	
	Article 45(2)				
561	2. The data access application shall include:		2. The data access application shall include:	2. The data access application shall include **a data utilisation plan with the following information**:	
	Article 45(2), point (-a)				
561a			***(-a) the health data applicant's identity, description of professional functions and operations,***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			including the identity of the natural persons who will have access to electronic health data, if a data permit is granted; the list of natural persons can be updated and in that case it shall be notified to the health data access body;		
	Article 45(2), point (aa)				
561b				**(aa) a description of the applicant's identity, professional function and activities, including the identity of the natural persons who will have**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				access to the electronic health data;	
		Article 45(2), point (a)			
562	(a) a detailed explanation of the intended use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;		(a) a detailed explanation of the intended use of the electronic health data~~,~~ including for which of the purposes referred to in Article 34(1)**,** access is ~~*sought*~~***necessary***;	(a) ~~a~~ detailed explanation of the intended **use and expected benefit related to the** use of the electronic health data, including for which of the purposes referred to in Article 34(1) access is sought;	
		Article 45(2), point (aa)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
562a			***(aa) a description of how the health data applicant is qualified vis-à-vis the intended purposes of data use, including professional qualifications to demonstrate appropriate expertise, consistent with ethical practice and applicable laws and regulations;***		
	Article 45(2), point (ab)				
562b			***(ab) an explanation of the expected benefits and how***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			these benefits contribute to the purposes referred to in Article 34(1);		
	Article 45(2), point (b)				
563	(b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from several Member States;		(b) a description of the requested electronic health data, their ***timeframe,*** format and data sources, where possible, including geographical coverage where data is requested from several Member States;	(b) a description of the requested electronic health data, their format and data sources, where possible, including geographical coverage where data is requested from **health data holder in** several Member States **or authorised participants in the cross-border infrastructure referred to in Article 52**;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 45(2), point (c)				
564	(c) an indication whether electronic health data should be made available in an anonymised format;		(c) an ~~*indication*~~***explanation*** whether electronic health data ~~*should*~~***needs to*** be made available in ~~*an anonymised*~~***a pseudonymised*** format ***and why the envisaged purpose for processing cannot be pursued using anonymised data***;	(c) ~~an indication~~ **a description** whether electronic health data **need to** ~~should~~ be made available in ~~an~~**a pseudonymised or** anonymised format;	
	Article 45(2), point (d)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
565	(d) where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format;		(d) ~~*where applicable, an explanation*~~***a description*** of the ~~*reasons for seeking access to electronic health data in a pseudonymised format*~~***safeguards planned to prevent any other use or any misuse of the electronic health data***;	~~(d) where applicable, an explanation of the reasons for seeking access to electronic health data in a pseudonymised format;~~ [MOVED TO PARA 4(aa)]	
		Article 45(2), point (e)			
566	(e) a description of the safeguards planned to prevent any other use of the electronic health data;		(e) a description of the safeguards ***proportionate to the risks,*** planned to ~~*prevent any other*~~	(e) a description of the safeguards planned to prevent any ~~other use~~ **misuse** of the electronic	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			~~use~~***protect the rights and interests*** of the ~~*electronic*~~ health data ***holder***;	health data**, including re-identification of natural persons in the dataset**;	
	Article 45(2), point (ea)				
566a				**(ea) in case the applicant intends to bring datasets it already holds into the secure processing environment, a description of those datasets;**	
	Article 45(2), point (f)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
567	(f) a description of the safeguards planned to protect the rights and interests of the data holder and of the natural persons concerned;		(f) ***for personal electronic health data,*** a description of the ~~*safeguards planned*~~***necessary technical and organisational measures pursuant to Article 32 of Regulation (EU) 2016/679;*** to protect the rights and interests of the ~~*data holder and of the*~~***natural persons concerned, including to prevent any re-identification of*** natural persons ~~*concerned*~~***in the dataset***;	(f) a description of the safeguards planned to protect the rights and interests of the **health** data holder and of the natural persons concerned;	
		Article 45(2), point (g)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
568	(g) an estimation of the period during which the electronic health data is needed for processing;		(g) ~~an~~***a justified*** estimation of the period during which the electronic health data is needed for processing;	(g) an ~~estimation~~**indication** of the period during which the electronic health data is needed for processing **in a secure processing environment**;	
	Article 45(2), point (h)				
569	(h) a description of the tools and computing resources needed for a secure environment.		(h) a description of the tools and computing resources needed for a secure environment.	(h) a description of the tools and computing resources needed for a secure environment.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 45(2), point (ha)				
569a			***(ha) where applicable, information on the assessment of ethical aspects of the processing and details of any necessary ethics approval obtained by the competent ethics committee in line with national law, which may serve to replace their own ethics assessment;***		
	Article 45(2), point (hb)				
569b					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			(hb) a plan defining audiences and tools to provide information publicly on the results or outcomes of the access to the data in accordance with Article 46(11);		
		Article 45(2), point (hc)			
569c			***(hc) a declaration that the intended uses of the data requested do not pose a risk of stigmatisation of or causing harm to the dignity of individuals or the groups to which the dataset***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			requested relates.		
	Article 45(2), point (i)				
569d				**(i) information on the assessment of ethical aspects of the processing, where applicable and in line with national law.** [MOVED FROM ARTICLE 45(4)(b)]	
	Article 45(3)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
570	3. Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the request with other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data access application. For requests to access electronic health data from more than one Member States, the		3. ***Health data applicants*** ~~*Data users*~~ seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the ~~*request with*~~ ***application with the*** other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data access application. ~~*For requests to access*~~	~~3. Data users seeking access to electronic health data from more than one Member State shall submit a single application to one of the concerned health data access bodies of their choice which shall be responsible for sharing the request with other health data access bodies and authorised participants in HealthData@EU referred to in Article 52, which have been identified in the data access application. For requests to access electronic health data from more than one Member States, the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.		~~*electronic health data from more than one Member States*~~***In such a case***, the health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.	~~health data access body shall notify the other relevant health data access bodies of the receipt of an application relevant to them within 15 days from the date of receipt of the data access application.~~ [MOVED TO ARTICLE 45(5A) AND AMENDED]	
		Article 45(4)			
571	4. Where the applicant intends to access the		4. Where the ~~*applicant intends*~~***health data***	~~43~~. Where the applicant ~~intends to~~ **seeks for** access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	personal electronic health data in a pseudonymised format, the following additional information shall be provided together with the data access application:		***applicants intend*** to access the personal electronic health data in a pseudonymised format, the following additional information shall be provided together with the data access application:	the personal electronic health data in a pseudonymised format **in a secure processing environment**, the following additional information shall be provided together with the data access application:	
	Article 45(4), point (aa)				
571a				**(aa) a detailed justification on the reasons why access to electronic health data in an anonymised form is not sufficient for the intended use;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM PARA 2(D)]	
		Article 45(4), point (a)			
572	(a) a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679;		(a) a description of how the processing would comply with ~~*Article 6(1) of*~~ ***applicable Union and national law on data protection and privacy, notably*** Regulation (EU) 2016/679;	(a) a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 **or Articles 5(1) and 10(2) of Regulation (EU) 2018/1725**;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 45(4), point (ba)				
572a				**(ba) a description of how the processing would comply with Chapter V of Regulations (EU) 2016/679 or (EU) 2018/1725 respectively, where applicable;**	
	Article 45(4), point (b)				
573	(b) information on the assessment of ethical aspects of the processing, where applicable and in line		*deleted*	~~(b) information on the assessment of ethical aspects of the processing, where applicable and in line~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with national law.			~~with national law.~~ [MOVED TO ARTICLE 45(2)(i)]	
	Article 45(4), point (c)				
573a				**(c) a documented data protection impact assessment required by Article 35 of Regulation (EU) 2016/679 or Article 39 of Regulation (EU) 2018/1725, where applicable.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 45(5), first subparagraph				
574	5. For the implementation of the tasks referred to in Article 37(1), points (b) and (c), the public sector bodies and the Union institutions, bodies, offices and agencies shall provide the same information as requested under Article 45(2), except for point (g), where they shall submit information concerning the period for which the data can be accessed, the frequency of that access or the frequency		5. For the implementation of the tasks referred to in Article 37(1), points (b) and (c), the public sector bodies and the Union institutions, bodies, offices and agencies shall provide the same information as requested under Article 45(2), except for point (g), where they shall submit information concerning the period for which the data can be accessed, the frequency of that access or the frequency	~~54~~. ~~For the implementation of the tasks referred to in Article 37(1), points (b) and (c),~~ The public sector bodies and the Union institutions, bodies, offices and agencies shall provide the same information as requested under Article 45(2) **and 45(4)**, except for point (g) **in 45(2)**, where they shall submit information concerning the period for which the **electronic health** data can be accessed, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of the data updates.		of the data updates.	frequency of that access or the frequency of the data updates.	
	Article 45(5), second subparagraph				
575	Where the public sector bodies and the Union institutions, bodies, offices and agencies intend to access the electronic health data in pseudonymised format, a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 or Article 5(1) of Regulation (EU)		*deleted*	~~Where the public sector bodies and the Union institutions, bodies, offices and agencies intend to access the electronic health data in pseudonymised format, a description of how the processing would comply with Article 6(1) of Regulation (EU) 2016/679 or Article 5(1) of Regulation (EU)~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	2018/1725, as applicable, shall also be provided.			~~2018/1725, as applicable, shall also be provided.~~	
	Article 45(5)				
575a				**5. Where an applicant seeks access to electronic health data from health data holders established in different Member State or from other authorised participants in the cross-border infrastructure referred to in Article 52, the applicant shall submit a single data access application through the Health Data Access Body**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				of their main establishment or through the services provided by the Commission in the cross-border infrastructure HealthData@EU referred to in Article 52. The application shall be automatically forwarded to the authorised participants identified in the data access application and to the Health Data Access Bodies of the Member States where the data holders and the authorised participants identified in the data access application have their main establishment.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				MOVED FROM ARTICLE 45(3)	
	Article 45(6)				
576	6. The Commission may, by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in accordance with		6. The Commission ~~may~~***shall***, by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in	~~6. The Commission may, by means of implementing acts, set out the templates for the data access application referred to in this Article, the data permit referred to in Article 46 and the data request referred to in Article 47. Those implementing acts shall be adopted in accordance with~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the procedure referred to in Article 68(2).		accordance with the procedure referred to in Article 68(2).	~~the procedure referred to in Article 68(2).~~ [MOVED TO ARTICLE 47A]	
		Article 45(7)			
577	7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of		7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of the list for	~~7. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of information in paragraphs 2, 4, 5 and 6 of this Article, to ensure the adequacy of the list for~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the list for processing a data access application at national or cross-border level.		processing a data access application at national or cross-border level.	~~processing a data access application at national or cross-border level.~~	
	Article 46				
578	Article 46 Data permit		Article 46 Data permit	Article 46 Data permit	
	Article 46(1)				
579	1. Health data access bodies shall assess if the		1. Health data access bodies shall ~~*assess if the*~~	-1. **The** health data access bodies shall ~~assess if the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	application fulfils one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit.		***issue a data permit only when, after an assessment of the data access*** application***, they find that it*** fulfils ~~*one*~~***all*** of the ~~*purposes listed in Article 34(1) of this Regulation, if*~~***following criteria:*** ***(a) the purpose described in the health data access application is one of the purposes listed in Article 34(1);*** ***(b)*** the requested data is necessary***, adequate and proportionate*** for the purpose ***or purposes*** listed	~~application fulfils one of the purposes listed in Article 34(1) of this Regulation, if the requested data is necessary for the purpose listed in the application and if the requirements in this Chapter are fulfilled by the applicant. If that is the case, the health data access body shall issue a data permit.~~**decide to grant or refuse access to electronic health data on the basis of the following criteria:**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			in the ***health data access*** application***;***		
			(c) in the case of pseudonomised data, there is sufficient justification that the purpose cannot be achieved with anonymised data;		
			(d) the processing complies with Article 6(1) and Article 9(2) of Regulation (EU) 2016/679 in ~~*and if the requirements in this Chapter are fulfilled by the applicant. If that is*~~ the case~~,~~ ***of access to pseudonymised***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			electronic health data;		
			(e) the health data ~~*access body shall issue a data permit*~~***applicant demonstrates sufficient technical and organisational measures to prevent any other use or misuse of the electronic health data and to protect the rights and interests of the data holder and of the natural persons concerned;***		
			(f) the information on the assessment of ethical aspects of the processing, where applicable, is in line		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			with national law; ***(g) all other requirements in this Chapter are fulfilled by the health data applicant***.		
	Article 46(-1), first subparagraph, point (a)				
579a				**(a) the purpose described in the data permit application matches one or more of the purposes listed in Article 34(1) of this Regulation;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 46(-1), first subparagraph, point (b)				
579b				**(b) the requested data is necessary for the purpose described in the data access application taking into account the provisions of data minimisation and purpose limitation in Article 44;**	
	Article 46(-1), first subparagraph, point (c)				
579c				**(c) the processing complies with Article 6(1) of Regulation (EU)**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2016/679 or Article 5(1) of Regulation (EU) 2018/1725, in case of access to pseudonymised electronic health data, as well as Chapter V in those Regulations respectively, where applicable;	
	Article 46(-1), first subparagraph, point (d)				
579d				**(d) the information provided in the application demonstrates sufficient safeguards to protect the rights and interests of the health data holder and of the natural**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				persons concerned as well as to prevent misuse;	
	Article 46(-1), first subparagraph, point (e)				
579e				**(e) the information on the assessment of ethical aspects of the processing, where applicable, complies with national law;**	
	Article 46(-1), first subparagraph, point (f)				
579f				**(f) other requirements in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this Chapter.	
	Article 46(1), (1A)				
579g				**1A. The health data access body shall also take into account the following risks:**	
	Article 46(-1), second subparagraph, point (a)				
579h				**(a) risks for national defence, security, public security and public order;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 46(-1), second subparagraph, point (b)				
579i				**(b) risks of undermining protected IP-rights and trade secrets and privacy of natural persons;**	
	Article 46(-1), second subparagraph, point (c)				
579j				**(c) risk of undermining confidential data in governmental databases of regulatory authorities;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 46(-1), second subparagraph, point (d)				
579k				**(d) risk of misuse, including the prohibited use in Article 35.**	
	Article 46(2)				
580	2. Health data access bodies shall refuse all applications including one or more purposes listed in Article 35 or where requirements in this		2. Health data access bodies shall refuse all applications ~~*including one or more purposes listed in Article 35 or*~~ where requirements in this Chapter	2. **If the** health data access ~~bodies shall refuse all applications including one or more purposes listed in Article 35 or~~**body in its assessment comes to the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Chapter are not met.		are not met.	**conclusion that the requirements in paragraph 1 are met and the risks referred to in paragraph 2 are sufficiently mitigated, the health data access body shall issue a data permit. Health data access bodies shall refuse all applications** where **the** requirements in this Chapter are not met. **Alternatively, a health data access body may decide to provide an answer in an anonymous statistical format under article 47, if this approach mitigates the risks and if the purpose of the data access application can be**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				fulfilled in this manner.	
		Article 46(3)			
581	3. A health data access body shall issue or refuse a data permit within 2 months of receiving the data access application. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period for responding to a data access application by 2 additional months where necessary,		3. ~~A~~***After the health data applicant has demonstrated the effective implementation of their security measures referred to in Article 45(2), points (e) and (f), the*** health data access body shall issue or refuse a data permit within 2 months of receiving ***a complete data access application. If the health data access body finds that*** the data access application	3. **By way of derogation from that Regulation (EU) 2022/868,**a health data access body shall issue or refuse a data permit within ~~2~~**3** months of receiving the data access application. ~~By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final],~~ The health data access body may extend the period for responding to a data access	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	taking into account the complexity of the request. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued.		***is incomplete, it shall notify the health data applicant, who shall be given the possibility of completing their application. If the health data applicant does not fulfill this request within four weeks, a permit shall not be granted***. By way of derogation from that Regulation ~~*[...] [Data Governance Act COM/2020/767 final]*~~,***(EU) 2022/868*** the health data access body may extend the period for responding to a data access application by 2 additional months where necessary, taking into account the complexity of the request. In such cases,	application by ~~2~~**3** additional months where necessary, taking into account the **urgency and** complexity of the request **and the volume of requests submitted for decision**. In such cases, the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. ~~Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued~~.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the health data access body shall notify the applicant as soon as possible that more time is needed for examining the application, together with the reasons for the delay. ~~*Where a health data access body fails to provide a decision within the time limit, the data permit shall be issued.*~~		
	Article 46(3A)				
581a				**3A. When handling a data access application for cross-border access to electronic health data**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				referred to in Article 45(5A), health data access bodies and relevant authorised participants in HealthData@EU referred to in Article 52, shall remain responsible for taking decisions to grant or refuse access to electronic health data within their remit in accordance with the requirements in this Chapter. The concerned health data access bodies and authorised participants shall inform each other of their decisions and may take the information into consideration when	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				deciding on granting or refusing access to electronic health data. [MOVED FROM ARTICLE 54(1)]	
	Article 46(3AA)				
581b				**3AA. Member States may provide for an accelerated application procedure for public sector bodies and Union institutions, bodies, offices and agencies if the processing of the data is to**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				be carried out for the purposes in Article 34(1), letters (a) to (c).	
	Article 46(4)				
582	4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the data holder. The health data access body shall make available the electronic health data to the data user within 2 months after receiving them from the data holders, unless the		4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the data holder ***and inform them whether the data will be made accessible in anonymised or pseudonymised form***. The health data access body shall make available the	4. Following the issuance of the data permit, the health data access body shall immediately request the electronic health data from the **health** data holder. The health data access body shall make available the electronic health data to the **health** data user within 2 months after receiving them from the **health** data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data access body specifies that it will provide the data within a longer specified timeframe.		electronic health data to the ***health*** data user within 2 months after receiving them from the data holders~~, unless the health data access body specifies that it will provide the data within a longer specified timeframe~~.	holders, unless the health data access body specifies that it will provide the data within a longer specified timeframe.	
		Article 46(4a)			
582a				**4a. In situations referred to in paragraph 3A the concerned health data access bodies and authorised participants who issued a data permit,**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				may decide to provide access to the electronic health data in the secure processing environment provided by the Commission as referred to in Article 52(10).	
		Article 46(5)			
583	5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the applicant.		5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the ***health data*** applicant.	5. When the health data access body refuses to issue a data permit, it shall provide a justification for the refusal to the applicant.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 46(6)				
584	6. The data permit shall set out the general conditions applicable to the data user, in particular:		6. The data permit shall set out the general conditions applicable to the ***health*** data user, in particular:	6. **When the health data access body issues a** ~~The~~ data permit**, it** shall set out the general conditions applicable to the **health** data user~~, in particular~~ **in the data permit. The data permit shall contain the following**:	
	Article 46(6), point (a)				
585	(a) types and format of electronic health data		(a) ~~*types*~~***categories*** and format of electronic health	(a) ~~types~~**categories, specification** and format of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accessed, covered by the data permit, including their sources;		data accessed, covered by the data permit, including their sources;	electronic health data accessed, covered by the data permit, including their sources **and if the electronic health data will be accessed in a pseudonymised format in the secure processing environment**;	
		Article 46(6), point (b)			
586	(b) purpose for which data are made available;		(b) ***a detailed description of the*** purpose for which data are made available;	(b) **a detailed description of the** purpose for which data are made available;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 46(6), point (ba)				
586a			***(ba) the identity of the user as well as the concrete persons who are authorised to have access to the electronic health data in the secure processing environment;***		
	Article 46(6), point (ba)				
586b				**(ba) the identity of authorised persons who will have the right to access the electronic**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				health data in the secure processing environment;	
	Article 46(6), point (c)				
587	(c) duration of the data permit;		(c) duration of the data permit;	(c) duration of the data permit;	
	Article 46(6), point (d)				
588	(d) information about the technical characteristics and tools available to the data user within the secure		(d) information about the technical characteristics and tools available to the ***health*** data user within the secure	(d) information about the technical characteristics and tools available to the **health** data user within the secure	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	processing environment;		processing environment;	processing environment;	
	Article 46(6), point (e)				
589	(e) fees to be paid by the data user;		(e) fees to be paid by the ***health*** data user;	(e) fees to be paid by the **health** data user;	
	Article 46(6), point (f)				
590	(f) any additional specific conditions in the data permit granted.		(f) any additional specific conditions in the data permit granted.	(f) any additional specific conditions in the data permit granted.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 46(7)				
591	7. Data users shall have the right to access and process the electronic health data in accordance with the data permit delivered to them on the basis of this Regulation.		7. Data users shall have the right to access and process the electronic health data in ***a secure processing environment in*** accordance with the data permit delivered to them on the basis of this Regulation.	7. Data users shall have the right to access and process the electronic health data in accordance with the data permit delivered to them on the basis of this Regulation. [MOVED TO ARTICLE 35C(1)]	
	Article 46(8)				
592	8. The Commission is		8. The Commission is	~~8. The Commission is~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph 7 of this Article, in accordance with the procedure set out in Article 67.		empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph ~~7~~**6** of this Article, in accordance with the procedure set out in Article 67.	~~empowered to adopt delegated acts to amend the list of aspects to be covered by a data permit in paragraph 7 of this Article, in accordance with the procedure set out in Article 67.~~	
	Article 46(9)				
593	9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed 5 years. This duration may be extended once, at the		9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed 5 years. This duration may be extended once, at the	9. A data permit shall be issued for the duration necessary to fulfil the requested purposes which shall not exceed ~~5~~ **10** years. This duration may be extended once, at the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	request of the data user, based on arguments and documents to justify this extension provided, 1 month before the expiry of the data permit, for a period which cannot exceed 5 years. By way of derogation from Article 42, the health data access body may charge increasing fees to reflect the costs and risks of storing electronic health data for a longer period of time exceeding the initial 5 years. In order to reduce such costs and fees, the health data access body may also propose to the data user to store the dataset in storage system with		request of the data user, based on arguments and documents to justify this extension provided, 1 month before the expiry of the data permit, for a period which cannot exceed 5 years. By way of derogation from Article 42, the health data access body may charge increasing fees to reflect the costs and risks of storing electronic health data for a longer period of time exceeding the initial 5 years. In order to reduce such costs and fees, the health data access body may also propose to the data user to store the dataset in storage system with reduced	request of the **health** data user, based on arguments and documents to justify this extension provided, 1 month before the expiry of the data permit, for a period which cannot exceed ~~5~~ **10** years. ~~By way of derogation from Article 42,~~ The health data access body may charge increasing fees to reflect the costs and risks of storing electronic health data for a longer period of time exceeding the initial ~~5~~ ~~years~~**period** . In order to reduce such costs and fees, the health data access body may also propose to the **health** data user to store the dataset in storage system	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	reduced capabilities. The data within the secure processing environment shall be deleted within 6 months following the expiry of the data permit. Upon request of the data user, the formula on the creation of the requested dataset shall be stored by the health data access body.		capabilities. The data within the secure processing environment shall be deleted ~~*within 6 months*~~***without undue delay*** following the expiry of the data permit. Upon request of the data user, the formula on the creation of the requested dataset shall be stored by the health data access body.	with reduced capabilities. **Such reduced capabilities shall not affect the security of the processed dataset. The electronic health** ~~The~~ data within the secure processing environment shall be deleted within 6 months following the expiry of the data permit. Upon request of the **health** data user, the formula on the creation of the requested dataset ~~shall~~ **may** be stored by the health data access body.	
		Article 46(10)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
594	10. If the data permit needs to be updated, the data user shall submit a request for an amendment of the data permit.		10. If the data permit needs to be updated, the data user shall submit a request for an amendment of the data permit.	10. If the data permit needs to be updated, the **health** data user shall submit a request for an amendment of the data permit.	
	Article 46(11)				
595	11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion		*deleted*	~~11. Data users shall make public the results or output of the secondary use of electronic health data, including information relevant for the provision of healthcare, no later than 18 months after the completion~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health			~~of the electronic health data processing or after having received the answer to the data request referred to in Article 47. Those results or output shall only contain anonymised data. The data user shall inform the health data access bodies from which a data permit was obtained and support them to make the information public on health data access bodies' websites. Whenever the data users have used electronic health data in accordance with this Chapter, they shall acknowledge the electronic health data sources and the fact that electronic health~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data has been obtained in the context of the EHDS.			~~data has been obtained in the context of the EHDS.~~ [MOVED TO ARTICLE 35C(3)]	
		Article 46(12)			
596	12. Data users shall inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset.		*deleted*	~~12. Data users shall inform the health data access body of any clinically significant findings that may influence the health status of the natural persons whose data are included in the dataset.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED TO ARTICLE 35C(4), SEE ALSO ARTICLE 35G]	
	Article 46(13)				
597	13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	13. The Commission may, by means of implementing act, develop a logo for acknowledging the contribution of the EHDS. That implementing act shall be adopted in accordance with the ~~advisory~~ **examination** procedure	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				referred to in Article 68(2).	
	Article 46(14)				
598	14. The liability of health data access bodies as joint controller is limited to the scope of the issued data permit until the completion of the processing activity.		14. The liability of health data access bodies as ~~*joint*~~ controller is limited to the scope of the issued data permit until the completion of the processing activity ***and in accordance with Article 51***.	~~14. The liability of health data access bodies as joint controller is limited to the scope of the issued data permit until the completion of the processing activity.~~	
	Article 47				
599					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47 Data request		Article 47 ***Health*** data request	Article 47 Data request [MOD.SU.6]	
	Article 47(1)				
600	1. Any natural or legal person may submit a data request for the purposes referred to in Article 34. A health data access body shall only provide an answer to a data request in an anonymised statistical format and the data user		1. ~~*Any natural or legal person*~~***The health data applicant*** may submit a ***health*** data request for the purposes referred to in Article 34 ***with the aim of obtaining an answer only in anonymised or aggregated statistical***	1. ~~Any~~**A** natural or legal person may submit a ~~data~~ request for ~~the purposes referred to in Article 34.~~ ~~A~~**electronic** health data ~~access body shall only provide an answer to a data request in an anonymised~~**in a** statistical format ~~and the~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	shall have no access to the electronic health data used to provide this answer.		***format***. A health data access body shall ~~*only*~~***not*** provide an answer to a ***health*** data request in ~~*an anonymised statistical*~~***any other*** format and the ***health*** data user shall have no access to the electronic health data used to provide this answer.	~~data user shall have no access~~**for the purposes referred to in Article 34** to the ~~electronic~~ health data ~~used to provide this answer.~~**access body.** [LAST SENTENCE MOVED TO PARA 3 AND AMENDED]	
		Article 47(2)			
601	2. A data request shall include the elements mentioned in paragraphs 2		2. A ***health*** data request shall include the elements mentioned in paragraphs 2	2. A data request ~~shall include the elements mentioned in paragraphs 2~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(a) and (b) of Article 45 and if needed may also include:		(a) and (b) of Article 45 and if needed may also include:	~~(a) and (b) of Article 45 and if needed may also include~~**referred to in paragraph 1 shall include the following information** :	
		Article 47(2), point (a)			
602	(a) a description of the result expected from the health data access body;		(a) a description of the result expected from the health data access body;	(a) a description of the ~~result expected from the health data access body~~**applicant's identity, professional function and activities**;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47(2), point (b)				
603	(b) a description of the statistic's content.		(b) a description of the statistic's content.	(b) a ~~description~~**detailed explanation of the intended use of the electronic health data, including for which** of the ~~statistic's content.~~**purposes referred to in Article 34(1) access is sought;**	
	Article 47(2), point (c)				
603a				**(c) a description of the requested electronic health data, their format**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and data sources, where possible;	
	Article 47(2), point (d)				
603b				**(d) a description of the statistic's content;**	
	Article 47(2), point (e)				
603c				**(e) a description of the safeguards planned to prevent any misuse of the electronic health data.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47(2), point (f)				
603d				**(f) a description of how the processing would comply with Articles 6(1) of Regulation (EU) 2016/679 or Articles 5(1) and 10(2) of Regulation (EU) 2018/1725.**	
	Article 47(2a), first subparagraph				
603e				**2a. The health data access body shall assess if the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				request is complete and take into account the following risks:	
	Article 47(2a), second subparagraph				
603f				**(a) risks for national defense, security, public security and public order;**	
	Article 47(2a), third subparagraph				
603g				**(b) risks of undermining protected IP-rights and**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				trade secrets;	
	Article 47(2a), fourth subparagraph				
603h				**(c) risks of undermining confidential data in governmental databases of market regulatory authorities;**	
	Article 47(2a), fifth subparagraph				
603i				**(d) risks of misuse, including the prohibited**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				use in Article 35.	
	Article 47(3)				
604	3. Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, the health data access body shall assess, within 2 months and, where possible, provide the result to the data user within 2 months.		3. ~~*Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request,*~~***The health data access body shall assess*** the health data ~~*access body shall assess*~~***request***, within 2 months and, where possible, provide the result to the ***health*** data user within 2 months.	3. Where an applicant has requested a result in an anonymised form, including statistical format, based on a data request, the health data access body shall assess **the request**, within ~~2~~ **3** months and, where possible, provide the result to the **health** data user within ~~2~~ **3** months. **The health data access body shall only provide an answer in an anonymised statistical**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				format and the health data user shall have no access to the electronic health data used to provide the answer. [LAST SENTENCE MOVED FROM PARA 1]	
	Article 47A				
604a				**Article 47A** **Templates to support access to electronic health data for secondary use**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47a, first paragraph				
604b				**1. The Commission may, by means of implementing acts, set out the templates for the data access application referred to in Article 45, the data permit referred to in Article 46 and the data request referred to in Article 47** [MOVED FROM ARTICLE 45(6)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47a, second paragraph				
604c				**2. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU referred to in Article 45(5A), including the single application template, a common data permit template, standard templates for common electronic health data access contractual arrangements, and common procedures for**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				handling cross-border requests, pursuant to Articles 45, 46 and 47. [MOVED FROM ARTICLE 54(3)]	
	Article 47a, third paragraph				
604d				**3. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the examination procedure referred to in Article 68(2).**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47B				
604e				**Article 47B** **Data applications and data requests from third countries**	
	Article 47b, first paragraph				
604f				**1. Without prejudice to Articles 45, 46 and 47, for health data access bodies designated by the Member**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				States and the Union data access service, data applications and data requests submitted by a data user established in a third country shall be considered eligible if the third country concerned	
		Article 47b, first paragraph, point (a)			
604g				**(a) is covered by an implementing act referred to in Article 52 (5);** **or**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 47b, first paragraph, point (b)				
604h				**(b) allows EU applicants access to electronic health data in that third country under conditions that are not more restrictive than provided for in this regulation and therefore are covered by the implementing acts referred to in paragraph (2).**	
	Article 47b, second paragraph				
604i					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2. The Commission shall adopt implementing acts establishing the list of third countries referred to in paragraph (1) point b). These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.	
	Article 47b, third paragraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
604j				**3. Health data access bodies may also decide on the eligibility of data applications submitted by a data user established in a third country not covered by paragraph 1 on a case-by-case basis.**	
	Article 48				
605	Article 48 Making data available for public sector bodies and Union institutions, bodies,		Article 48 Making data available***, without a data permit,*** for public sector bodies and	~~Article 48~~ ~~Making data available for public sector bodies and Union institutions, bodies,~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	offices and agencies without a data permit		Union institutions, bodies, offices and agencies ~~*without a data permit*~~***with a legal mandate in the field of public health***	~~offices and agencies without a data permit~~	
		Article 48, first paragraph			
606	By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector		By derogation from Article 46 of this Regulation, a ***health*** data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform	~~By derogation from Article 46 of this Regulation, a data permit shall not be required to access the electronic health data under this Article. When carrying out those tasks under Article 37 (1), points (b) and (c), the health data access body shall inform public sector~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make		public sector bodies and ~~the~~ Union institutions, offices, agencies and bodies ***with a legal mandate in the field of public health***, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data	~~bodies and the Union institutions, offices, agencies and bodies, about the availability of data within 2 months of the data access application, in accordance with Article 9 of Regulation […] [Data Governance Act COM/2020/767 final]. By way of derogation from that Regulation […] [Data Governance Act COM/2020/767 final], the health data access body may extend the period by 2 additional months where necessary, taking into account the complexity of the request. The health data access body shall make~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.		access body shall make available the electronic health data to the ***health*** data user within 2 months after receiving them from the ***health*** data holders, unless it specifies that it will provide the data within a longer specified timeframe. ***Articles 43 and 43a shall be applicable to the situations covered under this Article.***	~~available the electronic health data to the data user within 2 months after receiving them from the data holders, unless it specifies that it will provide the data within a longer specified timeframe.~~	
		Article 49			
607	Article 49			Article 49	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Access to electronic health data from a single data holder		*deleted*	Access to electronic health data from a single **health** data holder **in Member States**	
	Article 49(1)				
608	1. Where an applicant requests access to electronic health data only from a single data holder in a single Member State, by way of derogation from Article 45(1), that applicant may file a data access application or a data request directly to the data holder. The data access application		*deleted*	1. **Member States may allow any or specific health data holder to fulfil the tasks referred to in Article 37(1)(a) in situations** where an applicant requests access to electronic health data only from a single **health** data holder in a single Member State**. In such cases**, by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. Multi-country requests and requests requiring a combination of datasets from several data holders shall be adressed to health data access bodies.			way of derogation from Article 45(1) **and Article 47(1)**, that applicant may file a data access application or a data request directly to ~~the~~**that health** data holder. The data access application shall comply with the requirements set out in Article 45 and the data request shall comply with requirements in Article 47. ~~Multi-country requests and requests requiring a combination of datasets from several data holders shall be adressed to health data access bodies.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 49(1a)				
608a				**1a. The Commission may allow that data applications or data requests are submitted directly to an Union institution, agency or body. In such case, this Article applies mutatis mutandis.**	
	Article 49(2)				
609	2. In such case, the data holder may issue a data			2. In **situations referred to in paragraph 1 in this**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. The data holder shall then provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.		*deleted*	**Article, the health** ~~such case, the~~ data holder may issue a data permit in accordance with Article 46 or provide an answer to a data request in accordance with Article 47. **When issuing a data permit, the health**~~The~~ data holder shall ~~then~~ provide access to the electronic health data in a secure processing environment in compliance with Article 50 and may charge fees in accordance with Article 42.	
		Article 49(3)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
610	3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controllers.		*deleted*	~~3. By way of derogation from Article 51, the single data provider and the data user shall be deemed joint controllers.~~ [SEE ARTICLE 51]	
	Article 49(4)				
611	4. Within 3 months the data holder shall inform the relevant health data access body by electronic means of all data access applications		*deleted*	4. ~~Within 3 months the~~**The single health** data holder**, referred to in paragraph 1 of this Article,** shall **within 3 months** inform the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under Article 37(1) and Article 39.			relevant health data access body by electronic means of all data access applications filed and all the data permits issued and the data requests fulfilled under this Article in order to enable the health data access body to fulfil its obligations under ~~Article 37(1) and Article~~ **Articles 37 and** 39.	
		Article 50			
612	Article 50 Secure processing environment		Article 50 Secure processing environment	Article 50 Secure processing environment	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 50(1)				
613	1. The health data access bodies shall provide access to electronic health data only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures:		1. The health data access bodies shall provide access to electronic health data ***pursuant to a data permit*** only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, they shall take the following security measures:	1. The health data access bodies shall provide access to electronic health data **pursuant to a data permit** only through a secure processing environment, with technical and organisational measures and security and interoperability requirements. In particular, ~~they~~**the secure processing environment** shall ~~take~~ **comply with** the following security measures:	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 50(1), point (a)				
614	(a) restrict access to the secure processing environment to authorised persons listed in the respective data permit;		(a) restrict access to the secure processing environment to authorised persons listed in the respective data permit;	(a) restrict access to the secure processing environment to authorised **natural** persons listed in the respective data permit;	
	Article 50(1), point (b)				
615	(b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health		(b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health	(b) minimise the risk of the unauthorised reading, copying, modification or removal of electronic health	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data hosted in the secure processing environment through state-of-the-art technological means;		data hosted in the secure processing environment through state-of-the-art ~~*technological means*~~***technical and organisational mesures***;	data hosted in the secure processing environment through state-of-the-art technological means;	
		Article 50(1), point (c)			
616	(c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;		(c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;	(c) limit the input of electronic health data and the inspection, modification or deletion of electronic health data hosted in the secure processing environment to a limited number of authorised identifiable individuals;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 50(1), point (d)				
617	(d) ensure that data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;		(d) ensure that ***health*** data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;	(d) ensure that **health** data users have access only to the electronic health data covered by their data permit, by means of individual and unique user identities and confidential access modes only;	
	Article 50(1), point (e)				
618	(e) keep identifiable logs of		(e) keep identifiable logs of	(e) keep identifiable logs of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access to the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment;		access to the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment***, and in any event for not shorter than one year***;	access to **and activities in** the secure processing environment for the period of time necessary to verify and audit all processing operations in that environment;	
	Article 50(1), point (f)				
619	(f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.		(f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.	(f) ensure compliance and monitor the security measures referred to in this Article to mitigate potential security threats.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 50(1), point (fa)				
619a			***(fa) ensure that the secure processing environment is located within the Union.***		
	Article 50(2)				
620	2. The health data access bodies shall ensure that electronic health data can be uploaded by data holders and can be accessed by the data user in a secure processing environment. The data users shall only be		2. The health data access bodies shall ensure that electronic health data ***from health data holders in the format determined by the data permit*** can be uploaded by ***health*** data holders and can be accessed	2. The health data access bodies shall ensure that electronic health data can be uploaded by **health** data holders and can be accessed by the **health** data user in a secure processing environment. The **health**	

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	able to download non-personal electronic health data from the secure processing environment.		by the ***health*** data user in a secure processing environment. The ***health*** data users shall only be able to download ***or copy*** non-personal electronic health data from the secure processing environment***, in accordance with Article 37***.	**data access bodies** ~~data users~~ shall ~~only be~~ **ensure by reviewing that the health data users are only** able to download ~~non-personal~~ electronic health data **in an anonymised statistical format** from the secure processing environment.	
		Article 50(3)			
621	3. The health data access bodies shall ensure regular audits of the secure processing environments.		3. The health data access bodies shall ensure regular audits***, including by third parties, of the secure processing environments***	3. The health data access bodies shall ensure regular **third party** audits of the secure processing environments.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and take immediate corrective action for any shortcomings, risks or vulnerabilities identified in ~~*of*~~ the secure processing environments.		
	Article 50(3a)				
621a				**3a. Where recognised data altruism organisations under Chapter IV of Regulation (EU) 2022/868 process personal electronic health data using a secure processing environment, such environments shall**	

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				also comply with the security measures set out in point (a) to (f) in paragraph 1 in this Article. [MOVED FROM ARTICLE 40(1)]	
	Article 50(4)				
622	4. The Commission shall, by means of implementing acts, provide for the technical, information security and interoperability		4. The Commission shall, by means of implementing acts, provide for the technical, ***organisational,*** information security**,**	4. The Commission shall, by means of implementing acts, provide for the technical, information security and interoperability	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	requirements for the secure processing environments. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		***confidentiality, data protection*** and interoperability requirements for the secure processing environments***, after having consulted with ENISA***. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	requirements for the secure processing environments**, including the technical characteristics and tools available to the health data user within the secure processing environment**. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	
		Article 51			
623	Article 51		Article 51	Article 51	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Joint controllers		~~*Joint controllers*~~ ***Controllership***	~~Joint controllers~~ **Controllership**	
	Article 51(1)				
624	1. The health data access bodies and the data users, including Union institutions, bodies, offices and agencies, shall be deemed joint controllers of electronic health data processed in accordance with data permit.		1. ***The health data holder shall be deemed controller for e the requested personal electronic health data to*** the health data access ~~*bodies and the data users, including Union institutions, bodies, offices and agencies,*~~***body pursuant to Article 41(1) and (1a) of this Regulation. The health data access body shall be deemed***	1. **The health data holder shall be deemed controller for the disclosure of the requested personal electronic health data to** the health data access ~~bodies and the data users, including Union institutions, bodies, offices and agencies,~~**body pursuant to Article 35B(1) and (1a) of this Regulation. The health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			controller for the processing of the personal electronic health data when fulfilling its tasks pursuant to Article 37(1), point (d), of this Regulation. The health data user shall be deemed ~~*joint controllers of*~~ ***controller for the processing of personal*** electronic health data ~~*processed in accordance with*~~***in pseudonymised form in the secure processing environment pursuant to its data permit. The health data access body shall act as a processor for the processing by the health data user pursuant to a***	**data access body shall be deemed controller for the processing of the personal electronic health data when fulfilling its tasks pursuant to Article 37(1)(a)(i) of this Regulation. The health data user** shall be deemed ~~joint controllers of~~ **controller for the processing of personal** electronic health data ~~processed in accordance with~~**in pseudonymised form in the secure processing environment pursuant to its** data permit **and for the processing to generate an answer in an anonymised statistical**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data permit ***in the secure processing environment***.	**form following a data request pursuant to Article 46. The health data access body shall be deemed to act as a processor for the health data user's processing pursuant to a data permit in the secure processing environment when providing such environment and for the processing to generate an answer to a data request pursuant to Article 46.**	
	Article 51(1a)				
624a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				1a. In situations referred to in Article 49, the single health data holder shall be deemed controller for its processing of personal electronic health data related to the providing of electronic health data to the health data user pursuant to a data permit or a data request. The single health data holder shall be deemed to act as a processor for the health data user's processing pursuant to a data permit when providing a secure processing environment to the health data user.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 51(2)				
625	2. The Commission shall, by means of implementing acts, establish a template for the joint controllers' arrangement. Those implementing acts shall be adopted in accordance with the advisory procedure set out in Article 68(2).		2. The Commission shall, by means of implementing acts, establish a template for the joint controllers' arrangement. Those implementing acts shall be adopted in accordance with the advisory procedure set out in Article 68(2).	~~2. The Commission shall, by means of implementing acts, establish a template for the joint controllers' arrangement. Those implementing acts shall be adopted in accordance with the advisory procedure set out in Article 68(2).~~	
	Section 4				
626	Section 4 Cross-Border access to electronic health			Section 4 Cross-Border ~~access to~~**infrastructure for**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data for secondary use			**secondary use of** electronic health data ~~for secondary use~~	
	Article 52				
627	Article 52 Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)		Article 52 Cross-border infrastructure for secondary use of electronic health data (HealthData@EU)	Article 52 ~~Cross-border infrastructure for secondary use of electronic health data (~~***HealthData@EU***~~HealthData@EU)~~	
	Article 52(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
628	1. Each Member State shall designate a national contact point for secondary use of electronic health data, responsible for making electronic health data available for secondary use in a cross-border context and shall communicate their names and contact details to the Commission. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.		1. Each Member State shall designate a national contact point for secondary use of electronic health data, responsible for making electronic health data available for secondary use in a cross-border context and shall communicate their names and contact details to the Commission. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.	1. Each Member State shall designate ~~a~~**one** national contact point for secondary use of electronic health data**. The national contact point shall be an organisational and technical gateway, enabling and** ~~,~~responsible for making electronic health data available for secondary use in a cross-border context**. Each Member State** ~~and~~ shall ~~communicate their names~~**inform the Commission the name** and contact details ~~to the Commission~~**of the national**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				contact point by the date of application of this Regulation. The national contact point may be the coordinator health data access body pursuant to Article 36. The Commission and the Member States shall make this information publicly available.	
	Article 52(1a)				
628a				**1a. The Union data access service shall act as the Union Institutions', bodies, offices and agencies' contact point for**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				secondary use of electronic health data and shall be responsible for making electronic health data available for secondary use.	
	Article 52(2)				
629	2. The national contact points referred to in paragraph 1 shall be authorised participants in the cross-border infrastructure for secondary use of electronic health data (HealthData@EU). The national contact points shall		2. The national contact points referred to in paragraph 1 shall be authorised participants in the cross-border infrastructure for secondary use of electronic health data (HealthData@EU). The national contact points shall	2. The national contact points referred to in paragraph 1 **and the Union Institutions' contact point referred to in paragraph 1A** shall be authorised participants in the cross-border infrastructure for secondary use of electronic	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	facilitate the cross-border access to electronic health data for secondary use for different authorised participants in the infrastructure and shall cooperate closely with each other and with the Commission.		facilitate the cross-border access to electronic health data for secondary use for different authorised participants in the infrastructure and shall cooperate closely with each other and with the Commission.	health data (HealthData@EU). The national contact points **and the Union Institutions' contact point** shall facilitate the cross-border access to electronic health data for secondary use for different authorised participants in the infrastructure**. The national contact points and the Union Institutions' contact point** ~~and~~ shall cooperate closely with each other and with the Commission.	
	Article 52(3)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
630	3. Union institutions, bodies, offices and agencies involved in research, health policy or analysis, shall be authorised participants of HealthData@EU.		3. Union institutions, bodies, offices and agencies involved in ***health*** research, health policy or analysis, shall be authorised participants of HealthData@EU.	~~3. Union institutions, bodies, offices and agencies involved in research, health policy or analysis, shall be authorised participants of HealthData@EU.~~ [MOD.SU.7.rev2]	
	Article 52(4)				
631	4. Health-related research infrastructures or similar structures whose functioning is based on		4. Health-related research infrastructures or similar structures whose functioning is based on	**43**. Health-related research infrastructures or similar structures whose functioning is based on	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Union law and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory purposes shall be authorised participants of HealthData@EU.		Union law and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory purposes shall be authorised participants of HealthData@EU.	Union law and which support the use of electronic health data for research, policy making, statistical, patient safety or regulatory purposes ~~shall~~ **may** be authorised participants of HealthData@EU.	
	Article 52(5)				
632	5. Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation and provide		5. Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation***, where the***	~~5~~**4**. Third countries or international organisations may become authorised participants where they comply with the rules of Chapter IV of this Regulation**, the transfer**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	access to data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies. The Commission may adopt implementing acts establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of HealthData@EU for the purposes of secondary use of health data, is compliant with the Chapter IV of this Regulation and provides access to data users located		***transfer stemming from such connection complies with the rules in Chapter V of Regulation (EU) 2016/679 and Article 63a of this Regulation and where*** ~~*and*~~ provide access to data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies. The Commission may adopt implementing acts establishing that a national contact point of a third country or a system established at an international level is compliant with	**stemming from such connection would comply with the rules in Chapter V of Regulation (EU) 2016/679 and they** ~~and~~ provide access to **health** data users located in the Union, on equivalent terms and conditions, to the electronic health data available to their health data access bodies. The Commission ~~may~~**shall** adopt implementing acts establishing that a national contact point of a third country or a system established at an international level is compliant with requirements of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	in the Union to the electronic health data it has access to on equivalent terms and conditions. The compliance with these legal, organisational, technical and security requirements, including with the standards for secure processing environments pursuant to Article 50 shall be checked under the control of the Commission. These implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted		requirements of HealthData@EU for the purposes of secondary use of health data, is compliant with the Chapter IV of this Regulation ***and Chapter V of Regulation (EU) 2016/679*** and provides access to data users located in the Union to the electronic health data it has access to on equivalent terms and conditions. The compliance with these legal, organisational, technical and security requirements, including with the standards for secure processing environments pursuant to Article 50 shall be checked under the control of the	HealthData@EU for the purposes of secondary use of health data, is compliant with the Chapter IV of this Regulation and **Chapter V of Regulation (EU) 2016/679 and** provides access to **health** data users located in the Union to the electronic health data it has access to on equivalent terms and conditions. The compliance with these legal, organisational, technical and security requirements, including with the standards for secure processing environments pursuant to Article 50 shall be checked under the control of the Commission. These	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	pursuant to this paragraph publicly available.		Commission. These implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available.	implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68 (2). The Commission shall make the list of implementing acts adopted pursuant to this paragraph publicly available. **When adopting the implementing act, the national security interests of Member States shall be taken into account.**	
	Article 52(6)				
633	6. Each authorised		6. Each authorised	~~6~~**5**. Each authorised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross-border infrastructure and to allow the authorised participants to connect to each other within it.		participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross-border infrastructure and to allow the authorised participants to connect to each other within it.	participant shall acquire the required technical capability to connect to and participate in HealthData@EU. Each participant shall comply with the requirements and technical specifications needed to operate the cross-border infrastructure and to allow the authorised participants to connect to each other within it.	
		Article 52(7)			
634	7. The Commission is empowered to adopt		7. The Commission is empowered to adopt	~~7. The Commission is empowered to adopt~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.		delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.	~~delegated acts in accordance with Article 67 in order to amend this Article to add or remove categories of authorised participants in HealthData@EU, taking into account the opinion of the joint controllership group pursuant to Article 66 of this Regulation.~~	
		Article 52(8)			
635	8. The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-		8. The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-	~~8~~**6**. The Member States and the Commission shall set up HealthData@EU to support and facilitate the cross-	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure.		border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure.	border access to electronic health data for secondary use, connecting the national contact points for secondary use of electronic health data of all Member States and authorised participants in that infrastructure **and the central platform**.	
	Article 52(9)				
636	9. The Commission shall develop, deploy and operate a core platform for HealthData@EU by providing information technology services needed		9. The Commission shall develop, deploy and operate a core platform for HealthData@EU by providing information technology services needed	~~9~~**7**. The Commission shall develop, deploy and operate a **central and interoperability** ~~core~~ platform for HealthData@EU by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	to facilitate the connection between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the joint controllers as a processor.		to facilitate the connection between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the joint controllers as a processor.	providing information technology services needed to **support and** facilitate the ~~connection~~ **exchange of information** between health data access bodies as part of the cross-border infrastructure for the secondary use of electronic health data. The Commission shall only process electronic health data on behalf of the ~~joint~~ controllers as a processor.	
		Article 52(10)			
637	10. Where requested by		10. Where requested by	~~10~~**8**. Where requested by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	two or more health data access bodies, the Commission may provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50. Where two or more health data access bodies put electronic health data in the secure processing environment managed by the Commission, they shall be joint controllers and the Commission shall be processor.		two or more health data access bodies, the Commission may provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50. Where two or more health data access bodies put electronic health data in the secure processing environment managed by the Commission, they shall be joint controllers and the Commission shall be processor.	two or more health data access bodies **or authorised participants in this infrastructure**, the Commission ~~may~~ **shall** provide a secure processing environment for data from more than one Member State compliant with the requirements of Article 50. Where two or more health data access bodies put electronic health data in the secure processing environment managed by the Commission, they shall be ~~joint controllers~~ **controller** and the Commission shall be processor.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 52(11)				
638	11. The authorised participants shall act as joint controllers of the processing operations in which they are involved carried out in HealthData@EU and the Commission shall act as a processor.		11. The authorised participants shall act as joint controllers of the processing operations in which they are involved carried out in HealthData@EU and the Commission shall act as a processor.	~~11~~**9**. The authorised participants shall act as joint controllers of the processing operations in which they are involved carried out in HealthData@EU **for which they determine the purpose and the means** and the Commission shall act as a processor **for the processing of electronic health data for the purposes of secondary use pursued by the health data user**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 52(12)				
639	12. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations […] [Data Governance Act COM/2020/767 final] and […] [Data Act COM/2022/68 final].		12. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations ~~*[…] [Data Governance Act COM/2020/767 final]*~~ ***(EU) 2022/868*** and […] [Data Act COM/2022/68 final].	~~12~~**10**. Member States and the Commission shall seek to ensure interoperability of HealthData@EU with other relevant common European data spaces as referred to in Regulations ~~[…] [Data Governance Act COM/2020/767 final]~~**(EU) 2022/868** and […] [Data Act COM/2022/68 final].	
	Article 52(13), first subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
640	13. The Commission may, by means of implementing acts, set out:		13. The Commission ~~*may*~~***shall***, by means of ~~*implementing*~~***delegated*** acts, set out:	~~13~~**11**. The Commission ~~may~~**shall**, by means of implementing acts, set out:	
		Article 52(13), first subparagraph, point (a)			
641	(a) requirements, technical specifications, the IT architecture of HealthData@EU, conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and		(a) requirements, technical specifications, the IT architecture of HealthData@EU, ~~*conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and*~~	(a) requirements, technical specifications, the IT architecture of HealthData@EU, conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conditions for temporary or definitive exclusion from HealthData@EU;		~~*conditions for temporary or definitive exclusion from HealthData@EU*~~***which shall ensure state-of-the-art data security, confidentiality, and protection of electronic health data in the cross border infrastructure***;	conditions for temporary or definitive exclusion from HealthData@EU;	
		Article 52(13), first subparagraph, point (aa)			
641a			***(aa) conditions and compliance checks for authorised participants to join and remain connected to HealthData@EU and conditions for temporary or***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			definitive exclusion from HealthData@EU, including specific provisions for cases of serious misconduct or repeated violation;		
	Article 52(13), first subparagraph, point (b)				
642	(b) the minimum criteria that need to be met by the authorised participants in the infrastructure;		(b) the minimum criteria that need to be met by the authorised participants in the infrastructure;	(b) the minimum criteria that need to be met by the authorised participants in the infrastructure;	
	Article 52(13), first subparagraph, point (c)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
643	(c) the responsibilities of the joint controllers and processor(s) participating in the cross-border infrastructures;		(c) the responsibilities of the joint controllers and processor(s) participating in the cross-border infrastructures;	(c) the responsibilities of the ~~joint~~ controllers and processor(s) participating in the cross-border infrastructures;	
	Article 52(13), first subparagraph, point (d)				
644	(d) the responsibilities of the joint controllers and processor(s) for the secure environment managed by the Commission;		(d) the responsibilities of the joint controllers and processor(s) for the secure environment managed by the Commission;	(d) the responsibilities of the ~~joint~~ controllers and processor(s) for the secure environment managed by the Commission;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 52(13), first subparagraph, point (e)				
645	(e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.		(e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.	(e) common specifications for the interoperability and architecture concerning HealthData@EU with other common European data spaces.	
	Article 52(13), second subparagraph				
646	Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		~~*Those implementing acts*~~***The Commission*** shall ~~*be adopted in accordance with the advisory procedure referred to in Article*~~	Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in	

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			~~68(2)~~***consult with the ENISA in the drawing up of the delegated act***.	Article 68(2).	
	Article 52(14)				
647	14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be issued by the Joint Controllership group, based on the results of the compliance checks.		14. The approval for individual authorised participant to join HealthData@EU or to disconnect a participant from the infrastructure shall be issued by the Joint Controllership group, based on the results of the compliance checks.	14. **Subject to the outcome of the compliance check performed by the Commission concerning the fulfilment of the requirements in this Article, the Commission shall, by means of implementing act, take decisions to connect**~~The approval for~~ individual authorised	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				~~participant~~**participants** to join ~~HealthData@EU~~**the infrastructure** or to disconnect ~~a participant from the infrastructure~~**them. These implementing acts** shall be ~~issued by the Joint Controllership group, based on the results of the compliance checks~~**adopted in accordance with the examination procedure referred to in Article 68(2)**.	
	Article 53				
648					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 53 Access to cross-border sources of electronic health data for secondary use		Article 53 Access to cross-border ~~*sources of electronic health data*~~***registries and databases*** for secondary use	Article 53 ***Access to cross-border*** **registries or databases** ***of electronic health data for secondary use***~~Access to cross-border sources of electronic health data for secondary use~~	
	Article 53(1)				
649	1. In the case of cross-border registries and databases, the health data access body in which the data holder is registered shall be competent to		1. In the case of cross-border registries and databases, the health data access body in which the data holder is registered shall be competent to decide	1. In the case of cross-border registries and databases, the health data access body in which the **health** data holder **for the specific registry or**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	decide on data access applications to provide access to electronic health data. Where the registry has joint controllers, the health data access body that shall provide access to electronic health data shall be the body in the Member State where one of the joint controllers is established.		on data access applications to provide access to electronic health data. Where the registry has joint controllers, the health data access body that shall provide access to electronic health data shall be the body in the Member State where one of the joint controllers is established.	**database** is registered shall be competent to decide on data access applications to provide access to electronic health data **pursuant to a data permit**. Where ~~the registry has~~**such registries or databases have** joint controllers, the health data access body that shall **decide on the data access applications to** provide access to electronic health data shall be the body in the Member State where one of the joint controllers is established.	
		Article 53(2)			

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650	2. Where registries or databases from a number of Member States organise themselves into a single network of registries or databases at Union level, the associated registries may designate one of their members as a coordinator to ensure the provision of data from the registries' network for secondary use. The health data access body of the Member State in which the coordinator of the network is located shall be competent to decide on the data access applications to provide access to electronic		2. Where registries or databases from a number of Member States organise themselves into a single network of registries or databases at Union level, the associated registries may designate one of their members as a coordinator to ensure the provision of data from the registries' network for secondary use. The health data access body of the Member State in which the coordinator of the network is located shall be competent to decide on the data access applications to provide access to electronic	2. Where registries or databases from a number of Member States organise themselves into a single network of registries or databases at Union level, the associated registries may designate ~~one of their members as~~ a coordinator to ensure the provision of data from the registries' network for secondary use. The health data access body of the Member State in which the coordinator of the network is located shall be competent to decide on the data access applications to provide access to electronic	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health data for the network of registries or databases.		health data for the network of registries or databases.	health data for the network of registries or databases.	
	Article 53(3)				
651	3. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common		3. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common	~~3. The Commission may, by means of implementing acts, adopt the necessary rules for facilitating the handling of data access applications for HealthData@EU, including a common application form, a common data permit template, standard forms for common electronic health data access contractual arrangements, and common~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	procedures for handling cross-border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		procedures for handling cross-border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	~~procedures for handling cross-border requests, pursuant to Articles 45, 46, 47 and 48. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).~~ [MOVED TO ARTICLE 37A]	
	Article 54				
652	Article 54		Article 54 ***Cross-border access to and***	~~Article 54~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Mutual recognition		mutual recognition ***of data permits***	~~Mutual recognition~~	
	Article 54(1)				
653	1. When handling an access application for cross-border access to electronic health data for secondary use, health data access bodies and relevant authorised participants shall remain responsible for taking decisions to grant or refuse access to electronic health data within their remit in accordance with the requirements for access		1. When handling an access application for cross-border access to electronic health data for secondary use, health data access bodies and relevant authorised participants shall remain responsible for taking decisions to grant or refuse access to electronic health data within their remit in accordance with the requirements for access laid	~~1. When handling an access application for cross-border access to electronic health data for secondary use, health data access bodies and relevant authorised participants shall remain responsible for taking decisions to grant or refuse access to electronic health data within their remit in accordance with the requirements for access laid~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	laid down in this Chapter.		down in this Chapter. ***After a decision has been made regarding the granting or refusal of the health data permit, the health data access body shall inform the other health data bodies concerned by the same application about the decision.***	~~down in this Chapter.~~ [MOVED TO ARTICLE 46(3A)]	
		Article 54(2)			
654	2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health		2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health	~~2. A data permit issued by one concerned health data access body may benefit from mutual recognition by the other concerned health~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	data access bodies.		data access bodies.	~~data access bodies.~~ [SEE ARTICLE 46(3A)]	
	Section 5				
655	Section 5 Health data quality and utility for secondary use		Section 5 Health data quality and utility for secondary use	Section 5 Health data quality and utility for secondary use	
	Article 55				
656	Article 55		Article 55	Article 55	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Dataset description		Dataset description ***and dataset catalogue***	Dataset description **and datasets catalogue**	
	Article 55(1)				
657	1. The health data access bodies shall inform the data users about the available datasets and their characteristics through a metadata catalogue. Each dataset shall include information concerning the source, the scope, the main characteristics, nature of electronic health data and conditions for making electronic health data		1. The health data access bodies shall inform the data users about the available datasets and their characteristics through a metadata catalogue. Each dataset shall include information concerning the source, the scope, the main characteristics, nature of electronic health data and conditions for making electronic health data	1. The health data access ~~bodies~~**body** shall**, through a publicly available and standardised machine-readable datasets catalogue, provide information, in the form of metadata,** ~~inform the data users~~ about the available datasets and their characteristics ~~through a metadata catalogue.~~**. A description of** each dataset	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	available.		available.	shall include information concerning the source, the scope, the main characteristics, **the** nature of electronic health data and **the** conditions for making electronic health data available.	
	Article 55(1a)				
657a				**1a. The dataset descriptions in the national datasets catalogue of the Member States shall be available, at least, in an official language of the Union.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				The dataset catalogue for Union institutions provided by the Union data access service shall be available in all official languages of the Union.	
	Article 55(1b)				
657b				**1b. The datasets catalogue shall also be made available to single information points under Article 8 of Regulation (EU) 2022/868** MOVED FROM ARTICLE	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				37(1)(q) [MOD.SU.7.rev2]	
	Article 55(2)				
658	2. The Commission shall, by means of implementing acts, set out the minimum information elements data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		2. The Commission shall, by means of implementing acts, set out the minimum information elements data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	2. The Commission shall, by means of implementing acts, set out the minimum ~~information~~ elements **health** data holders are to provide for datasets and their characteristics. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 56				
659	Article 56 Data quality and utility label		Article 56 Data quality and utility label	Article 56 Data quality and utility label	
	Article 56(1)				
660	1. Datasets made available through health data access bodies may have a Union data quality and utility label provided by the data holders.		1. Datasets made available through health data access bodies may have a Union data quality and utility label provided by the data holders.	1. Datasets made available through health data access bodies may have a Union data quality and utility label ~~provided~~ **applied** by the **health** data holders.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
		Article 56(2)			
661	2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label, in accordance with the principles set out in paragraph 3.		2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label, in accordance with the principles set out in paragraph 3.	2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label, in accordance with the ~~principles~~ **elements** set out in paragraph 3.	
		Article 56(2a)			
661a			***2a. The health data access body shall assess whether***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the data meets the requirements in paragraph 3 and shall revoke the label in the event the data does not meet the required quality.		
	Article 56(3)				
662	3. The data quality and utility label shall comply with the following elements:		3. The data quality and utility label shall ~~*comply with*~~***cover*** the following elements:	3. The data quality and utility label shall ~~comply with~~ **cover** the following elements**, where applicable**:	
	Article 56(3), point (a)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
663	(a) for data documentation: meta-data, support documentation, data model, data dictionary, standards used, provenance;		(a) for data documentation: meta-data, support documentation, data model, data dictionary, standards used, provenance;	(a) for data documentation: meta-data, support documentation, data ~~model, data dictionary,~~**dictionary, format and** standards used, provenance**, and when applicable, data model**;	
	Article 56(3), point (b)				
664	(b) technical quality, showing the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;		(b) technical quality, showing the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;	(b) ~~technical quality, showing the~~ **for assessment of technical quality:** completeness, uniqueness, accuracy, validity, timeliness and consistency	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				of the data;	
	Article 56(3), point (c)				
665	(c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;		(c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;	(c) for data quality management processes: level of maturity of the data quality management processes, including review and audit processes, biases examination;	
	Article 56(3), point (d)				
666	(d) coverage:		(d) coverage:	(d) **for assessment of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	representation of multi-disciplinary electronic health data, representativity of population sampled, average timeframe in which a natural person appears in a dataset;		representation of multi-disciplinary electronic health data, representativity of population sampled, average timeframe in which a natural person appears in a dataset;	coverage: **time period, population coverage and, when applicable** ~~representation of multi-disciplinary electronic health data~~, representativity of population sampled, **and** average timeframe in which a natural person appears in a dataset;	
	Article 56(3), point (e)				
667	(e) information on access and provision: time between the collection of the electronic health data and their addition to the		(e) information on access and provision: time between the collection of the electronic health data and their addition to the dataset,	(e) **for** information on access and provision: time between the collection of the electronic health data and their addition to the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	dataset, time to provide electronic health data following electronic health data access application approval;		time to provide electronic health data following electronic health data access application approval;	dataset, time to provide electronic health data following **an** electronic health data access application approval;	
	Article 56(3), point (f)				
668	(f) information on data enrichments: merging and adding data to an existing dataset, including links with other datasets;		(f) information on data enrichments: merging and adding data to an existing dataset, including links with other datasets;	(f) **for** information on data ~~enrichments~~**modifications** : merging and adding data to an existing dataset, including links with other datasets~~;~~**.**	
	Article 56(4)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
669	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of principles for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.		4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of principles for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.	4. The Commission is empowered to adopt delegated acts in accordance with Article 67 to amend the list of ~~principles~~ **elements** for data quality and utility label. Such delegated acts may also amend the list set out under paragraph 3 by adding, modifying or removing requirements for data quality and utility label.	
		Article 56(5)			
670					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	5. The Commission shall, by means of implementing acts, set out the visual characteristics and technical specifications of the data quality and utility label, based on the elements referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). Those implementing acts shall take into account the requirements in Article 10 of Regulation […] [AI Act COM/2021/206 final] and any adopted common specifications or harmonised standards		5. The Commission shall, by means of implementing acts, set out the visual characteristics and technical specifications of the data quality and utility label, based on the elements referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). Those implementing acts shall take into account the requirements in Article 10 of Regulation […] [AI Act COM/2021/206 final] and any adopted common specifications or harmonised standards	5. The Commission shall, by means of implementing acts, set out the visual characteristics and technical specifications of the data quality and utility label, based on the elements referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2). Those implementing acts shall take into account the requirements in Article 10 of Regulation […] [AI Act COM/2021/206 final] and any adopted common specifications or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	supporting those requirements.		supporting those requirements.	harmonised standards supporting those requirements**, where applicable**.	
	Article 57				
671	Article 57 EU Datasets Catalogue		Article 57 EU Datasets Catalogue	Article 57 EU Datasets Catalogue	
	Article 57(1)				
672	1. The Commission shall establish an EU Datasets		1. The Commission shall establish an EU Datasets	1. The Commission shall establish **and publicly**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Catalogue connecting the national catalogues of datasets established by the health data access bodies and other authorised participants in HealthData@EU.		Catalogue connecting the national catalogues of datasets established by the health data access bodies and other authorised participants in HealthData@EU ***taking into consideration the health interoperability resources already developed across the Union***.	**provide** an EU Datasets Catalogue connecting the national ~~catalogues of~~ datasets **catalogues** established by the health data access bodies ~~and other~~**in each Member State as well as datasets catalogues of** authorised participants in HealthData@EU.	
		Article 57(2)			
673	2. The EU Datasets Catalogue and the national datasets catalogues shall be		2. The EU Datasets Catalogue and the national datasets catalogues shall be	2. The EU Datasets Catalogue and the national datasets catalogues **as well**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	made publicly available.		made publicly available.	**as datasets catalogues of authorised participants in HealthData@EU** shall be made publicly available.	
	Article 58				
674	Article 58 Minimum dataset specifications		Article 58 Minimum dataset specifications	Article 58 Minimum dataset specifications	
	Article 58, first paragraph				
675	The Commission may, by		The Commission may, by	The Commission may, by	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	means of implementing acts, determine the minimum specifications for cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		means of implementing acts, determine the minimum specifications for cross-border datasets for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	means of implementing acts, determine the minimum- specifications for **datasets of high impact for the** ~~cross-border datasets~~ for secondary use of electronic health data, taking into account existing Union infrastructures, standards, guidelines and recommendations. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	
	Chapter V				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
676	Chapter V Additional actions		Chapter V Additional actions	Chapter V Additional actions	
	Article 59				
677	Article 59 Capacity building		Article 59 Capacity building	Article 59 Capacity building	
	Article 59, first paragraph				
678	The Commission shall support sharing of best		The Commission shall support sharing of best	The Commission shall support sharing of best	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall draw up benchmarking guidelines for the primary and secondary use of electronic health data.		practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall draw up benchmarking guidelines for the primary and secondary use of electronic health data. ***The Commission shall issue guidance with regard to compliance of data holders with the provisions of Chapter IV, taking into account the specific conditions of data holders that are civil society,***	practices and expertise, aimed to build the capacity of Member States to strengthen digital health systems for primary and secondary use of electronic health data. To support capacity building, the Commission shall ~~draw up benchmarking guidelines~~ **in close cooperation and consultation with Member States establish indicators for self assessment** for the primary and secondary use of electronic health data.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			researchers, medical societies and SMEs		
	Article 59a				
678a			***Article 59a*** ***Digital health literacy and digital health access***		
	Article 59a(1), first paragraph				
678b			***1. In order to ensure successful implementation of the EHDS, Member***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			States shall support digital health literacy, promote public awareness, including through educational programmes for natural persons, health professionals and stakeholders, to inform the public of the rights and obligations in the EHDS and inform natural persons of the advantages, risks and potential gains to science and society of the primary and secondary use of electronic health data, and offer free of charge accessible training to health professionals in this regard. Those programmes shall be tailored to the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			needs of specific groups and shall be developed and reviewed, and where necessary updated, on a regular basis in consultation and cooperation with relevant experts and stakeholders.		
	Article 59a(1), second paragraph				
678c			***The Commission shall support Member States in this regard.***		
	Article 59a(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
678d			***2. Member States shall monitor and evaluate, on a regular basis, the digital health literacy of health professionals and natural persons, in particular about the primary and secondary use of health data, functionalities and conditions as well as rights of natural persons within the EHDS.***		
	Article 59a(3)				
678e			***3. Member States shall***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			promote the access to the infrastructure necessary for the effective management of natural persons' electronic health data, both within primary and secondary use.		
		Article 59a(4)			
678f			***4. Member States shall regularly inform the public at large about the role and benefits of the secondary use of health data and the role of health data access bodies, as well as the risks and consequences linked***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			with individual and collective digital health data rights arising from this Regulation.		
	Article 60				
679	Article 60 Additional requirements for public procurement and Union funding		Article 60 Additional requirements for public procurement and Union funding	Article 60 Additional requirements for public procurement and Union funding	
	Article 60(1)				
680					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	1. Public procurers, national competent authorities, including digital health authorities and health data access bodies, and the Commission shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, 23, 50, 56, as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion		1. Public procurers, national competent authorities, including digital health authorities and health data access bodies, and the Commission shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, 23, 50, 56, as relevant, as points of orientation for public procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion	1. ~~Public procurers, national competent~~**Contracting** authorities, including digital health authorities and health data access bodies **and Union institutions, bodies, offices or agencies, including**~~, and~~ the Commission**,** shall make reference to the applicable technical specifications, standards and profiles as referred to in Articles 6, **12, 23, 50, 52, 56, as well as to the requirements laid down in Regulations (EU) 2016/679 and (EU) 2018/1725, as relevant,**~~23, 50, 56, as relevant, as points of orientation~~ for public	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	funds.		funds.	procurements and when formulating their tender documents or calls for proposals, as well as when defining the conditions for Union funding regarding this Regulation, including enabling conditions for the structural and cohesion funds.	
	Article 60(2)				
681	2. The ex-ante conditionality for Union funding shall take into account the requirements developed in the framework		2. The ex-ante conditionality for Union funding shall take into account the requirements developed in the framework	2. The ~~ex-ante conditionality for Union~~**criteria for obtaining** funding **from the Union** shall take into	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	of Chapters II, III and IV.		of Chapters II, III and IV.	account ~~the requirements developed in the framework of Chapters II, III and IV.~~**:**	
	Article 60(1a), second subparagraph				
681a				**a) the requirements developed in Chapters II, III and IV;**	
	Article 60(1a), third subparagraph				
681b				**b) the requirements laid down in Regulations (EU) 2016/679 or (EU)**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				2018/1725, where applicable.	
	Article 60(2a)				
681c			***2a. Public procurers, national competent authorities, including digital health authorities and health data access bodies, and the Commission shall require, as a condition to procure or fund services provided by controllers and processors established in the Union processing personal electronic health***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data, that such controllers and processors:		
		Article 60(2a), point (a)			
681d			***(a) store those data in the Union, in accordance with Article 60a of this Chapter: and***		
		Article 60(2a), point (b)			
681e			***(b) have duly demonstrated that they are not subject to third country***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			law conflicting with Union data protection rules.		
	Article 60a				
681f			***Article 60a*** ***Storage of personal electronic health data***		
	Article 60a, first subparagraph				
681g			***For the purposes of primary and secondary use of personal electronic***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			health data, the storage of personal electronic health data shall exclusively take place within the territory of the Union, without prejudice to the provisions of Article 63.		
	Article 60a				
681h				**Article 60A** **Storage of personal electronic health data by health data access bodies and secure processing environments**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 60a(1)				
681i				**1. Health data access bodies, single data holders and the Union data access service shall store and process, personal health electronic data in the European Union when performing pseudonymisation, anonymisation and any other personal data processing operations referred to in Articles 45 to 49, through secure processing environments**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				within the meaning of article 50 and article 52(8) or through HealthData@EU. This requirement shall apply to any entity performing these tasks on their behalf.	
		Article 60a(2)			
681j				**2. By way of exception, the data referred to in paragraph 1 may be stored and processed in a third country, a territory or one or more specified sectors within that third country covered by an**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				adequacy decision, pursuant to Article 45 of Regulation (EU) 2016/679.	
	Article 61				
682	Article 61 Third country transfer of non-personal electronic data		Article 61 ~~*Third country transfer*~~***Sensitive nature*** of non-personal electronic ~~*data*~~ ***health data***	Article 61 ~~Third country transfer of non-personal electronic data~~ **T*ransfer of* anonymous electronic health data presenting a risk of re-identification to a third country or international organisation**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 61(1)				
683	1. Non-personal electronic data made available by health data access bodies, that are based on a natural person's electronic data falling within one of the categories of Article 33 [(a), (e), (f), (i), (j), (k), (m)] shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final], provided that their transfer to third countries presents a risk of re-identification		1. Non-personal electronic ***health*** data made available by health data access bodies, that are based on a natural person's electronic data falling within one of the categories of Article 33 ~~*[(a), (e), (f), (i), (j), (k), (m)]*~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation […] [Data Governance Act COM/2020/767 final]~~,~~ ~~*provided that their transfer to third countries presents a risk of re-identification*~~	1. ~~Non-~~ ~~personal~~**Anonymous** electronic **health** data made available by health data access bodies **to a health data user or its contractor in a third country according to a data permit pursuant to Article 46 or a data request pursuant to Article 47 or to an authorised participants or its contractor in a third country or an international organisation**, that are based on a natural person's electronic **health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	through means going beyond those likely reasonably to be used, in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future.		~~*through means going beyond those likely reasonably to be used, in view of the limited number of natural persons involved in that data, the fact that they are geographically scattered or the technological developments expected in the near future*~~.	data falling within one of the categories of Article 33 ~~[(a), (e), (f), (i), (j), (k), (m)]~~ shall be deemed highly sensitive within the meaning of Article 5(13) of Regulation ~~[…]~~ ~~[Data Governance Act COM/2020/767 final]~~**(EU) 2022/868**, provided that their transfer to third countries presents a risk of **becoming personal electronic health data allowing** re-identification through means going beyond those ~~likely~~ reasonably **likely** to be used, **in particular** in view of the limited number of natural persons involved in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				that data, the fact that they are geographically scattered or the technological developments expected in the near future.	
	Article 61(2)				
684	2. The protective measures for the categories of data mentioned in paragraph 1 shall depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation		2. The protective measures for the categories of data mentioned in paragraph 1 shall ~~depend on the nature of the data and anonymization techniques and shall~~ be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation	2. The protective measures for the categories of data mentioned in paragraph 1 shall– depend on the nature of the data and anonymization techniques and shall be detailed in the Delegated Act under the empowerment set out in Article 5(13) of Regulation	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	[…] [Data Governance Act COM/2020/767 final].		~~*[…] [Data Governance Act COM/2020/767 final]*~~ ***(EU) 2022/868***.	~~[…] [Data Governance Act COM/2020/767 final]~~**(EU) 2022/868** .	
		Article 62			
685	Article 62 International access and transfer of non-personal electronic health data		Article 62 International access and transfer of non-personal electronic health data	Article 62 ~~International access and~~ Transfer of **anonymous** ~~non-personal~~ electronic health data **to a third country or an international organisation**	
		Article 62(1)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
686	1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent international transfer or governmental access to non-personal electronic health data held in the Union where such transfer or access would create a		1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent international transfer or governmental access to non-personal electronic health data held in the Union where such transfer or access would create a	1. The digital health authorities, health data access bodies, the authorised participants in the cross-border infrastructures provided for in Articles 12 and 52 and **health** data users shall take all reasonable technical, legal and organisational measures, including contractual arrangements, in order to prevent **transfer to a third country or an international organisation, including** ~~international transfer or~~ governmental access ~~to non-personal~~ **in a third country of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.		conflict with Union law or the national law of the relevant Member State, without prejudice to paragraph 2 or 3 of this Article.	**anonymous** electronic health data held in the Union where such transfer ~~or access~~ would create a conflict with Union law or the national law of the relevant Member State~~, without prejudice to paragraph 2 or 3 of this Article~~.	
	Article 62(2)				
687	2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital		2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital	~~2. Any judgment of a third-country court or tribunal and any decision of a third-country administrative authority requiring a digital~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	health authority, health data access body or data users to transfer or give access to non-personal electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.		health authority, health data access body or data users to transfer or give access to non-personal electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.	~~health authority, health data access body or data users to transfer or give access to non-personal electronic health data within the scope of this Regulation held in the Union shall be recognised or enforceable in any manner only if based on an international agreement, such as a mutual legal assistance treaty, in force between the requesting third country and the Union or any such agreement between the requesting third country and a Member State.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 62(3)				
688	3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, data users is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer or give access to non-personal data within the scope of this Regulation held in the Union and compliance with such a decision would risk		3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, data users is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer or give access to non-personal data within the scope of this Regulation held in the Union and compliance with such a decision would risk	~~3. In the absence of an international agreement as referred to in paragraph 2 of this Article, where a digital health authority, a health data access body, data users is the addressee of a decision or judgment of a third-country court or tribunal or a decision of a third-country administrative authority to transfer or give access to non-personal data within the scope of this Regulation held in the Union and compliance with such a decision would risk~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only where:		putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only where:	~~putting the addressee in conflict with Union law or with the national law of the relevant Member State, transfer to or access to such data by that third-country authority shall take place only where:~~	
		Article 62(3), point (a)			
689	(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for		(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for	~~(a) the third-country system requires the reasons and proportionality of such a decision or judgment to be set out and requires such a decision or judgment to be specific in character, for~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	instance by establishing a sufficient link to certain suspected persons or infringements;		instance by establishing a sufficient link to certain suspected persons or infringements;	~~instance by establishing a sufficient link to certain suspected persons or infringements;~~	
		Article 62(3), point (b)			
690	(b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and		(b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and	~~(b) the reasoned objection of the addressee is subject to a review by a competent third-country court or tribunal; and~~	
		Article 62(3), point (c)			
691					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State		(c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State	~~(c) the competent third-country court or tribunal issuing the decision or judgment or reviewing the decision of an administrative authority is empowered under the law of that third country to take duly into account the relevant legal interests of the provider of the data protected under Union law or the national law of the relevant Member State~~	
		Article 62(4)			
692	4. If the conditions laid		4. If the conditions laid	~~4. If the conditions laid~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	down in paragraph 2 or 3 are met, digital health authority, a health data access body or a data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.		down in paragraph 2 or 3 are met, digital health authority, a health data access body or a data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.	~~down in paragraph 2 or 3 are met, digital health authority, a health data access body or a data altruism body shall provide the minimum amount of data permissible in response to a request, based on a reasonable interpretation of the request.~~	
		Article 62(5)			
693	5. The digital health authorities, health data access bodies, data users shall inform the data holder about the existence of a		5. The digital health authorities, health data access bodies, data users shall inform the data holder about the existence of a	~~5. The digital health authorities, health data access bodies, data users shall inform the data holder about the existence of a~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.		request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.	~~request of a third-country administrative authority to access its data before complying with that request, except where the request serves law enforcement purposes and for as long as this is necessary to preserve the effectiveness of the law enforcement activity.~~ [MOD.GA.3.rev1]	
		Article 63			
694					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 63 International access and transfer of personal electronic health data		Article 63 International access and transfer of personal electronic health data	Article 63 ~~International access and~~ **Additional conditions for** transfer of personal electronic health data **to a third country or an international organisation**	
		Article 63, first paragraph			
695	In the context of international access and transfer of personal electronic health data, Member States may maintain or introduce further conditions,		~~*In the context of*~~ International access and transfer of personal electronic health data~~,~~ ***shall be granted in accordance with Chapter V of Regulation (EU) 2016/679.***	In the context of ~~international access and~~ transfer of personal electronic health data **to a third country or an international organisation**, Member States may	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	including limitations, in accordance with and under the conditions of article 9(4) of the Regulation (EU) 2016/679.		Member States may maintain or introduce further conditions ***on international access to, and transfer of, personal electronic health data***, including limitations, in accordance with and under the conditions of article 9(4) of the Regulation (EU) 2016/679.	maintain or introduce further conditions, including limitations, in accordance with and under the conditions of Article 9(4) of **Regulation (EU) 2016/679, in addition to the requirements set out in Articles 13(3) and 52(5) of this Regulation and the requirements laid down in Chapter V of**~~the~~ Regulation (EU) 2016/679.	
		Article 63a			
695a			***Article 63a***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Reciprocity of access to electronic health data for secondary use		
	Article 63a(1)				
695b			***1. Notwithstanding Articles 62 and 63, only entities and bodies that are established in third countries included in the list referred to in paragraph 2 shall be allowed access to electronic health data in the secure processing environment and have the possibility of downloading non-personal***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			electronic health data held in the Union for the purposes of secondary use.		
	Article 63a(2)				
695c			***2. The Commission is empowered to adopt delegated acts in accordance with Article 67 supplementing this Regulation by setting up a list of third countries which are considered to provide for equivalent access to, and transfer of, electronic health data of its data holders for the purposes of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			secondary use of electronic health data by entities and bodies within the Union.		
	Article 63a(3)				
695d			***3. The Commission shall monitor the list of third countries benefiting from such access, and shall provide for a periodic review of the functioning of this Article.***		
	Article 63a(4)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
695e			***4. Where the Commission considers that a third country no longer meets the requirement to be included on the list referred to in paragraph 2, it shall adopt a delegated act to remove such third country that benefits from access.***		
	Chapter VI				
696	Chapter VI European governance and		Chapter VI European governance and	Chapter VI European governance and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	coordination		coordination	coordination	
	Article 64				
697	Article 64 European Health Data Space Board (EHDS Board)		Article 64 European Health Data Space Board (EHDS Board)	Article 64 European Health Data Space Board (EHDS Board)	
	Article 64(1)				
698	1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and		1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and	1. A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the exchange of information among Member States. The EHDS Board shall be composed of the high level representatives of digital health authorities and health data access bodies of all the Member States. Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and		the exchange of information among Member States. The EHDS Board shall be composed of***, one*** ~~*the*~~ high level ~~*representatives*~~***representative*** of digital health authorities and ***one high level representative of*** health data access bodies ~~*of all*~~***per Member State appointed by*** the Member ~~*States.*~~ ***State concerned. Where a Member State has designated several health data access bodies, the representative of the coordinating health data access body shall be a member of the EHDS Board;***	the exchange of information among Member States **and the Commission**. The EHDS Board shall be composed of ~~the high level~~ representatives of ~~digital health authorities and health data access bodies of all the Member States. Other~~ national authorities~~, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures shall have an observer role.		Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor ~~may~~***and Union agencies within the field of public health and cybersecurity shall also*** be invited to the meetings, where the issues discussed are of relevance for them. The Board may ~~also invite~~***invite stakeholders,*** experts and observers to attend its meetings, and may cooperate with other	~~attend its meetings, and may cooperate with other external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures~~ **nominated by each Member State. Each Member State** shall have ~~an observer role~~**one vote**. [SECOND, THIRD AND LAST SENTENCES AMENDED AND MOVED TO PARA 1(B)-1(E)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			external experts as appropriate. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures ~~*shall*~~***may*** have an observer role. ***The EHDS Board shall invite a representative of the European Parliament to attend its meetings as an observer.***		
	Article 64(1a)				
698a				**1a. A representative of the Commission and a representative of the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				Member States shall co-chair the meetings of the EHDS Board. (MOVED FROM PARA 6)	
	Article 64(1b)				
698b				**1b. Market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor, may be invited to the meetings, where the issues discussed**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				are of relevance for them. [MOVED FROM PARA 1 AND AMENDED]	
	Article 64(1c)				
698c				**1c. The Board may also invite other national authorities, experts and observers as well as other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures to attend its**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				meetings. When these participants are invited, they shall have an observer role. [MOVED FROM PARA 1 AND AMENDED]	
	Article 64(1d)				
698d				**1d. The Board may cooperate with other external experts as appropriate.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM PARA 1 AND AMENDED]	
	Article 64(1e)				
698e				**1e. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics discussed and their degree of sensitivity.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[MOVED FROM PARA 4]	
	Article 64(2)				
699	2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups, where digital health authorities or health data access bodies for a certain area shall be represented. The subgroups may have joint meetings, as required.		2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups, where digital health authorities or health data access bodies for a certain area shall be represented. The subgroups may have joint meetings, as required.	2. Depending on the functions related to the use of electronic health data, the EHDS Board may work in subgroups **for certain topics**, where digital health authorities or health data access bodies **shall be represented. The subgroups** ~~for a certain area~~ shall ~~be represented~~**support the EHDS Board with specific**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Members of the EHDS Board shall not have financial or other interests in industries or economic activities which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to such industries or economic activities shall be entered in a register held by the Commission which is accessible to the public, upon request, at the Commission's offices.	**expertise**. The subgroups may have joint meetings, as required.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			The EHDS Board's code of conduct shall make reference to the application of this Article, in particular in relation to the acceptance of gifts.		
	Article 64(3)				
700	3. The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure put forward by the Commission.		3. The ~~*composition, organisation, functioning and cooperation of the sub-groups shall be set out in the*~~***EHDS Board shall adopt rules of procedure and a code of conduct,***	**3. The EHDS Board shall adopt its rules of procedures on the basis of a proposal of the Commission. A two-thirds majority is required for the rules of procedures to**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			following a proposal from the Commission. Those rules of procedure ~~*put forward by the Commission*~~***shall provide for the composition, organisation, functioning and cooperation of the Board and its cooperation with the Advisory Board***.	**be adopted. The rules of procedures shall include rules pertaining to** the composition, ~~organisation, functioning~~**structure, operation** and cooperation of the sub-groups **and** shall ~~be set out in the~~ **regulate the role of invitees referred to in paragraphs 1b to 1e, taking into account the topics under discussion and the level of confidentiality involved. Regarding voting** rules**, the EHDS Board shall deliberate by consensus as far as possible. If consensus cannot be reached the EHDS Board shall deliberate by a**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				majority of two thirds of the Member States representatives. Each member shall have one vote ~~of procedure put forward by the Commission~~.	
		Article 64(4)			
701	4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics		*deleted*	~~4. Stakeholders and relevant third parties, including patients' representatives, shall be invited to attend meetings of the EHDS Board and to participate in its work, depending on the topics~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	discussed and their degree of sensitivity.			~~discussed and their degree of sensitivity.~~ [MOVED TO PARA 1E]	
		Article 64(5)			
702	5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article 26 of Regulation […] [Data Governance Act COM/2020/767 final], competent bodies set up		5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article 26 of Regulation […] [Data Governance Act COM/2020/767 final], competent bodies set up	5. The EHDS Board shall cooperate with other relevant bodies, entities and experts, such as the European Data Innovation Board referred to in Article ~~26 of Regulation […] [Data Governance Act COM/2020/767 final~~**29 of Regulation 2022/868**],	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies.		under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679 and cybersecurity bodies***, in particular the ENISA***.	competent bodies set up under Article 7 of Regulation […] [Data Act COM/2022/68 final], supervisory bodies set up under Article 17 of Regulation […] [eID Regulation], European Data Protection Board referred to in Article 68 of Regulation (EU) 2016/679**, cybersecurity bodies, and the European Open Science Cloud, in the effort of reaching advanced solutions for the FAIR data usage in research and innovation** ~~and cybersecurity bodies~~.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 64(6)				
703	6. The Commission shall chair the meetings of the EHDS Board.		6. The Commission shall chair the meetings of the EHDS Board.	~~6. The Commission shall chair the meetings of the EHDS Board.~~ [MOVED TO PARA 1A]	
	Article 64(7)				
704	7. The EHDS Board shall be assisted by a secretariat provided by the Commission.		7. The EHDS Board shall be assisted by a secretariat provided by the Commission.	7. The EHDS Board shall be assisted by a secretariat provided by the Commission.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 64(7a)				
704a			***7a. The EHDS Board shall publish meeting dates and minutes of the discussions and publish an annual report on its activities.***		
	Article 64(8)				
705	8. The Commission shall, by means of implementing acts, adopt the necessary measures for the		8. The Commission shall, by means of implementing acts, adopt the necessary measures for the	8. The Commission shall, by means of implementing acts, adopt the necessary measures for the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	establishment, management and functioning of the EHDS Board. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).		establishment~~, *management and functioning*~~ ***and operations*** of the EHDS Board. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2).	establishment~~, management and functioning~~ **and management** of the EHDS Board. Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 68(2).	
		Article 64a			
705a			***Article 64a*** ***Advisory forum***		
		Article 64a(1)			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
705b			***1. An advisory forum to advise the EHDS Board in the fulfilment of its tasks by providing stakeholder input in matters covered by this Regulation is hereby established.***		
		Article 64a(2), first subparagraph			
705c			***2. The advisory forum shall be composed of relevant stakeholders, including representatives of patients' organisations, health professionals,***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			industry, consumer organisations, scientific researchers and academia. The advisory forum shall have a balanced composition and represent the views of different relevant stakeholders.		
	Article 64a(2), second subparagraph				
705d			***Where commercial interests are represented in the advisory forum, they shall be balanced between large companies, SMEs and start-ups. Focus on primary and secondary use***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of electronic health data shall also be balanced.		
	Article 64a(3)				
705e			***3. Members of the advisory forum shall be appointed by the Commission following a public call for interest and a transparent selection procedure, in consultation with the European Parliament. Members of the advisory forum shall make an annual declaration of their interests, which shall be updated whenever relevant***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			and shall be made publicly available.		
	Article 64a(4)				
705f			***4. The term of office of the members of the advisory forum shall be two years and it shall be renewable only once consecutively.***		
	Article 64a(5)				
705g			***5. The advisory forum may establish standing or***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			temporary subgroups as appropriate for the purpose of examining specific questions related to the objectives of this Regulation.		
		Article 64a(6)			
705h			***6. The advisory forum shall draw up its rules of procedure and elect one co-chair from among its members whose term of office shall be two years, renewable once. A Commission representative shall be the other co-chair.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 64a(7)				
705i			***7. The advisory forum shall hold regular meetings. The advisory forum may invite relevant experts and other relevant stakeholders to its meetings. The Chair of the EHDS Board may attend, ex officio, the meetings of the advisory forum.***		
	Article 64a(8)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
705j			***8. In fulfilling its tasks as set out in paragraph 1, the advisory forum shall prepare opinions, recommendations or written contributions.***		
	Article 64a(9)				
705k			***9. The advisory forum shall prepare an annual report of its activities. That report shall be made publicly available.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 65				
706	Article 65 Tasks of the EHDS Board		Article 65 Tasks of the EHDS Board	Article 65 Tasks of the EHDS Board	
	Article 65(-1)				
706a			***-1. The EHDS Board shall promote the consistent application of this Regulation.***		
	Article 65(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
707	1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:		1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:	1. The EHDS Board shall have the following tasks relating to the primary use of electronic health data in accordance with Chapters II and III:	
	Article 65(1), point (a)				
708	(a) to assist Member States in coordinating practices of digital health authorities;		(a) to assist Member States in coordinating practices of digital health authorities;	(a) to assist Member States in coordinating practices of digital health authorities;	
	Article 65(1), point (b)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
709	(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:		(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, ***taking into account the regional and local level,*** in particular as regards:	(b) to issue written contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	
		Article 65(1), point (ba)			
709a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			deleted		
	Article 65(1), point (b)(i)				
710	*(i)* the provisions set out in Chapters II and III;		(i) the provisions set out in Chapters II and III;	(i) the provisions set out in Chapters II and III;	
	Article 65(1), point (b)(ii)				
711	(ii) development of online services facilitating secure access, including secure electronic identification, to		(ii) development of online services facilitating secure access, including secure electronic identification, to	(ii) development of online services facilitating secure access, including secure electronic identification, to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data for health professionals and natural persons;		electronic health data for health professionals and natural persons;	electronic health data for health professionals and natural persons;	
	Article 65(1), point (b)(iii)				
712	(iii) other aspects of the primary use of electronic health data.		(iii) other aspects of the primary use of electronic health data ***without prejudice to the powers of the supervisory authorities pursuant to Regulation (EU) 2016/679; the written contributions of the EHDS board shall not concern the interpretation or application of rights and obligations under***	~~(iii) other aspects of the primary use of electronic health data.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation (EU) 2016/679 or Regulation 2018/175.		
	Article 65(1), point (ba)				
712a			***(ba) to provide guidance and recommendations to digital health authorities;***		
	Article 65(1), point (c)				
713	(c) to facilitate cooperation between digital health authorities through capacity-building,		(c) to facilitate cooperation between digital health authorities through capacity-building,	(c) to facilitate cooperation between digital health authorities through capacity-building,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	establishing the structure for annual activity reporting, peer-review of annual activity reports and exchange of information;		establishing the structure for annual activity reporting, peer-review of annual activity reports and exchange of information;	establishing the structure for ~~annual~~ **biennial** activity reporting, ~~peer-review of annual activity~~**and exchange of information in those** reports ~~and exchange of information~~;	
		Article 65(1), point (d)			
714	(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;		(d) to share ***among the Members of the Board*** information concerning risks posed by EHR systems and serious incidents as well as their handling, ***without prejudice to the obligation to inform***	(d) to share information concerning risks posed by EHR systems and serious incidents as well as their handling;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			competent supervisory authorities pursuant to Regulation (EU) 2016/679;		
	Article 65(1), point (e)				
715	(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.		(e) to facilitate the exchange of views on the primary use of electronic health data with the ~~*relevant stakeholders, including representatives of patients, health professionals, researchers*~~***Advisory Forum referred to in Article 64(a)***, regulators and policy makers in the health sector ***to support the design***	(e) to facilitate the exchange of views on the primary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			of aligned implementation strategies, guidance and standards and to assess the needs for further improvement. In addition, the co-chairs of the advisory forum shall be invited at least once annually to a meeting of the EHDS Board to present its activities.		
		Article 65(2)			
716	2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in		2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in	2. The EHDS Board shall have the following tasks related to the secondary use of electronic health data in	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accordance with Chapter IV:		accordance with Chapter IV:	accordance with Chapter IV:	
	Article 65(3)				
716a				**3. The EHDS Board shall be consulted by the European Commission in the preparation of draft delegated acts before their adoption pursuant to the procedure laid down in Article 67, and in the preparation of draft implementing acts before presenting them to the committee referred to in Article 68.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 65(2), point (a)				
717	(a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;		(a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;	(a) to assist Member States in coordinating practices of health data access bodies in the implementation of provisions set out in Chapters IV, to ensure a consistent application of this Regulation;	
	Article 65(2), point (b)				
718	(b) to issue written		(b) to issue written	(b) to issue written	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:		contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	contributions and to exchange best practices on matters related to the coordination of the implementation at Member State level of this Regulation and of the delegated and implementing acts adopted pursuant to it, in particular as regards:	
		Article 65(2), point (b)(i)			
719	(i) implementation of rules for access to electronic health data;		(i) implementation of rules for access to electronic health data;	(i) implementation of rules for access to electronic health data;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 65(2), point (b)(ii)				
720	(ii) technical specifications or existing standards regarding the requirements set out in Chapter IV;		(ii) technical specifications or existing standards regarding the requirements set out in Chapter IV;	(ii) technical specifications or existing standards regarding the requirements set out in Chapter IV;	
	Article 65(2), point (b)(iii)				
721	(iii) incentives policy for promoting data quality and interoperability improvement;		(iii) incentives policy for promoting data quality and interoperability improvement;	(iii) incentives policy for promoting data quality and interoperability improvement;	
	Article 65(2), point (b)(iv)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
722	(iv) policies concerning fees to be charged by the health data access bodies and data holders;		(iv) policies concerning fees to be charged by the health data access bodies and data holders;	(iv) policies concerning fees to be charged by the health data access bodies and **health** data holders;	
	Article 65(2), point (b)(v)				
723	(v) the establishment and application of penalties;		*deleted*	*(v)* the establishment and application of penalties;	
	Article 65(2), point (b)(vi)				
724					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	(vi) other aspects of the secondary use of electronic health data.		(vi) other aspects of the secondary use of electronic health data ***without prejudice to the powers of the supervisory authorities pursuant to Regulation (EU) 2016/679***.	~~(vi) other aspects of the secondary use of electronic health data.~~	
		Article 65(2), point (c)			
725	(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for annual activity reporting, peer-review of annual activity reports and		(c) to facilitate cooperation ***and exchange of best practices*** between health data access bodies through capacity-building, establishing the structure for annual activity reporting, peer-review of annual	(c) to facilitate cooperation between health data access bodies through capacity-building, establishing the structure for ~~annual~~**biennial** activity reporting, ~~peer-review of annual activity reports and~~ **and** exchange	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	exchange of information;		activity reports and exchange of information ***pursuant to the obligations laid down in Article 37(1), point (g)***;	of information **in those reports**;	
		Article 65(2), point (d)			
726	(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling;		(d) to share information concerning risks and data protection incidents related to secondary use of electronic health data, as well as their handling; ***without prejudice to the obligation to inform competent supervisory authorities pursuant to***	(d) to share information concerning risks and ~~data protection~~ incidents related to secondary use of electronic health data, **such as risks and incidents in the secure processing environment as referred to in Article 50,** as well as their handling;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Regulation (EU) 2016/679;		
	Article 65(2), point (e)				
727	(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];		(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];	~~(e) to contribute to the work of the European Data Innovation Board to be established in accordance with Article 29 of the Regulation […] [Data Governance Act COM/2020/767 final];~~ SEE ARTICLE 64(5)]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 65(2), point (f)				
728	(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.		(f) to ~~*facilitate the*~~ exchange ~~*of*~~ views on the secondary use of electronic health data with the ~~*relevant stakeholders, including representatives of patients, health professionals, researchers,*~~ ***Advisory Forum referred to in Article 64(a)*** regulators and policy makers in the health sector~~.~~ ***, to support the design of aligned implementation strategies, guidance and standards and to assess the needs for further improvement;***	(f) to facilitate the exchange of views on the secondary use of electronic health data with the relevant stakeholders, including **health data holders, health data users,** representatives of patients, health professionals, researchers, regulators and policy makers in the health sector.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 65(2), point (fa)				
728a			***(fa) adopt recommendations to facilitate consistent provision of the secure processing environment compliant with the technical, information security and interoperability requirements.***		
	Article 66				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
729	Article 66 Joint controllership groups for Union infrastructures		Article 66 Joint controllership groups for Union infrastructures	Article 66 ~~Joint controllership~~**The Steering** Groups for ~~Union~~**the** infrastructures **MyHealth@EU and HealthData@EU**	
	Article 66(1)				
730	1. The Commission shall establish two groups dealing with joint controllership for the cross-border infrastructures provided for in Articles 12		1. The Commission shall establish two groups dealing with joint controllership for the cross-border infrastructures provided for in Articles 12	1. ~~The Commission shall establish two~~**Two Steering** groups ~~dealing with joint controllership~~ **are hereby established** for the cross-border infrastructures	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	and 52. The groups shall be composed of the representatives of the national contact points and other authorised participants in those infrastructures.		and 52. The groups shall be composed of the representatives of the national contact points and other authorised participants in those infrastructures.	provided for in Articles 12 and 52~~. The groups~~**; the MyHealth@EU Steering group and the HealthData@EU Steering group. Each group** shall be composed of ~~the representatives~~**one representative per Member State** of the **respective** national contact points ~~and other authorised participants in those infrastructures~~.	
	Article 66(1a)				
730a				**1a. The Steering groups**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				shall take operational decisions concerning the development and operation of the cross-border infrastructures referred to in Chapters II and IV, on changes of infrastructure, adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The groups shall also state their view on accepting individual authorised participants to join the infrastructures or to disconnect them.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				[(MOVED FROM PARA 6 AND AMENDED)]	
	Article 66(1b)				
730b				**1b. The Steering Groups shall take decisions by consensus. Where consensus cannot be reached, the adoption of a decision shall require the support of members representing two-thirds majority, where each Member State has one vote.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 66(2)				
731	2. The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure adopted by those groups.		2. The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure adopted by those groups.	2. The composition, organisation, functioning and cooperation of the ~~sub-groups~~**Steering groups** shall be set out in the rules of procedure adopted by those groups.	
	Article 66(2a)				
731a			***2a. The EHDS board shall provide recommendations***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to the Commission and the Member States on the implementation and enforcement of this Regulation, including cross-border interoperability of health data, and potential mechanisms of funding support to ensure equal development of health data systems across Europe in respect of the secondary use of electronic health data, without prejudice to the competences of the EDPB, where personal electronic health data are concerned.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 66(2b)				
731b			***2b. The EHDS board may commission studies and other initiatives in order to support the implementation and development of the EHDS.***		
	Article 66(2c)				
731c			***2c. The EHDS Board shall publish an annual report to include the implementation status of the EHDS and other relevant points of***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			development, including with respect to cross-border health data interoperability, and related implementation challenges.		
		Article 66(3)			
732	3. Stakeholders and relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work.		3. Stakeholders and relevant third parties, including patients'***, health professionals', consumers' and industry*** representatives, may be invited to attend meetings of the groups and to participate in their work.	3. ~~Stakeholders and relevant third parties, including patients' representatives,~~ **Other authorised participants** may be invited to ~~attend meetings of the groups and to participate in their work~~**exchange information**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				and views on relevant matters related to the cross-border infrastructures respectively provided for in Articles 12, 13 and 52. When these participants are invited, they shall have an observer role. [MOVED FROM ARTICLE 66(1) AND AMENDED]	
	Article 66(3a)				
732a				**3a. Stakeholders and**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				relevant third parties, including patients' representatives, may be invited to attend meetings of the groups and to participate in their work. [MOVED FROM ARTICLE 66(3)]	
	Article 66(4)				
733	4. The groups shall elect chairs for their meetings.		4. The groups shall elect chairs for their meetings.	4. The groups shall elect chairs for their meetings.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 66(5)				
734	5. The groups shall be assisted by a secretariat provided by the Commission.		5. The groups shall be assisted by a secretariat provided by the Commission.	5. The groups shall be assisted by a secretariat provided by the Commission.	
	Article 66(6)				
735	6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure,		6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure,	~~6. The groups shall take decisions concerning the development and operation of the cross-border infrastructures pursuant to Chapters II and IV, on changes of infrastructure,~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.		adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.	~~adding additional infrastructures or services, or ensuring interoperability with other infrastructures, digital systems or data spaces. The group shall also take decisions to accept individual authorised participants to join the infrastructures or to disconnect them.~~ [MOVED TO PARA 1A]	
	Article 66(6a)				
735a			***6a. The groups shall***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			consult relevant experts when carrying out their tasks, as well as on technical implementing measures related to cybersecurity, confidentiality and data protection, in particular experts from ENISA, EDPB and EDPS.		
	Article 66a				
735b				**Article 66A** **Roles and responsibilities of the Commission regarding the functioning**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				of the European Health Data Space	
	Article 66a(1), first subparagraph				
735c				**1. In addition to its role in making available electronic health data held by Union institutions, bodies, or agencies, in accordance with 36, 36A, 52(1A) and its tasks under Chapter III, including Article 26A, the Commission shall provide the development, maintenance, hosting and operation of the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				infrastructures and central services required to support the functioning of the European Health Data Space, to all relevant connected entities:	
	Article 66a(1), second subparagraph				
735d				**i. an interoperable, cross-border identification and authentication mechanism for natural persons and health professionals, in accordance with Article 9(3) and (4);**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 66a(1), third subparagraph				
735e				**ii. the central services and infrastructures for digital health of MyHealth@EU, in accordance with Article 12(1);**	
	Article 66a(1), fourth subparagraph				
735f				**iii. compliance checks for connecting authorised participants to MyHealth@EU, in accordance with Article 12(9);**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 66a(1), fifth subparagraph				
735g				**iv. the additional cross-border digital health services and infrastructures within the meaning of Article 13(1) of this Regulation**	
	Article 66a(1), sixth subparagraph				
735h				**v. as part of HealthData@EU, a service to submit**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				applications for making available electronic health data from health data holder in multiple Member States or from other authorised participants and to automatically forward them to the relevant contact points, in accordance with Article 45(5A);	
	Article 66a(1), seventh subparagraph				
735i				**vi. the central services and infrastructures of HealthData@EU in**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				accordance with Article 52, paragraphs (6) and (7);	
	Article 66a(1), eighth subparagraph				
735j				**vii. a secure processing environment in accordance with Article 52(8), in which health data access bodies may decide to make data available in accordance with Article 46(5A);**	
	Article 66a(1), ninth subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
735k				**viii. compliance checks for connecting authorised participants to HealthData@EU, in accordance with Article 52(12);**	
	Article 66a(1), tenth subparagraph				
735l				**ix. a federated EU dataset catalogue connecting the national dataset catalogues, in accordance with Article 57;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 66a(1), eleventh subparagraph				
735 m				**x. a secretariat for the EHDS Board, in accordance with Article 64(7);**	
	Article 66a(1), twelfth subparagraph				
735n				**xi. a secretariat for the steering groups, in accordance with Article 66(5).**	
	Article 66a(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
735o				**2. The services referred to in paragraph 1 shall meet sufficient quality standards in terms of availability, security, capacity, interoperability, maintenance, monitoring and evolution to ensure an effective functioning of the European Health Data Space. The Commission shall provide them in accordance with the operational decisions of the relevant Steering Groups. These standards, once defined, shall apply to subcontractors of the Commission.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 66a(3)				
735p				**3. The Commission shall adopt, by means of implementing acts, the rules and measures for the operation of the infrastructures and all required central services of the European Health Data Space with the required quality of service, simultaneously with the adoption of the implementing acts referred to in Articles 12, 13 and 52. Those**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				implementing acts shall be adopted in accordance with the examination procedure referred to in Article 68(2).	
	Article 66a(4)				
735q				**4. The Commission shall issue a biennial public report on the infrastructures and services supporting the European Health Data Space that it provides in accordance with paragraph 1.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	CHAPTER VII				
736	CHAPTER VII Delegation and Committee		CHAPTER VII Delegation and Committee	CHAPTER VII Delegation and Committee	
	Article 67				
737	Article 67 Exercise of the delegation		Article 67 Exercise of the delegation	Article 67 Exercise of the delegation	
	Article 67(1)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
738	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	
		Article 67(2)			
739	2. The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), 56(4) shall be conferred on the Commission for an indeterminate period of		2. The power to adopt delegated acts referred to in Articles 5(2), ***7(3), 9(2) 10(3), 13(3)*** ~~*10(3),*~~ 25(3), 32(4), ~~*33(7),*~~ 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), ***52(13), 56(4) and 63a(2)*** ~~*56(4)*~~ shall be	2. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~**32(4), and** 56(4) shall be conferred on the Commission for an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	time from the date of entry into force of this Regulation.		conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.	indeterminate period of time from the date of entry into force of this Regulation.	
		Article 67(3)			
740	3. The power to adopt delegated acts referred to in Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to		3. The power to adopt delegated acts referred to in Articles 5(2), ~~*10(3), 25(3), 32(4), 33(7),*~~ ***7(3)*** 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), ***52(13), 56(4) and 63a(2)*** ~~*56(4)*~~ may be revoked at any time by the European Parliament or by the Council. A decision to	3. The power to adopt delegated acts referred to in Articles 5(2), ~~10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~**32(4) and** 56(4) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.		revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	
		Article 67(4)			
741	4. Before adopting a delegated act, the Commission shall consult		4. Before adopting a delegated act, the Commission shall consult	4. Before adopting a delegated act, the Commission shall consult	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.		experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.	experts designated by each Member State in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.	
	Article 67(5)				
742	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 67(6)				
743	6. A delegated act adopted pursuant to Articles 5(2), 10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the		6. A delegated act adopted pursuant to Articles 5(2), ~~*10(3)*~~***7(3), 9(2), 13(3)***, 25(3), 32(4)~~*, 33(7)*~~, 37(4), 39(3), 41(7), 45(7), 46(8), 52(7), ***52(13), 56(4) or 63a(2)***~~*56(4)*~~ shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the	6. A delegated act adopted pursuant to Articles 5(2), ~~10(3), 25(3), 32(4), 33(7), 37(4), 39(3), 41(7), 45(7), 46(8), 52(7),~~**32(4), and** 56(4) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of 3 months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.		expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.	European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 3 months at the initiative of the European Parliament or of the Council.	
		Article 68			
744	Article 68 Committee procedure		Article 68 Committee procedure	Article 68 Committee procedure	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 68(1)				
745	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	
	Article 68(2)				
746	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.		2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article **4**5 of Regulation (EU) No 182/2011 shall apply.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 68(2a)				
746a			***2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.***		
	Chapter VIII				
747	Chapter VIII Miscellaneous		Chapter VIII Miscellaneous	Chapter VIII Miscellaneous	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 69				
748	Article 69 Penalties		Article 69 Penalties	Article 69 Penalties	
	Article 69, first paragraph				
749	Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and		Member States shall lay down the rules on ***other*** penalties applicable to infringements of this Regulation ***in particular for infringements which are not subject to administrative fines pursuant to Article 43a,***	**In addition to the measures laid down in Articles 30 and 43 of this Regulation and Chapter VIII of Regulation (EU) 2016/679,** Member States shall lay down the rules on penalties applicable to infringements of this	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.		and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.	Regulation and shall take all measures necessary to ensure that they are implemented. The penalties shall be effective, proportionate and dissuasive. ~~Member States shall notify the Commission of those rules and measures by date of application of this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them.~~ [LAST SENTENCE MOVED TO PARA 3]	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 69, first paragraph a				
749a				**Member States shall take into account the following non-exhaustive and indicative criteria for the imposition of penalties for infringements of this Regulation, where appropriate:**	
	Article 69, first paragraph a, point (a)				
749b				**(a) the nature, gravity, scale and duration of the infringement;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 69, first paragraph a, point (b)				
749c				**(b) any action taken by the infringer to mitigate or remedy the damage caused by the infringement;**	
	Article 69, first paragraph a, point (c)				
749d				**(c) any previous infringements by the infringer;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 69, first paragraph a, point (d)				
749e				**(d) the financial benefits gained or losses avoided by the infringer due to the infringement, insofar as such benefits or losses can be reliably established;**	
	Article 69, first paragraph a, point (e)				
749f				**(e) any other aggravating or mitigating factors applicable to the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				circumstances of the case;	
	Article 69, first paragraph a, point (f)				
749g				**(f) infringer's annual turnover of the preceding financial year in the Union.**	
	Article 69, third paragraph				
749h				**3. Member States shall notify the Commission of those rules and measures by date of application of**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				this Regulation and shall notify the Commission without delay of any subsequent amendment affecting them. [MOVED FROM PARA 1]	
	Article 69a				
749i			***Article 69a*** ***Right to receive compensation***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 69a, first paragraph				
749j			***Any person who has suffered material or non-material damage as a result of an infringement of this Regulation shall have the right to receive compensation, in accordance with national and Union law.***		
	Article 69b				
749k			***Article 69b*** ***Representation of a natural***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			person		
		Article 69b, first paragraph			
749l			***Where a natural person considers that their rights under this Regulation have been infringed, they shall have the right to mandate a not-for-profit body, organisation or association which is constituted in accordance with the law of a Member State, has statutory objectives which are in the public interest and is active in the field of the protection of personal***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			data, to lodge a complaint on their behalf or to exercise the rights referred to in 11a.		
	Article 69c				
749 m			***Article 69c*** ***Suspension of proceedings***		
	Article 69c(1)				
749n			***1. Where a competent court of a Member State***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			seised of proceedings against a decision by a digital health authority or health data access body has reason to believe that proceedings concerning the same access to electronic health data by the same health data user, such as for the same purpose of processing for secondary use are brought before a competent court in another Member State, it shall contact that court in order to confirm the existence of such related proceedings.		
	Article 69c(2)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
749o			***2. Where proceedings concerning the same subject matter and the same digital health authority or health data access body are pending before a court in another Member State, any court other than the court first seised may stay its proceedings or may, at the request of one of the parties, decline jurisdiction in favour of the court first seised if that court has jurisdiction over the proceedings in question and its law permits the consolidation of such***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			related proceedings.		
	Article 70				
750	Article 70 Evaluation and review		Article 70 Evaluation and review	Article 70 ***Evaluation, review and progress report***~~Evaluation and review~~	
	Article 70(1)				
751	1. After 5 years from the entry into force of this Regulation, the		1. ~~*After*~~***By*** 5 years from the entry into force of this Regulation, the	1. After ~~5~~ **7** years from the entry into force of this Regulation, the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by		Commission shall carry out a targeted evaluation of this Regulation especially with regards to ~~*Chapter III, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee*~~***the possibilities to further extend interoperability between EHR systems and electronic health data access services other than those established by the Member States, the possibility of expanding the access to MyHealth@EU infrastructure to third countries and international***	Commission shall carry out a targeted evaluation of this Regulation ~~especially with regards to Chapter III~~, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include ~~an assessment of the self-certification of EHR systems and reflect on the need to introduce a conformity assessment procedure performed by~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	notified bodies.		***organisations, the need to update the data categories in Article 33*** and the ~~*Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment. The evaluation shall include an assessment*~~***purposes of use in Article 34, the implementation and use by natural persons of the opt-out mechanism in secondary use as referred to in Article 33(5a), and opt-in mechanism in secondary use as referred to in Article 33(5b), the use and implementation*** of the ~~*self-certification of EHR systems and reflect on the*~~	~~notified bodies.~~**the following:**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			~~*need to introduce a conformity assessment procedure performed by notified bodies*~~***right referred to in Article 3(9), as well as the application of fees as referred to in Article 42 and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment***.		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 70(1), point (a)				
751a				**(a) an assessment of the certification framework of EHR systems in Chapter III and the need to introduce further tools regarding conformity assessment ;**	
	Article 70(1), point (aa)				
751b				**(aa) an assessment of the functioning of the Internal Market for the EHR systems;**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 70(1), point (b)				
751c				**(b) an assessment of the costs and benefits of implementation of the provisions for secondary use laid out in Chapter IV.**	
	Article 70(1a)				
751d			***1a. By... [please insert the date two years from the entry into force of this Regulation], the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Commission shall carry out an evaluation of the Union funding attributed to the setting up and functioning of the EHDS, in particular concerning the ability of the bodies established under this Regulation to carry out their tasks and obligations under this Regulation and of Member States in relation to applying the Regulation in a uniform and coherent manner. The Commission shall submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			Committee of the Regions, accompanied, where appropriate, by the necessary measures.		
	Article 70(2)				
752	2. After 7 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the		2. After 7 years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the	2. After ~~7~~ **9** years from the entry into force of this Regulation, the Commission shall carry out an overall evaluation of this Regulation, and submit a report on its main findings to the European Parliament and to the Council, the European Economic and Social Committee and the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.		Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment ***or other appropriate measures***.	Committee of the Regions, accompanied, where appropriate, by a proposal for its amendment.	
	Article 70(3)				
753	3. Member States shall provide the Commission with the information necessary for the preparation of that report.		3. Member States shall provide the Commission with the information necessary for the preparation of that report.	3. Member States shall provide the Commission with the information necessary for the preparation of that report **and the Commission shall take this information duly into account in that report**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 70(4)				
753a				**4. Every year following the entry into force of this Regulation and until its full application, the Commission shall submit a progress report to the Council on the state of play of the preparations for the full implementation of this Regulation. The report shall contain information about the degree of progress and the readiness of the Member States**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				including an assessment of the feasibility of reaching the time frames laid down in Article 72 of this Regulation and may also contain recommendations to Member States to improve preparedness for the application of this Regulation.	
	Article 71				
754	Article 71 Amendment to Directive 2011/24/EU		Article 71 Amendment to Directive 2011/24/EU	Article 71 Amendment to Directive 2011/24/EU	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 71, first paragraph				
755	Article 14 of Directive 2011/24/EU is deleted.		Article 14 of Directive 2011/24/EU is deleted.	Article 14 of Directive 2011/24/EU is deleted.	
	Article 71a				
755a			***Article 71a*** ***Amendments to Directive (EU) 2020/1828***		
	Article 71a, first paragraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
755b			***In the Annex of Directive (EU) 2020/1828, the following point is added:***		
	Article 71a, second paragraph				
755c			***(XX) Regulation (EU) XXX of the European Parliament and of the Council on the European Health Data Space.***		
	Chapter IX				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
756	Chapter IX Deferred application and final provisions		Chapter IX Deferred application and final provisions	Chapter IX Deferred application**,** **transitional** and final provisions	
	Article 72				
757	Article 72 Entry into force and application		Article 72 Entry into force and application	Article 72 Entry into force and application	
	Article 72, first paragraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
758	This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	**1.** This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	
	Article 72, second paragraph				
759	It shall apply from 12 months after its entry into force.		It shall apply from ~~12~~ ***24*** months after its entry into force.	~~It~~ **This Regulation** shall apply ~~from 12 months~~ **2 years** after ~~its~~ entry into force**, unless provided otherwise in paragraph 2**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 72, third paragraph				
760	However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:		However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31 shall apply as follows:	**2.** ~~However, Articles 3, 4, 5, 6, 7, 12, 14, 23 and 31~~**Articles 2A, 5, 6, 7A, 7B, 8A, 8B, 8C, 8D, 8E, 8F, 8G, 12, 13A, 13B, 14, 23, 31 and 32 in Chapters II and III** shall apply as follows:	
	Article 72, third paragraph, point (a)				
761	(a) from 1 year after date of entry into application to categories of personal		(a) from 1 year after date of entry into application to categories of personal	(a) from ~~1 year~~**5 years** after date of entry into ~~application~~ **force** to	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.;		electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data.;	categories of personal electronic health data referred to in Article 5(1), points (a), (b) and (c), and to EHR systems intended by the manufacturer to process such categories of data~~.~~;	
		Article 72, third paragraph, point (b)			
762	(b) from 3 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the manufacturer to		(b) from 3 years after date of entry into application to categories of personal electronic health data referred to in Article 5(1), points (d), (e) ***(f), and f(a)*** ~~*and (f),*~~ and to EHR systems intended by the	(b) from ~~3~~**7** years after date of entry into ~~application~~ **force** to categories of personal electronic health data referred to in Article 5(1), points (d), (e) and (f), and to EHR systems intended by the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	process such categories of data;		manufacturer to process such categories of data;	manufacturer to process such categories of data;	
	Article 72, third paragraph, point (c)				
763	(c) from the date established in delegated acts pursuant to Article 5(2) for other categories of personal electronic health data.		*deleted*	(c) from **1 year after** the date established in **a** delegated ~~acts~~**act** pursuant to Article 5(2) for ~~other~~**amendments of the main characteristics of personal electronic health data in Annex 1, provided that this date of entry into application is subsequent to the date of entry into application referred to in point (a) and (b) for the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				categories of personal electronic health data **concerned**.	
	Article 72, first paragraph (after point 2)				
763a				**The implementing acts referred to in Articles 2A(3), 6(1), 12(4) and 23(1) shall be adopted within 1 year after date of entry into force and apply as referred to in subparagraph 1 in this paragraph.**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Article 72, fourth paragraph				
764	Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3 years after date of entry into application.		Chapter III shall apply to EHR systems put into service in the Union pursuant to Article 15(2) from 3 years after date of entry into application.	Chapter III shall apply to EHR systems put into service in the Union ~~pursuant to~~**referred to in** Article ~~15(2) from 3~~**13B(2) from 7** years after date of entry into ~~application~~**force** .	
	Article 72, fourth paragraph a				
764a				**Chapter IV shall apply from 5 years after date of entry into force, except Article 33(1), points (b)**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				(e), (ea) (j), (l) and (n) which shall apply from 7 years after date of entry into force.	
		Article 72, fourth paragraph (after point 2)			
764b				**The implementing acts referred to in Articles 35F(5), 50(4), 52(13), 53(3), 55 and 56(5) shall be adopted within 2 year after date of entry into force and apply from 4 years after this Regulation enter into force and article 52(4) which shall apply from 10 years after the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				data of entry into force.	
	Article 72, third paragraph (after point 2)				
764c	This Regulation shall be binding in its entirety and directly applicable in all Member States. Moved reference text		This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States. Moved from row 765 [765 - 764c]	
	Article 72, fifth paragraph				
765					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	Moved to row 764c [765 - 764c]	
	Article 72, last paragraph				
765a					
	Formula				
766	Done at Strasbourg,		Done at Strasbourg,	Done at Strasbourg,	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Formula				
767	For the European Parliament		For the European Parliament	For the European Parliament	
	Formula				
768	The President		The President	The President	
	Formula				
769	For the Council		For the Council	For the Council	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Formula				
770	The President		The President	The President	
	Annex I				
771	Annex I		Annex I AMs 534, 535 & 536 merged.	Annex I	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex I, first paragraph				
772	Main characteristics of electronic health data categories		Main characteristics of electronic health data categories	Main characteristics of **priority categories of personal** electronic health data ~~categories~~**for primary use**	
	Annex I, Table 1, Column 1, Row 1				
773	Electronic health data category		Electronic health data category	Electronic health data category	
	Annex I, Table 1, Column 1, Row 2				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
774	1. Patient summary		1. Patient summary	1. Patient summary	
	Annex I, Table 1, Column 1, Row 3				
775	2. Electronic prescription		2. Electronic prescription	2. Electronic prescription	
	Annex I, Table 1, Column 1, Row 4				
776	3. Electronic dispensation		3. Electronic dispensation	3. Electronic dispensation	
	Annex I, Table 1, Column 1, Row 5				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
777	4. Medical image and image report		4. Medical image and image report	4. Medical image and image report	
	Annex I, Table 1, Column 1, Row 6				
778	5. Laboratory result		5. Laboratory result	5. Laboratory result	
	Annex I, Table 1, Column 1, Row 7				
779	6. Discharge report		6. Discharge report	6. Discharge report	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex I, Table 1, Column 2, Row 1				
780	Main characteristics of electronic health data included under the category		Main characteristics of electronic health data included under the category	Main characteristics of electronic health data included under the category	
	Annex I, Table 1, Column 2, Row 2				
781	Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following		Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The ***patient***	Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	information is part of a patient summary: 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7. Current, resolved, closed or inactive problems 8. Textual information related to medical history 9. Medical devices and		***summary shall be harmonized across Member States and include a minimum data set that can be expanded to include disease-specific data. The*** following information is part of a patient summary: 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7. Current, resolved, closed	information is part of a patient summary: 1.- Personal details 2.- Contact information 3.- Information on insurance 4.- Allergies 5.- Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7.- Current, resolved, closed or inactive problems 8.- Textual information related to medical history	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	implants 10. Procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare		or inactive problems ***in an international classification coding system*** 8. Textual information related to medical history 9.- Medical devices and implants 10. ***Medical*** procedures 11. Functional status ***11a (new) Prescription, dispensation and administration of current and past medications across the continuum of care, including, hospital and ambulatory/day hospitals***	9.- Medical devices and implants 10. Procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	disease such as details about the impact or characteristics of the disease		12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease ***18a (new) Blood type***	18. Information on a rare disease such as details about the impact or characteristics of the disease	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex I, Table 1, Column 2, Row 3				
782	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.		Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.	Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.	
	Annex I, Table 1, Column 2, Row 4				
783	Information on the supply of a medicinal product to a natural person by a pharmacy based on an		Information on the supply of a medicinal product to a natural person by a pharmacy based on an	Information on the supply of a medicinal product to a natural person by a pharmacy based on an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	electronic prescription.		electronic prescription.	electronic prescription.	
	Annex I, Table 1, Column 2, Row 5				
784	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.		Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.	Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.	
	Annex I, Table 1, Column 2, Row 6				
785	Electronic health data		Electronic health data	Electronic health data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.		representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.	representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.	
		Annex I, Table 1, Column 2, Row 7			
786	Electronic health data related to a healthcare encounter or episode of care and including essential		Electronic health data related to a healthcare encounter or episode of care and including essential	Electronic health data related to a healthcare encounter or episode of care and including essential	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	information about admission, treatment and discharge of a natural person.		information about admission, treatment and discharge of a natural person.	information about admission, treatment and discharge of a natural person.	
	Annex II				
787	Annex II		Annex II	Annex II	
	Annex II, first paragraph				
788	Essential requirements for EHR systems and products claiming interoperability		Essential requirements for EHR systems and products claiming interoperability	Essential requirements for **the harmonised components of** EHR systems and products	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	with EHR SYSTEMS		with EHR SYSTEMS	claiming interoperability with EHR SYSTEMS	
	Annex II, second paragraph				
789	The essential requirements laid down in this Annex shall apply mutatis mutandis to products claiming interoperability with EHR systems.		The essential requirements laid down in this Annex shall apply mutatis mutandis to products claiming interoperability with EHR systems.	The essential requirements laid down in this Annex shall apply mutatis mutandis to ~~products~~**medical devices, in vitro diagnostic medical devices, AI systems, and wellness apps** claiming interoperability with EHR systems.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex II, point 1.				
790	1. General requirements		1. General requirements	1. General requirements	
	Annex II, third paragraph				
791	1.1. An electronic health record system (EHR system) shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose and its use does not		1.1. An electronic health record system (EHR system) shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose and its use does not	1.1. **The harmonised components of** an electronic health record system (EHR system) shall achieve the performance intended by its manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, ~~it~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	put at risk patient safety.		put at risk patient safety.	~~is~~**they are** suitable for ~~its~~**their** intended purpose and ~~its~~**their** use does not put at risk patient safety.	
		Annex II, fourth paragraph			
792	1.2. An EHR system shall be designed and developed in such a way that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its		1.2. An EHR system shall be designed and developed in such a way that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its	1.2. ~~An~~**The harmonised components of the** EHR system shall be designed and developed in such a way that ~~it~~**the system** can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	intended use.		intended use.	characteristics and performance during its intended use.	
	Annex II, fifth paragraph				
793	1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.		1.3. An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.	1.3. ~~An EHR system shall be designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons, in line with the intended purpose of the EHR system, as set out in Chapter II of this Regulation.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex II, sixth paragraph				
794	1.4. An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system.		1.4. An EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system.	1.4. **The harmonised components of** an EHR system that is intended to be operated together with other products, including medical devices, shall be designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared between the device and the EHR system **in relation to those two components**.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex II, point 2.				
795	2. Requirements for interoperability		2. Requirements for interoperability	2. Requirements for interoperability	
	Annex II, seventh paragraph				
796	2.1. An EHR system shall allow personal electronic health data to be shared between health professionals or other entities from the health system, and between health professionals and patient or health professional portals		2.1. An EHR system shall allow personal electronic health data to be shared between health professionals or other entities from the health system, and between health professionals and patient or health professional portals	2.1. ~~An EHR system shall allow personal electronic health data to be shared between health professionals or other entities from the health system, and between health professionals and patient or health professional portals~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	in a commonly used electronic interoperable format, which includes, inter-alia, dataset content, data structures, formats, vocabularies, taxonomies, exchange formats, standards, specifications, profiles for exchange and code lists, thus enabling system to system communication.		in a commonly used electronic interoperable format, which includes, inter-alia, dataset content, data structures, formats, vocabularies, taxonomies, exchange formats, standards, specifications, profiles for exchange and code lists, thus enabling system to system communication.	~~in a commonly used electronic interoperable format, which includes, inter-alia, dataset content, data structures, formats, vocabularies, taxonomies, exchange formats, standards, specifications, profiles for exchange and code lists, thus enabling system to system communication.~~	
		Annex II, point 2.1.a.			
796a				**2.1.a. Where an EHR system is designed to store or intermediate personal**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				electronic health data, it shall provide an interface enabling access to the personal electronic health data processed by it in the European health record exchange format, by means of the European interoperability component for EHR systems.	
	Annex II, point 2.1.b.				
796b				**2.1.b. Where an EHR system is designed to store or intermediate personal electronic health data, it**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				shall be able to receive personal electronic health data in the European health record exchange format, by means of the European interoperability component for EHR systems.	
	Annex II, point 2.1.c.				
796c				**2.1.c. Where an EHR system is designed to provide access to personal electronic health data, it shall be able to receive personal electronic health data in the European**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				health record exchange format, by means of the European interoperability component for EHR systems.	
	Annex II, eighth paragraph				
797	2.2. An EHR system shall be interoperable and compatible with the European infrastructures set out in this Regulation for the cross-border sharing of electronic health data.		2.2. An EHR system shall be interoperable and compatible with the European infrastructures set out in this Regulation for the cross-border sharing of electronic health data.	2.2. ~~An EHR system shall be interoperable and compatible with the European infrastructures set out in this Regulation for the cross-border sharing of electronic health data.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex II, ninth paragraph				
798	2.3. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data structured in a structured way that supports the data sharing in a structured, commonly used and machine-readable format, enabling system to system communication.		2.3. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data structured in a structured way that supports the data sharing in a structured, commonly used***, open*** and machine-readable format, enabling system to system communication~~.~~	2.3. An EHR system that includes a functionality for entering structured personal electronic health data shall enable the entry of data ~~structured in a structured way that supports the data sharing in a structured, commonly used and machine-readable format, enabling system to system communication~~ **with granularity sufficient to enable the provision of the entered personal electronic health data in the European health**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				record exchange format.	
	Annex II, tenth paragraph				
799	2.4. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes.		2.4. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes.	2.4. **The harmonised components of** an EHR system shall not include features that prohibit, restrict or place undue burden on authorised access, personal electronic health data sharing, or use of personal electronic health data for permitted purposes.	
	Annex II, eleventh paragraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
800	2.5. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product.		2.5. An EHR system shall not include features that prohibit, restrict or place undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product. ***Authorised exporting of personal electronic health data shall be free of charge, without undue delay, or in in any event within one month from the request and in a structured, commonly used and machine-readable format, in line with the interoperability and***	2.5. **The harmonised components of** an EHR system shall not include features that prohibit, restrict or place undue burden on authorised exporting of personal electronic health data for the reasons of replacing the EHR system by another product.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			security requirements to be developed according to Articles 23 and 50.		
	Annex II, eleventh paragraph a				
800a			***An EHR system shall be developed in interoperable format that enables data portability.***		
	Annex II, point 3.				
801	3. Requirements for		3. Requirements for	3. Requirements for	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	security		security	security **and for logging**	
	Annex II, twelfth paragraph				
802	3.1. An EHR system shall be designed and developed in such a way that it ensures safe and secure processing of electronic health data, and that it prevents unauthorised access to such data.		3.1. An EHR system shall be designed and developed in such a way that it ensures ***highly*** safe and secure processing of electronic health data, and that it prevents unauthorised access to such data***, and that it duly takes into consideration the principles of data minimization and data protection by design***.	3.1. ~~An EHR system shall be designed and developed in such a way that it ensures safe and secure processing of electronic health data, and that it prevents unauthorised access to such data.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			AMs 540&541 merged.		
	Annex II, thirteenth paragraph				
803	3.2. An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals, including checks on professional rights and qualifications.		3.2. An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals, including checks on professional rights and qualifications.	3.2. ~~An EHR system designed to be used by health professionals shall provide reliable mechanisms for the identification and authentication of health professionals, including checks on professional rights and qualifications.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex II, fourteenth paragraph				
804	3.3. An EHR system designed to be used by health professionals shall support the use of information on professional rights and qualifications as part of the access control mechanisms, such as role-based access control.		3.3. An EHR system designed to be used by health professionals shall support the use of information on professional rights and qualifications as part of the access control mechanisms, such as role-based access control.	3.3. ~~An EHR system designed to be used by health professionals shall support the use of information on professional rights and qualifications as part of the access control mechanisms, such as role-based access control.~~	
	Annex II, fifteenth paragraph				
805	3.4. An EHR system designed to enable access		3.4. An EHR system designed to enable access	3.4. **The harmonised logging component of** an	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	by health professionals or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record, at least the following information on every access event or group of events:		by health professionals or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record, at least the following information on every access event or group of events:	EHR system designed to enable access by health ~~professionals~~**providers** or other individuals to personal electronic health data shall provide sufficient logging mechanisms that record, at least the following information on every access event or group of events:	
	Annex II, fifteenth paragraph, point (a)				
806	(a) identification of the health professional or other individual having accessed electronic health data;		(a) identification of the health professional or other individual having accessed electronic health data;	(a) identification of the health ~~professional~~**provider** or other ~~individual~~**individuals**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				having accessed **personal** electronic health data;	
	Annex II, fifteenth paragraph, point (b)				
807	(b) identification of the individual;		(b) identification of the individual;	(b) identification of the **specific** individual **or individuals having accessed personal electronic health data**;	
	Annex II, fifteenth paragraph, point (c)				
808	(c) categories of data		(c) categories of data	(c) categories of data	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	accessed;		accessed;	accessed;	
	Annex II, fifteenth paragraph, point (d)				
809	(d) time and date of access;		(d) time and date of access;	(d) time and date of access;	
	Annex II, fifteenth paragraph, point (e)				
810	(e) origin(s) of data.		(e) origin(s) of data.	(e) origin(s) of data.	
	Annex II, sixteenth paragraph				
811					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	3.5. An EHR system shall include tools and mechanism to allow natural persons to restrict health professionals' access to their personal electronic health data. It shall also include mechanisms that allow access to personal electronic health data in emergency situations, and ensure that access is strictly logged.		3.5. An EHR system shall include tools and mechanism to allow natural persons to restrict health professionals' access to their personal electronic health data. It shall also include mechanisms that allow access to personal electronic health data in emergency situations, and ensure that access is strictly logged.	3.5. ~~An EHR system shall include tools and mechanism to allow natural persons to restrict health professionals' access to their personal electronic health data. It shall also include mechanisms that allow access to personal electronic health data in emergency situations, and ensure that access is strictly logged.~~	
		Annex II, seventeenth paragraph			
812	3.6. An EHR system shall include tools or		3.6. An EHR system shall include tools or	3.6. **The harmonised components of** an EHR	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes.		mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes.	system shall include tools or mechanisms to review and analyse the log data, or it shall support the connection and use of external software for the same purposes.	
		Annex II, eighteenth paragraph			
813	3.7. An EHR system designed to be used by health professionals shall support digital signatures or similar non-repudiation mechanisms.		3.7. An EHR system designed to be used by health professionals shall support digital signatures or similar non-repudiation mechanisms.	3.7. ~~An EHR system designed to be used by health professionals shall support digital signatures or similar non-repudiation mechanisms.~~	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex II, nineteenth paragraph				
814	3.8. An EHR system designed for the storage of electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.		3.8. An EHR system designed for the storage of electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data ***as well as the specific purposes of data processing***.	3.8. **The harmonised components of** an EHR system ~~designed for the storage of~~**that store personal** electronic health data shall support different retention periods and access rights that take into account the origins and categories of electronic health data.	
	Annex II, twentieth paragraph				
815					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	3.9. An EHR system designed to be used by natural persons shall enable their identification using any recognised electronic identification means as defined in Regulation (EU) No 910/2014, regardless of the Member State that has issued it. If the service supports other electronic identification means, they shall be of assurance levels 'substantial' or 'high'.		3.9. An EHR system designed to be used by natural persons shall enable their identification using any recognised electronic identification means as defined in Regulation (EU) No 910/2014, regardless of the Member State that has issued it. If the service supports other electronic identification means, they shall be of assurance levels 'substantial' or 'high'.	3.9. ~~An EHR system designed to be used by natural persons shall enable their identification using any recognised electronic identification means as defined in Regulation (EU) No 910/2014, regardless of the Member State that has issued it. If the service supports other electronic identification means, they shall be of assurance levels 'substantial' or 'high'.~~	
		Annex III			
816					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex III		Annex III	Annex III	
	Annex III, first paragraph				
817	Technical documentation		Technical documentation	Technical documentation	
	Annex III, second paragraph				
818	The technical documentation referred to in Article 24 shall contain at least the following information, as applicable to the relevant EHR system:		The technical documentation referred to in Article 24 shall contain at least the following information, as applicable to the relevant EHR system:	The technical documentation referred to in Article 24 shall contain at least the following information, as applicable to the **harmonised**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				components of EHR systems in the relevant EHR system:	
	Annex III, third paragraph				
819	1. A detailed description of the EHR system including:		1. A detailed description of the EHR system including:	1. A detailed description of the EHR system including:	
	Annex III, third paragraph, point (a)				
820	(a) its intended purpose, the date and the version of the EHR system;		(a) its intended purpose, the date and the version of the EHR system;	(a) its intended purpose, the date and the version of the EHR system;	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex III, third paragraph, point (b)				
821	(b) the categories of electronic health data that the EHR system has been designed to process;		(b) the categories of electronic health data that the EHR system has been designed to process;	(b) the categories of **personal** electronic health data that the EHR system has been designed to process;	
	Annex III, third paragraph, point (c)				
822	(c) how the EHR system interacts or can be used to interact with hardware or software that is not part of		(c) how the EHR system interacts or can be used to interact with hardware or software that is not part of	(c) how the EHR system interacts or can be used to interact with hardware or software that is not part of	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	the EHR system itself;		the EHR system itself;	the EHR system itself;	
	Annex III, third paragraph, point (d)				
823	(d) the versions of relevant software or firmware and any requirement related to version update;		(d) the versions of relevant software or firmware and any requirement related to version update;	(d) the versions of relevant software or firmware and any requirement related to version update;	
	Annex III, third paragraph, point (e)				
824	(e) the description of all forms in which the EHR system is placed on the		(e) the description of all forms in which the EHR system is placed on the	(e) the description of all forms in which the EHR system is placed on the	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	market or put into service;		market or put into service;	market or put into service;	
	Annex III, third paragraph, point (f)				
825	(f) the description of hardware on which the EHR system is intended to run;		(f) the description of hardware on which the EHR system is intended to run;	(f) the description of hardware on which the EHR system is intended to run;	
	Annex III, third paragraph, point (g)				
826	(g) a description of the system architecture explaining how software components build on or		(g) a description of the system architecture explaining how software components build on or	(g) a description of the system architecture explaining how software components build on or	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	feed into each other and integrate into the overall processing, including where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts/components and including sufficient explanation to understand the drawings and diagrams;		feed into each other and integrate into the overall processing, including where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts/components and including sufficient explanation to understand the drawings and diagrams;	feed into each other and integrate into the overall processing, including where appropriate, labelled pictorial representations (e.g. diagrams and drawings), clearly indicating key parts/components and including sufficient explanation to understand the drawings and diagrams;	
		Annex III, third paragraph, point (h)			
827	(h) the technical specifications, such as features, dimensions and		(h) the technical specifications, such as features, dimensions and	(h) the technical specifications, such as features, dimensions and	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	performance attributes, of the EHR system and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the data structures, storage and input/output of data;		performance attributes, of the EHR system and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the data structures, storage and input/output of data;	performance attributes, of the EHR system and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications, including a detailed description of the data structures, storage and input/output of data;	
		Annex III, third paragraph, point (i)			
828	(i) a description of any change made to the system		(i) a description of any change made to the system	(i) a description of any change made to the system	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	throughout its lifecycle;		throughout its lifecycle;	throughout its lifecycle;	
	Annex III, third paragraph, point (j)				
829	(j) the instructions of use for the user and, where applicable, installation instructions.		(j) the instructions of use for the user and, where applicable, installation instructions.	(j) the instructions of use for the user and, where applicable, installation instructions.	
	Annex III, fourth paragraph				
830	2. A detailed description of the system in place to evaluate the EHR system performance, where		2. A detailed description of the system in place to evaluate the EHR system performance, where	2. A detailed description of the system in place to evaluate the EHR system performance, where	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	applicable.		applicable.	applicable.	
	Annex III, fifth paragraph				
831	3. The references to any common specification used in accordance with Article 23 and in relation to which conformity is declared.		3. The references to any common specification used in accordance with Article 23 and in relation to which conformity is declared.	3. The references to any common specification used in accordance with Article 23 and in relation to which conformity is declared.	
	Annex III, sixth paragraph				
832	4. The results and critical analyses of all verifications and validation tests		4. The results and critical analyses of all verifications and validation tests	4. The results and critical analyses of all verifications and validation tests	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III of this Regulation, in particular the applicable essential requirements;		undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III of this Regulation, in particular the applicable essential requirements;	undertaken to demonstrate conformity of the EHR system with the requirements laid down in Chapter III of this Regulation, in particular the applicable essential requirements~~;~~**.**	
		Annex III, seventh paragraph			
833	5. A copy of the information sheet referred to in Article 25.		5. A copy of the information sheet referred to in Article 25.	5. A copy of the information sheet referred to in Article 25.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex III, eighth paragraph				
834	6. A copy of the EU declaration of conformity.		6. A copy of the EU declaration of conformity.	6. A copy of the EU declaration of conformity.	
	Annex IV				
835	Annex IV		Annex IV	Annex IV	
	Annex IV, first paragraph				
836	EU declaration of conformity		EU declaration of conformity	EU declaration of conformity	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex IV, second paragraph				
837	The EU declaration of conformity shall contain all of the following information:		The EU declaration of conformity shall contain all of the following information:	The EU declaration of conformity **for the harmonised components of EHR systems** shall contain all of the following information:	
	Annex IV, third paragraph				
838	1. The name of the EHR system, version and any additional unambiguous		1. The name of the EHR system, version and any additional unambiguous	1. The name of the EHR system, version and any additional unambiguous	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	reference allowing identification of the EHR system.		reference allowing identification of the EHR system.	reference allowing identification of the EHR system.	
	Annex IV, fourth paragraph				
839	2. Name and address of the manufacturer or, where applicable, their authorised representative.		2. Name and address of the manufacturer or, where applicable, their authorised representative.	2. Name and address of the manufacturer or, where applicable, their authorised representative.	
	Annex IV, fifth paragraph				
840	3. A statement that the EU declaration of conformity is		3. A statement that the EU declaration of conformity is	3. A statement that the EU declaration of conformity is	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	issued under the sole responsibility of the manufacturer.		issued under the sole responsibility of the manufacturer.	issued under the sole responsibility of the manufacturer.	
		Annex IV, sixth paragraph			
841	4. A statement that the EHR system in question is in conformity with the provisions laid down in Chapter III of this Regulation and, if applicable, with any other relevant EU legislation that provides for the issuing of an EU declaration of conformity.		4. A statement that the EHR system in question is in conformity with the provisions laid down in Chapter III of this Regulation and, if applicable, with any other relevant EU legislation that provides for the issuing of an EU declaration of conformity.	4. A statement that the EHR system in question is in conformity with the provisions laid down in Chapter III of this Regulation and, if applicable, with any other relevant EU legislation that provides for the issuing of an EU declaration of conformity**, complemented by the result from the**	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
				testing environment mentioned in article 26A obtained for the EHR system.	
		Annex IV, seventh paragraph			
842	5. References to any relevant harmonized standards used and in relation to which conformity is declared.		5. References to any relevant harmonized standards used and in relation to which conformity is declared.	5. References to any relevant ~~harmonized~~**harmonised** standards used and in relation to which conformity is declared.	
		Annex IV, eighth paragraph			

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
843	6. References to any common specifications used and in relation to which conformity is declared.		6. References to any common specifications used and in relation to which conformity is declared.	6. References to any common specifications used and in relation to which conformity is declared.	
		Annex IV, ninth paragraph			
844	7. Place and date of issue of the declaration, signature plus name and function of the person who signed, and, if applicable, an indication of the person on whose behalf it was signed.		7. Place and date of issue of the declaration, signature plus name and function of the person who signed, and, if applicable, an indication of the person on whose behalf it was signed.	7. Place and date of issue of the declaration, signature plus name and function of the person who signed, and, if applicable, an indication of the person on whose behalf it was signed.	

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex IV, tenth paragraph				
845	8. Where applicable, additional information.		8. Where applicable, additional information.	8. Where applicable, additional information.	
	Annex IVa				
845a			***ANNEX IVa***		
	Annex IVa, (1)				
845b			***1. EU type-examination is the part of a conformity***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			assessment procedure in which a notified body examines the technical design of an EHR system and verifies and attests that the technical design of the EHR system meets the applicable requirements of this Regulation.		
	Annex IVa, (2)				
845c			***EU type-examination shall be carried out by assessment of the adequacy of the technical design of the EHR system through examination of the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			technical documentation, plus examination of a specimen of the EHR system that is representative of the production envisaged (production type).		
	Annex IVa(3), first subparagraph				
845d			***3. Application for EU type-examination***		
	Annex IVa(3), second subparagraph				
845e					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			The manufacturer shall lodge an application for EU type-examination with a single notified body of his or her choice. The application shall include:		
		Annex IVa(3), second subparagraph, point a			
845f			***(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex IVa(3), second subparagraph, point b				
845g			***(b) a written declaration that the same application has not been lodged with any other notified body;***		
	Annex IVa(3), second subparagraph, point c				
845h			***(c) the technical documentation described in Annex III;***		
	Annex IVa(3), second subparagraph, point d				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
845i			***(d) the specimen(s) of the EHR system representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme.***		
	Annex IVa(4), first subparagraph				
845j			***4. EU type-examination***		
	Annex IVa(4), second subparagraph				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
845k			***The notified body shall:***		
	Annex IVa(4), second subparagraph, point a				
845l			***(a) examine the technical documentation to assess the adequacy of the technical design of the EHR system;***		
	Annex IVa(4), second subparagraph, point b				
845 m			***(b) verify that the EHR***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			system has been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or technical specifications adopted by the Commission;		
	Annex IVa(4), second subparagraph, point c				
845n			***(c) carry out appropriate examinations and tests, or have them carried out, to***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, those have been applied correctly;		
		Annex IVa(4), second subparagraph, point d			
845o			***(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or technical specifications adopted by the Commission, the solutions***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential requirements and have been applied correctly.		
		Annex IVa(5), first subparagraph			
845p			***5. Evaluation report***		
		Annex IVa(5), second subparagraph			
845q			***The notified body shall***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, as mentioned in Article 27, point (j), the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.		
	Annex IVa(6)				
845r					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			6. EU type-examination certificate		
		Annex IVa(6), point 1			
845s			***6.1 Where the type meets the applicable essential requirements, the notified body shall issue an EU type-examination certificate to the manufacturer. The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex IVa(6), point 2				
845t			***6.2 The EU type-examination certificate shall contain at least the following information:***		
	Annex IVa(6), point 2, point a				
845u			***(a) the name and identification number of the notified body;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex IVa(6), point 2, point b				
845v			***(b) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;***		
	Annex IVa(6), point 2, point c				
845 w			***(c) an identification of the EHR system covered by the certificate (type number);***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex IVa(6), point 2, point d				
845x			***(d) a statement that the EHR system complies with the applicable essential requirements;***		
	Annex IVa(6), point 2, point e				
845y			***(e) where harmonised standards or technical specifications adopted by the Commission have been fully or partially applied,***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the references of those standards or parts thereof;		
	Annex IVa(6), point 2, point f				
845z			***(f) where other technical specifications have been applied, the references of those technical specifications;***		
	Annex IVa(6), point 2, point g				
845aa			***(g) where applicable, the performance level(s) or***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			protection class of the machinery product;		
	Annex IVa(6), point 2, point h				
845ab			***(h) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal; (i) any conditions attached to the issuing of the certificate.***		
	Annex IVa(6), point 3				
845ac			***6.3 Where the type does***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			not satisfy the applicable essential requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.		
	Annex IVa(7)				
845ad			***7. Review of the EU type-examination certificate***		
	Annex IVa(7), point 1				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
845a e			***7.1 The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art, which indicate that the approved type may no longer comply with the applicable essential requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.***		
	Annex IVa(7), point 2				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
845af			***7.2 The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type and of all modifications to the technical documentation that may affect the conformity of the EHR system with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			form of an addition to the original EU type-examination certificate.		
	Annex IVa(7), point 3				
845a g			***7.3 The manufacturer shall ensure that the EHR system continues to fulfil the applicable essential requirements in light of the state of the art.***		
	Annex IVa(7), point 4				
845a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
h			***7.4 The manufacturer shall ask the notified body to review the EU type-examination certificate either:***		
	Annex IVa(7), point 4, point a				
845a i			***(a) in the case of a modification to the approved type referred to in point 7.2;***		
	Annex IVa(7), point 4, point b				
845a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
j			***(b) in the case of a change in the state of the art referred to in point 7.3;***		
	Annex IVa(7), point 4, point c				
845a k			***(c) at the latest, before the date of expiry of the certificate. In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his or her application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			certificate.		
		Annex IVa(7), point 5			
845a 1			***7.5 The notified body shall examine the EHR system type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable essential***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.		
		Annex IVa(7), point 6			
845am			***7.6 Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			the notified body with the following:		
		Annex IVa(7), point 6, point a			
845an			***(a) His or her name and address and data identifying the EU type-examination certificate concerned;***		
		Annex IVa(7), point 6, point b			
845ao			***(b) confirmation that there has been no modification***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			to the approved type as referred to in point 7.2, nor to the relevant harmonised standards or technical specifications adopted by the Commission or other technical specifications applied;		
		Annex IVa(7), point 6, point c			
845ap			***(c) confirmation that there has been no change in the state of the art as referred to in point 7.3;***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
	Annex IVa(7), point 7				
845aq			***7.7 If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the EHR system concerned.***		
	Annex IVa(8), first subparagraph				
845ar			***8. Each notified body shall***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted. Each notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto, which it has refused, withdrawn, suspended or otherwise		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			restricted, and, upon request, concerning the EU type-examination certificates and/or additions thereto which it has issued.		
		Annex IVa(8), second subparagraph			
845as			***The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On request, the Commission and the Member States***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.		
	Annex IVa(9)				

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
845at			***9. The manufacturer shall keep a copy of the EU type-examination certificate together with the technical documentation at the disposal of the national authorities, for 10 years after the EHR system has been placed on the market.***		
	Annex IVa(10)				
845au			***10. The manufacturer's authorised representative may lodge the application referred to in point 3 and***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.		
	Annex IVa, re annex 1				
845a v			***Medical directives*** AM 536, line 6a (new), first column		
	Annex IVa, re annex I				
845a					

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
w			***Electronic health data related to the legal documentation that states a person's wishes about receiving medical care if that person is no longer able to make medical decisions because of a serious illness or injury and that may also give a person (such as a spouse, relative, or friend) the authority to make medical decisions in such situations. Electronic health data related to the patient's will and consent in specific medical acts.***		

	Commission Proposal		EP Mandate	Council Mandate	Draft Agreement
			AM 536, line 6a (new), second column This one refers to Annex I and introduces a new row in the table "6a. Medical directives"		