



Brussels, 10.7.2013  
COM(2013) 495 final

2013/0240 (NLE)

Proposal for a

**COUNCIL REGULATION**

**on the Innovative Medicines Initiative 2 Joint Undertaking**

(Text with EEA relevance)

{SWD(2013) 245 final}

{SWD(2013) 246 final}

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE PROPOSAL**

#### **General context**

In the context of the economic and financial crisis Europe is taking steps to find a path to sustainable growth. At the same time, Europe is faced with a series of important major challenges, such as climate change, finding sources of clean energy and improving the health and wellbeing of its citizens while containing the costs of healthcare.

One of the aims of Horizon 2020, Europe's flagship programme for research and innovation, is to strengthen European industry by taking action to support research and innovation across a range of industrial sectors. In particular, Horizon 2020 encourages public-private partnerships in research and innovation to help tackle some of the key challenges Europe faces, including in the public health sector.

The proposal for a public-private partnership builds on the Innovative Medicines Initiative Joint Undertaking (IMI JU) established under the 7<sup>th</sup> Research Framework Programme ('FP7') by Regulation (EC) No 73/2008 of the Council of 20 December 2007. IMI JU is a public-private partnership between the European Commission and the biopharmaceutical industry, and its objective is to improve the drug development process by supporting more efficient research and development cooperation among academia, small and medium enterprises ('SMEs') and the biopharmaceutical industry, in order to deliver better and safer medicines for patients.

This proposal is in line with the Commission Communication Public-private partnerships, in Horizon 2020: a powerful tool to deliver on innovation and growth in Europe <sup>1</sup>.

#### **Reasons for and objectives of the proposed Innovative Medicines Joint Undertaking**

A Joint Undertaking in the area of innovative medicines is needed:

- Because the challenges it will tackle are vital for public health in Europe and for its citizens: improving their health and wellbeing by providing new and more effective diagnostics and treatments, while helping safeguard the future international competitiveness of the European biopharmaceutical and life-science industries such as diagnostics, vaccines, biomedical imaging and medical information technologies;

- Because it will help tackle a series of obstacles to effective research and innovation in this area: high risks of engaging in expensive and complex development of diagnostics and treatments, decreasing productivity of the drug and vaccine development processes and the lack of economic incentives to develop such interventions; high risks of supporting shared databases and networks that could speed up treatment development and help achieve lifelong health and wellbeing for all, particularly important in the context of an ageing population and the associated increase in chronic and degenerative diseases; the emergence and potential re-emergence of infectious diseases (including the increase in anti-microbial resistance); limited knowledge spill-overs due to a lack of open-innovation eco-systems among the various actors from academia, SMEs and industry; and the threat posed by zoonoses.

- Because industry on its own will not invest due to these obstacles, and because public support from the Member States acting alone is too fragmented and cannot achieve the coordinated, long-term, large-scale, transnational, cross-sectorial effort required.

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<sup>1</sup> COM(2013) [...]

- Because a JU at EU level can help the life-science industries to set a long-term research and innovation strategic agenda in a pan-European structure, create the necessary critical mass, leverage private investment, provide stable funding, facilitate knowledge sharing and reduce risk at lower costs. A JU will help create networks for open innovation, which bring together the main stakeholders along the entire drug development value chain.

- Because a JU can contribute to the EU's goal in other policy areas such as the Commission Communication on Combatting Antimicrobial Resistance, where the current IMI is one of the key implementation measures, the European contribution to the Global One Health Initiative, the European Innovation Partnership on Active and Healthy Ageing, the European Partnership for Action Against Cancer, as well as the European Pact for Mental Health and action related to the Commission Communication on Alzheimer's disease and other dementias.

Therefore, the new proposal aims to address bottlenecks in areas of public health interest, which are limiting the efficiency, effectiveness and quality of the drug development activities needed to bring innovative medicines to the market.

### **Building on past experience**

The proposed JU builds upon the achievements of the previous IMI JU set up under FP7.

IMI JU has mobilised resources by bringing together partners from the pharmaceutical industry, academia, SMEs, patient organisations and regulators in focused projects; it has stepped up cooperation between stakeholders in the health research and innovation field by opening access to other partners' expertise and it has increase the collaboration between the pharmaceutical industry and other stakeholders in Europe. It has also fostered the development of comprehensive research agendas, and horizontal policy coordination.

The interim evaluation of the IMI Joint Undertaking has underlined that IMI enables mutual learning and has built understanding of rationales and approaches among the different stakeholders. This has benefit to all parties and has significantly contributed to the transition from a closed to an open innovation model in biopharmaceutical research, supported by a fair intellectual property regime. No other European programme has enabled cross-company collaboration within the pharmaceutical sector on the scale that has been achieved in IMI.

## **2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS**

### **Consultation of interested parties and use of expertise**

Extensive consultations with stakeholders have been organised, including Member States, SMEs in the life sciences, medical imaging and information technology industries conducted through a series of dedicated meetings (Impact Assessment, Annex 1). The impact assessment report also draws on the results of the current JTI evaluation and the work of a group of experts. A public consultation was held from 11 July to 4 October 2012<sup>2</sup>. In addition, an online consultation for participants of on-going IMI projects was conducted<sup>3</sup>.

### **Impact assessment**

The proposed Regulation has been subject to a Commission impact assessment, which is attached to the proposal.

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<sup>2</sup> [http://ec.europa.eu/research/consultations/life\\_science\\_h2020/report\\_public\\_consultation.pdf](http://ec.europa.eu/research/consultations/life_science_h2020/report_public_consultation.pdf)

<sup>3</sup> [ftp://ftp.cordis.europa.eu/pub/fp7/health/docs/outcome-imi-participants\\_en.pdf](ftp://ftp.cordis.europa.eu/pub/fp7/health/docs/outcome-imi-participants_en.pdf)

### **3. LEGAL ELEMENTS OF THE PROPOSAL**

#### **Summary of the proposed action**

The proposal consists of a Council Regulation on the Innovative Medicines 2 Joint Undertaking. The IMI Joint Undertaking was initially established by Regulation (EC) No 73/2008 of the Council of 20 December 2007, which is to be repealed.

#### **Legal basis**

The proposal is based on Article 187 of the Treaty on the Functioning of the European Union.

The Rules for Participation and Dissemination of Horizon 2020 will apply. However, given specific operational needs of this initiative, derogations from these Rules are necessary. Nevertheless, these specific derogations are not included in the present proposal at this stage, in order not to prejudice the inter-institutional discussions concerning the appropriate legal basis/procedural modalities for their adoption, which are still pending in the context of the legislative works concerning the Commission proposal for a Regulation of the European Parliament and of the Council laying down the Rules for Participation and dissemination in Horizon 2020 (COM(2011) 0810 - 2011/0399 (COD)). The specific derogations will be introduced at a later stage in view of the outcome of the abovementioned discussions.

A first derogation will allow to limit the eligibility for funding to entities such as SMEs, secondary and higher education establishments, non-profit organizations, and companies encountering difficulties to access finance, such as mid-caps or medium-sized companies. Secondly, in order to facilitate and speed up the delivery of innovative medicines to patients and to improve the drug research and development in Europe, IMI2 Joint Undertaking requires derogations from the intellectual property rules which concern relevant definitions, ownership, protection, exploitation, dissemination, transfer and licensing of results and access rights.

#### **Subsidiarity and proportionality**

The proposal is designed to maximise EU added value and impact, focusing on objectives and activities that cannot be sufficiently achieved by Member States acting alone. The industrial challenge of bringing biomedical research and innovation to new products and thereby impacting the health of EU citizens is so large and complex that Member States acting alone do not have the necessary framework to set up transnational collaborative platforms for strategic industrial research.

Public intervention at EU level is necessary as only the EU is able to provide sustained, large-scale public sponsorship able to facilitate the kind of cross-border, cross-sector, interdisciplinary research and innovation consensus-building and implementation required. Intervening at EU level by supporting transnational cooperation between firms on long-term strategic research agendas produces the following added value over and above what Member States acting alone can achieve. Joint undertakings are the best set up to achieve the critical mass, in particular by implementation of joint agenda setting, mobilising of additional funding and having a larger leverage effect on industrial R&D investment.

In accordance with the principle of proportionality, the provisions of this regulation do not go beyond what is necessary to achieve its objectives.

#### **4. BUDGETARY IMPLICATION**

The Legislative Financial Statement presented with this regulation sets out the indicative budgetary implications. The Union contribution shall be up to EUR 1 725 million<sup>4</sup> including EFTA contribution. The envelope is in current prices. The Union contribution shall be made from the ‘Health, demographic change and wellbeing’ challenge, DG Research & Innovation envelope, as part of the implementation of Horizon 2020 – The Framework Programme for Research and Innovation. The maximum amount of Union contribution for administrative costs shall be EUR 44,85 million.

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<sup>4</sup> The amount is indicative and will depend on the final amount for the DG Research & Innovation under the above-mentioned challenge.

Proposal for a

## **COUNCIL REGULATION**

### **on the Innovative Medicines Initiative 2 Joint Undertaking**

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 187 and the first paragraph of Article 188 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament<sup>5</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>6</sup>,

Whereas:

- (1) Public-private partnerships in the form of Joint Technology Initiatives (JTIs) were initially provided for in Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework programme of the European Community for research, technological development and demonstration activities (2007-2013)<sup>7</sup>.
- (2) Council Decision No 2006/971/EC of 19 December 2006 concerning the Specific Programme 'Cooperation' implementing the Seventh Framework programme of the European Community for research, technological development and demonstration activities (2007-2013)<sup>8</sup> identified specific public-private partnerships to be supported, including a public-private partnership on Innovative Medicines Joint Technology Initiative between the Union and the European Federation of Pharmaceutical Industries and Associations (hereinafter "EFPIA").
- (3) Europe 2020 Strategy<sup>9</sup> underscores the need to develop favourable conditions for investment in knowledge and innovation so as to achieve smart, sustainable and inclusive growth in the Union. Both the European Parliament and the Council have endorsed this strategy.
- (4) Regulation (EU) No .../2013 of the European Parliament and of the Council of ... 2013 establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)<sup>10</sup> aims to achieve a greater impact on research and innovation by combining Horizon 2020 Framework Programme and private sector funds in public-private partnerships in key areas where research and innovation can contribute

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<sup>5</sup> OJ C [...], [...], p. [...]

<sup>6</sup> OJ C [...], [...], p. [...]

<sup>7</sup> OJ L 412 30.12.2006, p. 1

<sup>8</sup> OJ L 400 30.12.2006, p. 86

<sup>9</sup> COM(2010)2020 final

<sup>10</sup> OJ ... [H2020 FP]

to the Union's wider competitiveness goals and help tackle societal challenges. Union involvement in those partnerships could take the form of financial contributions to joint undertakings established on the basis of Article 187 of the Treaty under Decision No 1982/2006/EC.

- (5) In accordance with Decision (EU) No .../2013 of the Council of ... 2013 establishing the Specific Programme implementing Horizon 2020 (2014-2020)<sup>11</sup> further support should be provided to joint undertakings established under Decision No 1982/2006/EC under the conditions specified in Decision (EU) No [...]/2013..
- (6) The Innovative Medicines Initiative (hereinafter "IMI") Joint Undertaking set up by Regulation (EC) No 73/2008 of the Council of 20 December 2007 setting up the IMI Joint Undertaking<sup>12</sup> has demonstrated the effective mobilisation of resources by bringing together several partners from the pharmaceutical industry, academia, small and medium-sized enterprises (hereinafter "SMEs"), patient organisations and regulators.
- (7) It has also stepped up cooperation between stakeholders in the health research and innovation field by allowing access to other partners' expertise and increasing the collaboration between the pharmaceutical industry and other stakeholders in the Union by developing comprehensive research agendas and horizontal policy coordination. No other European or national programme has enabled cross-company collaboration within the pharmaceutical sector on the scale that has been achieved by IMI. The interim evaluation of the IMI Joint Undertaking<sup>13</sup> underlined that it enables mutual learning and provides the opportunity to improve the reciprocal understanding of the stakeholders, which benefits all parties and has significantly contributed to the transition towards an open innovation model in biopharmaceutical research.
- (8) Research related to the future of medicine shall be undertaken in areas where combination of societal, public health and biomedical industry competitiveness goals requires pooling of resources and fostering collaboration between the public and private sectors, with the involvement of SMEs. The scope of the initiative should be expanded to all areas of life science research and innovation. The areas would be of public health interest, as identified by the World Health Organisation report on priority medicines for Europe and the World, which is currently being updated with the new version expected to be released in 2013. The initiative should consequently seek to involve a broader range of partners, including mid-caps, from different sectors (e.g. biomedical imaging, medical information technology, diagnostic and/or animal health industries). A wider participation would help to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with high impact on public health.
- (9) The continuation of this initiative should also take into account the experience acquired from the operations of the IMI Joint Undertaking including the results of its interim evaluation and stakeholders' recommendations<sup>14</sup> and be implemented using a more fit-for-purpose structure and rules in order to enhance efficiency and ensure simplification at operational level. To this effect, the Innovative Medicines Initiative 2 (hereinafter "IMI2") Joint Undertaking should adopt financial rules specific to its needs in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 of the

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<sup>11</sup> OJ ... [H2020 SP]

<sup>12</sup> OJ L 30 of 4.2.2008 [FP7 JTI JU Regulation]

<sup>13</sup> SEC(2011) 1072 final

<sup>14</sup> [http://ec.europa.eu/research/consultations/life\\_science\\_h2020/consultation\\_en.htm](http://ec.europa.eu/research/consultations/life_science_h2020/consultation_en.htm)

European Parliament and the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union<sup>15</sup>.

- (10) The private Members to the IMI2 Joint Undertaking have expressed in writing their agreement to pursue the research activities in the area of the IMI2 Joint Undertaking within a structure better adapted to the nature of a public-private partnership. It is appropriate that the private-sector Members to the IMI2 Joint Undertaking accept the Statutes contained in the Annex by means of a letter of endorsement.
- (11) As a means to further develop IMI2 Joint Undertaking's objectives, membership should be open to other legal entities. Moreover, legal entities interested in supporting IMI2 Joint Undertaking's objectives in their specific areas of research should be offered the possibility to become Associated Partners in the IMI2 Joint Undertaking.
- (12) In order to achieve its objectives, the IMI2 Joint Undertaking should provide financial support to participants mainly in the form of grants following open and competitive calls for proposals.
- (13) Contributions from the private Members should relate to the administrative costs of the IMI2 Joint Undertaking and, together with the Associated Partners for their specific area of research, to the co-financing required to carry out research and innovation actions supported by the IMI2 Joint Undertaking.
- (14) Participation in indirect actions funded by the IMI2 Joint Undertaking should comply with Regulation (EU) No ... /2013 of the European Parliament and of the Council of ... 2013 laying down the rules for the participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)"<sup>16</sup>.
- (15) The Union financial contribution should be managed in accordance with the principle of sound financial management and with the relevant rules on indirect management set out in Regulation (EU, Euratom) No 966/2012 and Commission delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012<sup>17</sup>.
- (16) Audits of recipients of Union funds under this Regulation should be carried out in such a manner that the administrative burden is reduced, in compliance with Regulation (EU) No [...] /2013 [Horizon 2020 Framework Programme].
- (17) The financial interests of the Union and of the other Members of the IMI2 Joint Undertaking should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties in accordance with Regulation (EU, Euratom) No 966/2012.
- (18) The Commission's internal auditor should exercise the same powers over the IMI2 Joint Undertaking as those exercised in respect of the Commission.
- (19) In accordance with Article 287(1) of the Treaty on the Functioning of the European Union, the constituent instrument of bodies, offices or agencies set up by the Union may preclude the examination of the accounts of all revenue and expenditure of those bodies, offices or agencies by the Court of Auditors. In accordance with Article 60(5) of Regulation (EU, Euratom) No 966/2012, the accounts of the bodies under Article

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<sup>15</sup> OJ L 298 26.10.2012, p. 1.

<sup>16</sup> OJ ... [H2020 RfP]

<sup>17</sup> OJ L 362 31.12.2012, p. 1

209 Regulation (EU, Euratom) No 966/2012 are to be examined by an independent audit body which is to give an opinion inter alia on the reliability of the accounts and the legality and regularity of the underlying transactions. Avoidance of duplication of the examination of the accounts justifies that the accounts of the IMI2 Joint Undertaking should not be subject to examination by the Court of Auditors.

- (20) In accordance with the principles of subsidiarity and proportionality as set out in Article 5 of the Treaty on European Union, the objectives of the IMI2 Joint Undertaking in strengthening industrial research and innovation across the Union cannot be sufficiently achieved by the Member States and can therefore, by reason of avoiding duplication, retaining critical mass and ensuring that public financing is used in an optimal way, be better achieved by the Union. This Regulation confines itself to the minimum required in order to achieve those objectives and does not go beyond what is necessary for that purpose.
- (21) The IMI Joint Undertaking was set up for a period up to 31 December 2017. The IMI2 Joint Undertaking should provide continued support to the Innovative Medicines research programme by enlarging the scope of the activities under a modified set of rules. The transition from the IMI Joint Undertaking to the IMI2 Joint Undertaking should be aligned and synchronized with the transition from the Seventh Framework programme to the Horizon 2020 Framework Programme to ensure optimal use of the funding available for research. In the interest of legal certainty and clarity, Council Regulation (EC) No 73/2008 should therefore be repealed and transitional provisions should be set out.

HAS ADOPTED THIS REGULATION:

#### *Article 1*

##### Establishment

1. For the implementation of the Joint Technology Initiative on Innovative Medicines, a joint undertaking within the meaning of Article 187 of the Treaty (hereinafter "IMI2 Joint Undertaking"), is established for a period from 1 January 2014 until 31 December 2024.
2. The IMI2 Joint Undertaking shall replace and succeed the IMI Joint Undertaking as established by Regulation (EC) No 73/2008.
3. The IMI2 Joint Undertaking shall constitute a body entrusted with the implementation of a public-private partnership referred to in Article 209 of Regulation (EU, Euratom) No 966/2012.
4. The IMI2 Joint Undertaking shall have legal personality. In each of the Member States, it shall have the most extensive legal capacity accorded to legal persons under the laws of those Member States. It may, in particular, acquire or dispose of movable and immovable property and may be party to legal proceedings.
5. The seat of the IMI2 Joint Undertaking shall be located in Brussels, Belgium.
6. The Statutes of the IMI2 Joint Undertaking are set out in the Annex.

#### *Article 2*

##### Objectives

The IMI 2 Joint Undertaking shall have the following objectives:

- (a) to contribute to the implementation of Regulation (EU) No [...]/2013/EU [the Horizon 2020 Framework Programme], in particular part ... of Decision (EU) No [...]/2013/EU [the Specific Programme implementing the Horizon 2020 Framework Programme], and in particular to improving European citizens' health and wellbeing.
- (b) to contribute to the objectives of the Joint Technology Initiative on Innovative Medicines, in particular to:
  - i) increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;
  - ii) reduce the time to reach clinical proof of concept in medicine development, such as for immunological, respiratory, neurological and neurodegenerative diseases;
  - iii) develop new therapies for diseases for which there is a high unmet need, such as Alzheimer's disease and limited market incentives, such as antimicrobial resistance;
  - iv) develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
  - v) reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;
  - vi) improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.

### *Article 3*

#### Union contribution

1. The maximum Union contribution, including EFTA appropriations, to the IMI2 Joint Undertaking to cover administrative costs and operational costs shall be EUR 1 725 million which shall consist of the following:
  - (a) up to EUR 1 500 million to match the contribution of EFPIA, or its constituent entities or their affiliated entities;
  - (b) up to EUR 225 million to match additional contributions from other Members Associated Partners, or from their constituent or their affiliated entities.

The contribution of the Union shall be paid from the appropriations in the general budget of the Union allocated to the Horizon 2020 Specific Programme implementing the Horizon 2020 Framework Programme in accordance with Article 58(1)(c)(iv) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 for bodies referred to in Article 209 of that Regulation.

2. The arrangements for the Union financial contribution shall be set out in a delegation agreement and annual transfer of funds agreements to be concluded between the Commission, on behalf of the Union, and the IMI2 Joint Undertaking.
3. The delegation agreement referred to in paragraph 2 shall address the elements set out in Article 58(3) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 and in Article 40 of the Commission delegated Regulation (EU) No 1268/2012 as well as inter alia the following:

- (a) the requirements for the IMI2 Joint Undertaking's contribution regarding the relevant performance indicators referred to in Annex II to Decision (EU) No ... [the Specific Programme implementing the Horizon 2020 Framework Programme];
- (b) the requirements for the IMI2 Joint Undertaking's contribution in view of the monitoring referred to in Annex III to Decision (EU) No ... [the Specific Programme implementing the Horizon 2020 Framework Programme];
- (c) the specific performance indicators related to the functioning of the IMI2 Joint Undertaking;
- (d) the arrangements regarding the provision of data necessary to ensure that the Commission is able to meet its dissemination and reporting obligations;
- (e) the use of and changes to human resources, in particular the recruitment by function group, grade and category, the reclassification exercise and any changes to the number of staff members.

#### *Article 4*

##### Contributions of Members other than the Union and of Associated Partners

1. EFPIA shall make or arrange for its constituent entities or their affiliated entities to make contributions of at least EUR 1 500 million. Other Members other than the Union or Associated Partners shall make, or arrange for their constituent entities or their affiliated entities to make, the contributions corresponding to the amounts they have committed when becoming a Member or an Associated Partner.
2. The contribution referred to in paragraph 1 shall consist of contributions to the IMI2 Joint Undertaking as laid down in Clause 13(2), Clause 13(3)(b) and Clause 13(3)(c) of the Statutes contained in the Annex.
3. The Members other than the Union and Associated Partners shall report each year by 31 January to the Governing Board of the IMI2 Joint Undertaking on the value of the contributions referred to in paragraph 2 made in each of the previous financial years.
4. For the purpose of valuing the contributions referred to in Clause 13(3)(b) of the Statutes contained in the Annex, the costs shall be determined according to the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where each entity is established, and to the applicable International Accounting Standards/International Financial Reporting Standards. The costs shall be certified by an independent external auditor appointed by the entity concerned. The valuation of the contributions shall be verified by the IMI2 Joint Undertaking. In case of remaining uncertainties, it may be audited by the IMI2 Joint Undertaking.
5. The Commission may terminate, proportionally reduce or suspend the Union financial contribution to the IMI2 Joint Undertaking or trigger the winding up procedure referred to in Clause 21(2) of the Statutes contained in the Annex if those Members and Associated Partners, their constituent entities or their affiliated entities do not contribute, contribute only partially or contribute late with regard to the contributions referred to in paragraph 2.

## *Article 5*

### Financial rules

The IMI2 Joint Undertaking shall adopt its specific Financial rules in accordance with Article 209 of Regulation (EU, Euratom) No 966/2012 and Regulation (EU) No ... [Delegated Regulation on the model Financial Regulation for PPPs].

## *Article 6*

### Staff

1. The Staff Regulations of Officials of the Union and the Conditions of Employment of Other Servants of the European Union as laid down by Council Regulation (EEC, Euratom, ECSC) No 259/68<sup>18</sup> and the rules adopted by agreement between the institutions of the Union for giving effect to those Staff Regulations and those Conditions of Employment of Other Servants shall apply to the staff employed by the IMI2 Joint Undertaking.

2. The Governing Board shall exercise, with respect to the staff of the IMI2 Joint Undertaking, the powers conferred by the Staff Regulations on the Appointing Authority and by the Conditions of Employment on the Authority Empowered to Conclude Contract of Employment (hereinafter "the appointing authority powers").

The Governing Board shall adopt, in accordance with Article 110 of the Staff Regulations, a decision based on its Article 2(1) and Article 6 of the Conditions of Employment delegating the relevant appointing authority powers to the Executive Director and defining the conditions under which this delegation of powers can be suspended. The Executive Director shall be authorised to sub-delegate those powers.

Where exceptional circumstances so require, the Governing Board may by way of a decision temporarily suspend the delegation of the appointing authority powers to the Executive Director and those sub-delegated by the latter and exercise them itself or delegate them to one of its members or to a staff member of the Joint Undertaking other than the Executive Director.

3. The Governing Board shall adopt appropriate implementing rules to the Staff Regulations and the Conditions of Employment in accordance with Article 110 of the Staff Regulations.

4. The staff resources shall be determined by the staff establishment plan of the IMI2 Joint Undertaking indicating the number of temporary posts by function group and by grade and the number of contract staff expressed in full-time equivalents, in line with its annual budget.

5. The staff of the IMI2 Joint Undertaking shall consist of temporary staff and contract staff.

6. All costs related to the staff shall be borne by the IMI2 Joint Undertaking.

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<sup>18</sup> OJ 56, 4.3.1968, p. 1.

## *Article 7*

### Seconded national experts and trainees

1. The IMI2 Joint Undertaking may make use of seconded national experts and trainees not employed by the Joint Undertaking. The number of seconded national experts expressed in full-time equivalents shall be added to information on staff as referred to in Article 6(4) of this Regulation in line with the annual budget.
2. The Governing Board shall adopt a decision laying down rules on the secondment of national experts to the IMI2 Joint Undertaking and on the use of trainees.

## *Article 8*

### Privileges and Immunities

The Protocol on the Privileges and Immunities of the Union shall apply to the IMI2 Joint Undertaking and its staff.

## *Article 9*

### Liability of the IMI2 Joint Undertaking

1. The contractual liability of the IMI2 Joint Undertaking shall be governed by the relevant contractual provisions and by the law applicable to the agreement, decision or contract in question.
2. In the case of non-contractual liability, the IMI2 Joint Undertaking shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its staff in the performance of their duties.
3. Any payment by the IMI2 Joint Undertaking in respect of the liability referred to in paragraphs 1 and 2 and the costs and expenses incurred in connection therewith shall be considered as expenditure of the IMI2 Joint Undertaking and shall be covered by the resources of the IMI2 Joint Undertaking.
4. The IMI2 Joint Undertaking shall be solely responsible for meeting its obligations.

## *Article 10*

### Jurisdiction of the Court of Justice and applicable law

1. The Court of Justice shall have jurisdiction under the conditions laid down in the Treaty as well as in the following cases:
  - (a) in any dispute between the Members of IMI2 Joint Undertaking which relates to the subject matter of this Regulation;
  - (b) pursuant to any arbitration clause contained in agreements, decisions or contracts concluded by the IMI2 Joint Undertaking;
  - (c) in disputes relating to compensation for damage caused by the staff of the IMI2 Joint Undertaking in the performance of their duties;
  - (d) in any dispute between the IMI2 Joint Undertaking and its servants within the limits and under the conditions laid down in the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Union.

2. Regarding any matter not covered by this Regulation or by other acts of Union law, the law of the State where the seat of the IMI2 Joint Undertaking is located shall apply.

#### *Article 11*

##### Evaluation

1. By 31 December 2017 the Commission shall conduct an interim evaluation of the IMI2 Joint Undertaking. The Commission shall communicate the conclusions thereof, accompanied by its observations, to the European Parliament and to the Council by 30 June 2018.
2. On the basis of the conclusions of the interim evaluation referred to in paragraph 1 the Commission may act in accordance with Article 4(5) or take any other appropriate action.
3. Within six months after the winding up of the IMI2 Joint Undertaking, but no later than two years after the triggering of the winding up procedure referred to in Clause 21 of the Statutes contained in the Annex, the Commission shall conduct a final evaluation of the IMI2 Joint Undertaking. The results of that final evaluation shall be presented to the European Parliament and to the Council.

#### *Article 12*

##### Discharge

1. The discharge of the budget implementation with regard to the Union contribution to the IMI2 Joint Undertaking shall be part of the discharge given by the European Parliament, upon recommendation of the Council, to the Commission in accordance with the procedure provided for in Article 319 of the Treaty.
2. The IMI2 Joint Undertaking shall fully cooperate with the institutions involved in the discharge procedure and provide, as appropriate, any necessary additional information. In this context, it may be requested to be represented in meetings with the relevant institutions or bodies and assist the Commission authorising officer by delegation.

#### *Article 13*

##### Ex-post audits

1. Ex-post audits of expenditure on indirect actions shall be carried out by the IMI2 Joint Undertaking in accordance with Article 23 of Regulation (EU) No ... [the Horizon 2020 Framework Programme] as part of the Horizon 2020 Framework Programme indirect actions.
2. To ensure coherence, the Commission may decide to carry out the audits referred to in paragraph 1 on those participants which have received funding from the IMI2 Joint Undertaking.

## Article 14

### Protection of the financial interests of the Members

1. Without prejudice to Clause 17(4), of the Statutes contained in the Annex, the IMI2 Joint Undertaking shall grant Commission staff and other persons authorised by it, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.
2. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)<sup>19</sup> and Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities<sup>20</sup> with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with an agreement or decision or a contract funded under this Regulation.
3. Without prejudice to paragraphs 1 and 2 contracts, agreements and decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering:
  - (a) the IMI2 Joint Undertaking and OLAF to conduct such audits and investigations, according to their respective competences.
  - (b) the Commission and the Court of Auditors to conduct such audits on the recipients of funding from the IMI2 Joint Undertaking according to their respective competences.
4. The IMI2 Joint Undertaking shall ensure that the financial interests of its Members are adequately protected by carrying out or commissioning appropriate internal and external controls.
5. The IMI2 Joint Undertaking shall accede to the Inter-institutional Agreement of 25 May 1999 between the European Parliament, the Council and the Commission concerning internal investigations by OLAF<sup>21</sup>. The IMI2 Joint Undertaking shall adopt the necessary measures needed to facilitate internal investigations conducted by OLAF.

## Article 15

### Confidentiality

Without prejudice to Article 16, the IMI2 Joint Undertaking shall ensure the protection of sensitive information whose disclosure could damage the interests of its Members or of participants in the activities of the IMI2 Joint Undertaking.

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<sup>19</sup> OJ L 136, 31.05.1999

<sup>20</sup> OJ L 292, 15.11.1996, p. 2-5

<sup>21</sup> OJ L 136 from 31.5.1999, p. 1

## *Article 16*

### Transparency

1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents<sup>22</sup>, shall apply to documents held by the IMI2 Joint Undertaking.
2. The IMI2 Joint Undertaking Governing Board may adopt practical arrangements for implementing Regulation (EC) No 1049/2001.
3. Without prejudice to Article 10, decisions taken by the IMI2 Joint Undertaking pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman under the conditions laid down in Article 228 of the Treaty.

## *Article 17*

### Rules for participation and dissemination

Regulation (EU) No ... [Rules for participation and dissemination in Horizon 2020] shall apply to the actions funded by the IMI2 Joint Undertaking. In accordance with that Regulation, the IMI2 Joint Undertaking shall be considered as a funding body and shall provide financial support to indirect actions as set out in Clause 1 of the Statutes contained in the Annex.

## *Article 18*

### Support from the host State

An administrative agreement may be concluded between the IMI2 Joint Undertaking and the State where its seat is located concerning privileges and immunities and other support to be provided by this State to the IMI2 Joint Undertaking.

## *Article 19*

### Repeal and transitional provisions

1. Regulation (EC) No 73/2008 is repealed with effect from 1 January 2014.
2. Without prejudice to paragraph 1, actions initiated under Regulation (EC) No 73/2008 and financial obligations related to those actions shall continue to be governed by that Regulation until their completion.

The actions arising from calls for proposals provided for in Annual Implementation Plans adopted under Regulation (EC) No .../2008 shall also be regarded as actions initiated under that Regulation.

The interim evaluation referred to in Article 11(1) shall include a final evaluation of the IMI Joint Undertaking operations under Regulation (EC) No 73/2008.

3. This Regulation shall not affect the rights and obligations of staff engaged under Regulation (EC) No 73/2008.

The employment contracts of staff referred to in the first subparagraph may be renewed under this Regulation in accordance with the Staff Regulations.

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<sup>22</sup> OJ L 145 from 31.05.2001

The Executive Director appointed on the basis of Regulation No 73/2008 shall, for the remaining period of term of office, be assigned to the functions of the Executive Director as provided for in this Regulation with effect from 1 January 2014. The other conditions of contract shall remain unchanged.

4. Unless otherwise agreed between the Members of the IMI Joint Undertaking pursuant to Regulation (EC) No 73/2008, all rights and obligations including assets, debts or liabilities of the Members of the IMI Joint Undertaking pursuant to that Regulation are transferred to the Members of the IMI2 Joint Undertaking pursuant to this Regulation.
5. Any unused appropriations under Regulation (EC) No 73/2008 shall be transferred to the IMI2 Joint Undertaking.

#### *Article 20*

##### Entry into force

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 be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council  
The President

## ANNEX

### STATUTES OF THE IMI2 JOINT UNDERTAKING

#### 1 - Tasks

The IMI2 Joint Undertaking shall carry out the following tasks:

- (a) to mobilise the public and private sector resources needed to achieve the objectives of IMI2 Joint Undertaking;
- (b) to regularly review and make any necessary adjustments to the Strategic Research Agenda of the IMI2 Joint Undertaking in light of scientific developments occurring during its implementation;
- (c) to establish and develop close and long-term cooperation between the Union, other Members, Associated Partners, and the other stakeholders such as other industries, regulatory bodies, patient organisations, academia and clinical centres, as well as cooperation between industry and academia;
- (d) to facilitate coordination with European, national and international activities in this area, and to communicate and interact with the Member States and the countries associated with Horizon 2020 Framework Programme;
- (e) to effectively support research and innovation in life sciences mainly through grants;
- (f) to define and carry out the IMI2 Joint Undertaking annual work plan mainly through calls for proposals;
- (g) to initiate calls for proposals and any other necessary procedure for funding, to evaluate proposals, to award funding to projects according to the applicable rules, within the limits of available funds;
- (h) information, communication, exploitation and dissemination activities by applying *mutatis mutandis* the provisions of Article 22 of the Regulation (EU) No [...]/2013 [the Horizon 2020 Framework Programme];
- (i) to organise a meeting at least annually with interest groups to ensure openness and transparency of the research activities of the IMI2 Joint Undertaking with its stakeholders;
- (j) any other task needed to achieve the objectives referred to in Article 2 of this Regulation.

#### 2 - Members and Associated Partners

1. The Members of the IMI2 Joint Undertaking shall be the following:
  - (a) the Union, represented by the Commission;
  - (b) upon acceptance of these Statutes by means of a letter of endorsement, the European Federation of Pharmaceutical Industries and Associations (hereinafter "EFPIA").
2. Provided that it contributes to the funding referred to in Clause 13 of these Statutes to achieve the objectives of the IMI2 Joint Undertaking set out in Article 2 of this Regulation and accepts these Statutes, any legal entity that directly or indirectly supports research and innovation in a Member State or in a country associated with

the Horizon 2020 Framework Programme may apply to become a Member of the IMI2 Joint Undertaking.

3. Upon acceptance of these Statutes by means of a letter of endorsement, any legal entity other than a Member or a constituent entity of a Member or any affiliated entity of either, supporting the objectives of the IMI2 Joint Undertaking in its specific area of research, in a Member State or in a country associated with the Horizon 2020 Framework Programme, may apply to join IMI2 as an Associated Partner. The letter of endorsement shall detail the scope of the association in terms of content, of activities and duration.
4. Associated Partners shall contribute like Members other than the Union to the IMI2 Joint Undertaking's operational costs, in accordance with Clause 13 of these Statutes. The letter of endorsement shall detail the Associated Partners' contribution to IMI2 Joint Undertaking and that the Union will match, in accordance with Articles 3 and 4 of this Regulation.

### 3 - Changes to membership and to association

1. Any application for becoming a Member or an Associated Partner to the IMI2 Joint Undertaking shall be addressed to the Governing Board, accompanied in the case of application for becoming a Member by a proposal to adapt the composition of the Governing Board set out in Clause 5.
2. The Governing Board shall assess the application taking into account the relevance and the potential added value of the applicant for the achievement of the objectives of the IMI2 Joint Undertaking. It shall then decide on the application.
3. Any Member or Associated Partner may terminate its membership or association to the IMI2 Joint Undertaking. The termination shall become effective and irrevocable six months after notification to the other Members and Associated Partners. As of then, the former Member or Associated Partner shall be discharged from any obligations other than those approved or incurred by the IMI2 Joint Undertaking prior to terminating the membership or participation.
4. Membership of or association to the IMI2 Joint Undertaking may not be transferred to a third party without prior agreement of the Governing Board.
5. The Commission shall publish on its website immediately upon any change to membership or association pursuant to this Clause an updated list of Members and Associated Partners of the IMI2 Joint Undertaking together with the date when such change takes effect.

### 4 – Organization of the IMI2 Joint Undertaking

1. The bodies of the IMI2 Joint Undertaking shall be:
  - (a) the Governing Board;
  - (b) the Executive Director;
  - (c) the Scientific Committee;
  - (d) the States Representatives Group;
  - (e) the Stakeholder Forum.
2. The Scientific Committee, the States Representatives Group and the Stakeholder Forum shall be advisory bodies to the IMI2 Joint Undertaking.

## 5 – Composition of the Governing Board

The Governing Board shall be composed of 5 representatives per Member.

## 6 – Functioning of the Governing Board

1. Without prejudice to paragraph 2, each Member shall have a percentage out of 100 voting rights corresponding to the percentage of its contribution to the IMI2 Joint Undertaking.

The Commission shall hold 50% of the voting rights. The vote of the Commission shall be indivisible. Each Member may allocate its voting rights among its representatives in the Governing Board. The Members shall use their best efforts to achieve consensus. Failing consensus, the Governing Board shall take its decisions by a majority of at least 75% of all votes including the votes of those who are not in attendance.

The chairperson of the Governing Board shall be appointed on a rotating annual basis by each the Union and the other Members, in turn.

2. The Governing Board shall hold its ordinary meetings at least twice a year. It may hold extraordinary meetings at the request of any Member or at the request of the chairperson. The meetings of the Governing Board shall be convened by its chairperson and shall normally take place at the seat of the IMI2 Joint Undertaking.

The Executive Director shall take part in the deliberations, but shall have no voting rights.

The Governing Board shall invite any Associated Partner to take part in its deliberations for those points on the agenda that concern its association. Associated Partners shall have no voting rights.

The chairperson of the States Representatives Group shall attend meetings of the Governing Board as an observer.

The Governing Board may invite, on a case-by-case basis, other persons to attend its meetings as observers, in particular representatives of regional authorities of the Union.

The representatives of the Members shall not be personally liable for actions they have undertaken in their capacity as representatives on the Governing Board.

The Governing Board shall adopt its own rules of procedure.

## 7 – Tasks of the Governing Board

1. The Governing Board shall have overall responsibility for the strategic orientation and the operations of the IMI2 Joint Undertaking and shall supervise the implementation of its activities.
2. The Governing Board shall in particular carry out the following tasks:
  - (a) assess, accept or reject applications for new membership or association in accordance with Clause 3;
  - (b) decide on the termination of the membership or association in the IMI2 Joint Undertaking of any Member or Associated Partner that does not fulfil its obligations;
  - (c) adopt the Financial rules of the IMI2 Joint Undertaking in accordance with Article 5 of this Regulation;

- (d) adopt the annual budget of the IMI2 Joint Undertaking, including the staff establishment plan indicating the number of temporary posts by function group and by grade as well as the number of contract staff and seconded national experts expressed in full-time equivalents;
- (e) exercise the appointing authority powers with respect to the staff, in accordance with Article 6(2);
- (f) appoint, dismiss, extend the term of office of, provide guidance to and monitor the performance of the Executive Director;
- (g) approve the organisational structure of the Programme Office referred to in Clause 9(5) upon recommendation by the Executive Director;
- (h) adopt the annual work plan and the corresponding expenditure estimates, proposed by the Executive Director in close cooperation with advisory groups referred to in Clause 7(2)(q), after having consulted the Scientific Committee and the States Representatives Group;
- (i) approve the annual accounts;
- (j) approve the annual activity report, including the corresponding expenditure;
- (k) arrange, as appropriate, for the establishment of an internal audit capability of the IMI2 Joint Undertaking;
- (l) approve the calls for proposals as well as, where appropriate, the related rules for submission, evaluation, selection, award and evaluation review procedures, proposed by the Executive Director in close cooperation with advisory groups referred to in Clause 7(2)(q);
- (m) approve the list of proposals selected for funding;
- (n) establish the IMI2 Joint Undertaking's communications policy upon recommendation of the Executive Director;
- (o) where appropriate, establish implementing rules in line with Article 6(3);
- (p) where appropriate, establish rules on the secondment of national experts to the IMI2 Joint Undertaking and on the use of trainees in line with Article 7;
- (q) where appropriate, set up advisory groups in addition to the bodies to the IMI2 Joint Undertaking;
- (r) where appropriate, submit to the Commission any request to amend this Regulation proposed by any Member of the IMI2 Joint Undertaking;
- (s) be responsible for any task which is not specifically allocated to one of the bodies of the IMI2 Joint Undertaking; it may assign such tasks to one of those bodies.

#### 8 – Appointment, dismissal or extension of the term of office of the Executive Director

1. The Executive Director shall be appointed by the Governing Board from a list of candidates proposed by the Commission, following an open and transparent selection procedure. The Commission shall associate the representation from the other members of the IMI2 Joint Undertaking in the selection procedure as appropriate.

In particular, an appropriate representation from the other members of the IMI2 Joint Undertaking shall be ensured at the pre-selection stage of the selection procedure.

For that purpose, the private members shall appoint by common accord a representative as well as an observer on behalf of the Governing Board.

2. The Executive Director is a member of staff and shall be engaged as a temporary agent of the IMI2 Joint Undertaking under point (a) of Article 2 of the Conditions of Employment of Other Servants of the Union.

For the purpose of concluding the contract of the Executive Director, the IMI2 Joint Undertaking shall be represented by the chairperson of the Governing Board.

3. The term of office of the Executive Director shall be three years. By the end of that period, the Commission associating the private members as appropriate shall undertake an assessment of the performance of the Executive Director and the IMI2 Joint Undertaking's future tasks and challenges.
4. The Governing Board, acting on a proposal from the Commission which takes into account the assessment referred to in paragraph 3, may extend the term of office of the Executive Director once, for no more than four years.
5. An Executive Director whose term of office has been extended may not participate in another selection procedure for the same post at the end of the overall period.
6. The Executive Director may be dismissed only upon a decision of the Governing Board acting on a proposal from the Commission associating the private members as appropriate.

#### 9 - Tasks of the Executive Director

1. The Executive Director shall be the chief executive responsible for the day-to-day management of the IMI2 Joint Undertaking in accordance with the decisions of the Governing Board.
2. The Executive Director shall be the legal representative of the IMI2 Joint Undertaking. He/she shall be accountable to the Governing Board.
3. The Executive Director shall implement the budget of the IMI2 Joint Undertaking.
4. The Executive Director shall in particular carry out the following tasks in an independent manner:
  - (a) prepare and submit for adoption to the Governing Board the draft annual budget, including the corresponding staff establishment plan indicating the number of temporary posts in each grade and function group and the number of contract staff and seconded national experts expressed in full-time equivalents;
  - (b) prepare in close cooperation with advisory bodies referred to in Clause 7(2)(q) and submit for adoption to the Governing Board the annual work plan and the corresponding expenditure estimates;
  - (c) submit for approval to the Governing Board the annual accounts;
  - (d) prepare and submit for approval to the Governing Board the annual activity report, including the corresponding expenditure;
  - (e) submit for approval to the Governing Board the list of proposals selected for funding;
  - (f) sign individual grant agreements or decisions;
  - (g) sign procurement contracts;

- (h) implement the IMI2 Joint Undertaking's communications policy;
  - (i) organise, direct and supervise the operations and the staff of the IMI2 Joint Undertaking within the constraints of the delegation by the Governing Board as provided for in Article 6(2) of this Regulation;
  - (j) establish and ensure the functioning of an effective and efficient internal control system and report any significant change to it to the Governing Board;
  - (k) ensure that risk assessment and risk management are performed;
  - (l) take any other measures needed for assessing the progress of the IMI2 Joint Undertaking towards achieving its objectives;
  - (m) perform any other tasks entrusted or delegated to the Executive Director by the Governing Board.
5. The Executive Director shall set up a Programme Office for the execution, under his/her responsibility, of all support tasks arising from this Regulation. The Programme Office shall be composed of the staff of the IMI2 Joint Undertaking and shall in particular carry out the following tasks:
- (a) provide support in establishing and managing an appropriate accounting system in accordance with the Financial rules of the IMI2 Joint Undertaking;
  - (b) manage the calls for proposals as provided for in the annual work plan and administer the grant agreements or decisions, including their coordination;
  - (c) provide to the Members and to the other bodies of the IMI2 Joint Undertaking all relevant information and support necessary for them to perform their duties as well as responding to their specific requests;
  - (d) act as the secretariat of the bodies of the Joint Undertaking and provide support to any advisory group set up by the Governing Board.

#### 10 - Scientific Committee

1. The Scientific Committee shall consist of no more than 7 members appointed for a renewable period of one year. It shall elect a chairperson from amongst its members for one year.  
  
Additional experts may be appointed if necessary for specific ad-hoc tasks and limited duration.
2. The members of the Scientific Committee shall reflect a balanced representation of world-wide recognized experts from academia, industry and regulatory bodies. Collectively, the Scientific Committee members shall have the necessary scientific competencies and expertise covering the technical domain needed to make strategic science-based recommendations to the IMI2 Joint Undertaking.
3. The Governing Board shall establish the specific criteria and selection process for the composition of the Scientific Committee and shall appoint its members. The Governing Board shall take into consideration the potential candidates proposed by the IMI2 States Representatives Group.
4. The Scientific Committee shall carry out the following tasks:
  - (a) advise on the scientific priorities to be addressed in the annual work plans;
  - (b) advise on the scientific achievements described in the annual activity report.

5. The Scientific Committee shall meet at least once a year. The meetings shall be convened by its chairperson.
6. The Scientific Committee may, with the agreement of the chairperson, invite other persons to attend its meetings.
7. The Scientific Committee shall adopt its own rules of procedure.

#### 11- States Representatives Group

1. The IMI2 States Representatives Group shall consist of one representative of each Member State and of each country associated to the Horizon 2020 Framework Programme. It shall elect a chairperson from amongst its members.
2. The States Representatives Group shall meet at least once a year. The meetings shall be convened by its chairperson. The chairperson of the Governing Board and the Executive Director or their representatives shall attend the meetings.  
The chairperson of the States Representatives Group may invite other persons to attend its meetings as observers, in particular representatives of regional authorities of the Union and representatives of SME associations.

3. The States Representatives Group shall in particular review information and provide advice on the following matters:
  - (a) programme progress in the IMI2 Joint Undertaking and achievement of its targets;
  - (b) updating of strategic orientation;
  - (c) links to the Horizon 2020 Framework Programme;
  - (d) annual work plans;
  - (e) involvement of SMEs.
4. The States Representatives Group shall also provide information to and act as an interface with the IMI2 Joint Undertaking on the following matters:
  - (a) the status of relevant national or regional research and innovation programmes and identification of potential areas of cooperation, including deployment;
  - (b) specific measures taken at national level or regional level with regard to dissemination events, dedicated technical workshops and communication activities.

5. The States Representatives Group may issue, on its own initiative, recommendations to the IMI2 Joint Undertaking on technical, managerial and financial matters, in particular when those matters affect national or regional interests.

The IMI2 Joint Undertaking shall inform the States Representatives Group of the follow up it has given to such recommendations.

6. The States Representatives Group shall adopt its own rules of procedure.

#### 12 - Stakeholder Forum

1. The Stakeholder Forum shall be open to all public and private stakeholders, international interest groups from Member States, associated countries as well as from other countries.

2. The Stakeholder Forum shall be informed of the activities of the IMI2 Joint Undertaking and shall be invited to provide comments.
3. The meetings of the Stakeholder Forum shall be convened by the Executive Director.

#### 13 - Sources of financing

1. The IMI2 Joint Undertaking shall be jointly funded by the Union, the Members other than the Union and the Associated Partners, or their constituent entities or their affiliated entities, through financial contributions paid in instalments and contributions consisting of the costs incurred by them in implementing indirect actions and that are not reimbursed by the IMI2 Joint Undertaking.
2. The administrative costs of the IMI2 Joint Undertaking shall not exceed EUR 89,7 million and shall be covered through financial contributions divided equally on an annual basis between the Union and the Members other than the Union. If part of the contribution for administrative costs is not used, it may be made available to cover the operational costs of the IMI2 Joint Undertaking.
3. The operational costs of the IMI2 Joint Undertaking shall be covered through the following contributions:
  - (a) a financial contribution by the Union;
  - (b) in kind contributions by the Members other than the Union and the Associated Partners, or their constituent entities or their affiliated entities, consisting of the costs incurred by them in implementing indirect actions, and in relation to advisory bodies referred to in Clause 7(2)(q) if foreseen in the annual work plan, less the contribution of the IMI2 Joint Undertaking and any other Union contribution to those costs;
  - (c) a financial contribution by the Members other than the Union and the Associated Partners, or their constituent entities or their affiliated entities, which may be made in addition to, or instead of point (b).
4. The resources of the IMI2 Joint Undertaking entered to its budget shall be composed of the following contributions:
  - (a) Members' financial contributions to the administrative costs;
  - (b) Members' and Associated Partners' financial contributions to the operational costs;
  - (c) any revenue generated by the IMI2 Joint Undertaking;
  - (d) other financial contributions, resources and revenues.

Any interest yielded by the contributions paid to the IMI2 Joint Undertaking by its Members and Associated Partners shall be considered to be its revenue.
5. All resources of the IMI2 Joint Undertaking and its activities shall be devoted to the objectives set out in Article 2 of this Regulation.
6. The IMI2 Joint Undertaking shall own all assets generated by it or transferred to it for the achievement of its objectives provided for in Article 2 of this Regulation.
7. Except when the IMI2 Joint Undertaking is wound up pursuant to Clause 21, any excess revenue over expenditure shall not be paid to the Members of the IMI2 Joint Undertaking.

#### 14 – Financial commitments

Financial commitments of the IMI2 Joint Undertaking shall not exceed the amount of financial resources available or committed to its budget by its Members and Associated Partners.

#### 15 - Financial year

The financial year shall run from 1 January to 31 December.

#### 16 – Operational and financial planning

1. The Executive Director shall submit for adoption to the Governing Board a draft annual work plan, which shall include a detailed plan of the research and innovation activities, the administrative activities and the corresponding expenditure estimates for the coming year. The draft work plan shall also include the estimated value of the contributions to be made in accordance with clause 13(3)(b).
2. The annual work plan for a particular year shall be adopted by the end of the previous year. The annual work plan shall be made publicly available.
3. The Executive Director shall prepare the draft annual budget for the following year and submit it to the Governing Board for adoption.
4. The annual budget for a particular year shall be adopted by the Governing Board by the end of the previous year.
5. The annual budget shall be adapted in order to take into account the amount of the Union contribution as set out in the Union budget.

#### 17 – Operational and financial reporting

1. The Executive Director shall report annually to the Governing Board on the performance of his duties in accordance with the Financial rules of the IMI2 Joint Undertaking.

By 15 February each year the Executive Director shall submit to the Governing Board for approval an annual activity report on the progress made by the IMI2 Joint Undertaking in the previous calendar year, in particular in relation to the annual work plan for that year. That report shall include, inter alia, information on the following matters:

- (a) research, innovation and other actions carried out and the corresponding expenditure;
  - (b) proposals submitted, including a breakdown by participant type, including SMEs, and by country;
  - (c) the actions selected for funding, including a breakdown by participant type, including SMEs, and by country and indicating the contribution of the IMI2 Joint Undertaking to the individual participants and actions.
2. Once approved by the Governing Board, the annual activity report shall be made publicly available.
  3. The IMI2 Joint Undertaking shall report annually to the Commission in accordance with Article 60(5) of Regulation (EU, Euratom) No 966/2012.
  4. The accounts of the IMI2 Joint Undertaking shall be examined by an independent audit body as laid down in Article 60(5) of Regulation (EU, Euratom) No 966/2012.

The accounts of the IMI2 Joint Undertaking shall not be subject to examination by the Court of Auditors.

## 18 - Internal audit

The Commission's internal auditor shall exercise the same powers over the IMI2 Joint Undertaking as those exercised in respect of the Commission.

## 19 - Liability of Members and insurance

1. The financial liability of the Members for the debts of the IMI2 Joint Undertaking shall be limited to their contribution already made for the administrative costs.
2. The IMI2 Joint Undertaking shall take out and maintain appropriate insurance.

## 20 - Conflict of interest

1. The IMI2 Joint Undertaking, its bodies and staff shall avoid conflict of interest in the implementation of their activities.
2. The IMI2 Joint Undertaking Governing Board may adopt rules for the prevention and management of conflicts of interest in respect of its Members, Associated Partners, bodies and staff. In those rules, provision shall be made to avoid conflict of interest for the representatives of the Members serving the Governing Board.

## 21 - Winding up

1. The IMI2 Joint Undertaking shall be wound up at the end of the period in Article 1 of this Regulation.
2. The winding up procedure shall be automatically triggered if the Commission or all other Members withdraw from the IMI2 Joint Undertaking.
3. For the purpose of conducting the proceedings to wind up the IMI2 Joint Undertaking, the Governing Board shall appoint one or more liquidators, who shall comply with the decisions of the Governing Board.
4. When the IMI2 Joint Undertaking is being wound up, its assets shall be used to cover its liabilities and the expenditure relating to its winding up. Any surplus shall be distributed among the Members at the time of the winding up in proportion to their financial contribution to the IMI2 Joint Undertaking. Any such surplus distributed to the Union shall be returned to the Union budget.
5. An ad hoc procedure shall be set up to ensure the appropriate management of any agreement concluded or decision adopted by the IMI2 Joint Undertaking as well as any procurement contract with a duration longer than its duration.

## **LEGISLATIVE FINANCIAL STATEMENT**

### **1. FRAMEWORK OF THE PROPOSAL/INITIATIVE**

- 1.1. Title of the proposal/initiative**
- 1.2. Policy area(s) concerned in the ABM/ABB structure**
- 1.3. Nature of the proposal/initiative**
- 1.4. Objectives**
- 1.5. Grounds for the proposal/initiative**
- 1.6. Duration and financial impact**
- 1.7. Management mode(s) envisaged**

### **2. MANAGEMENT MEASURES**

- 2.1. Monitoring and reporting rules**
- 2.2. Management and control system**
- 2.3. Measures to prevent fraud and irregularities**

### **3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE**

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected**
- 3.2. Estimated impact on expenditure**
  - 3.2.1. Summary of estimated impact on expenditure*
  - 3.2.2. Estimated impact on Innovative Medicines Initiative Joint Undertaking's appropriations*
  - 3.2.3. Estimated impact on Innovative Medicines Initiative Joint Undertaking's human resources*
  - 3.2.4. Compatibility with the current multiannual financial framework*
  - 3.2.5. Third-party contributions*
- 3.3. Estimated impact on revenue**

## LEGISLATIVE FINANCIAL STATEMENT

### 1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

#### 1.1. Title of the proposal/initiative

Proposal for a Council Regulation on the Innovative Medicines Initiative 2 Joint Undertaking

#### 1.2. Policy area(s) concerned in the ABM/ABB structure<sup>23</sup>

Policy area: Smart and Inclusive Growth

Activity: Horizon 2020 – The Framework Programme for Research and Innovation; ‘Societal challenges’; in the challenge ‘Health, demographic change and wellbeing’

#### 1.3. Nature of the proposal/initiative

The proposal/initiative relates to **a new action**

The proposal/initiative relates to **a new action following a pilot project/preparatory action**<sup>24</sup>

The proposal/initiative relates to **the extension of an existing action**

The proposal/initiative relates to **an action redirected towards a new action**

#### 1.4. Objective(s)

##### 1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

The action is part of the Smart and Inclusive Growth strategic objective.

The action is addressing two objectives of Horizon 2020 strategy:

- Objective number 1. Innovation Union
- Objective number 5. An industrial policy for the globalisation area

The objectives of the IMI2 JU are to:

- i. increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;
- ii. reduce the time to reach clinical proof of concept in immunological, respiratory, neurological and neurodegenerative diseases;
- iii. develop new therapies for diseases for which there is a high unmet need, such as Alzheimer's disease and limited market incentives, such as antimicrobial resistance;
- iv. develop diagnostic markers for diseases clearly linked to clinical relevance approved by regulators;
- v. reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks.

##### 1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

Specific objective Nbr 8

Societal challenge to improve the lifelong health and wellbeing of all.

ABM/ABB activity(ies) concerned

<sup>23</sup> ABM: Activity-Based Management – ABB: Activity-Based Budgeting.  
<sup>24</sup> As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

Societal challenges - JTI IMI2

1.4.3. *Expected result(s) and impact*

*Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.*

This issue is addressed in the Impact Assessment document attached to this proposal.

1.4.4. *Indicators of results and impact*

*Specify the indicators for monitoring implementation of the proposal/initiative.*

<b>Scientific and technological progress</b>		
	<b>Indicator</b>	<b>Target</b>
Monitoring achievement of objectives of the JU	<b>Monitoring the achievement of specific objectives</b>	See section 3.2 of the Impact Assessment Report
	Number of open innovation networks established	3 open innovation network between different industry sectors, and 2 clinical trial networks
	Number of strategic agenda setting beyond JU	Strategic agenda setting in 3 research areas defined by the specific objectives in section 3.2;
	Number of partnerships established	Partnerships in 16 research areas defined by the specific objectives in section 3.2
Monitoring implementation of the strategic research agenda	Number of data points analysed for reaching at unbiased molecular taxonomy of disease	5 million data points
	Number of diseases classified	4 diseases area
	Number of trials analysed for learning from negative results	125 trials
	Level of taking account of health and demographic change and wellbeing policy goals	Strategic research agenda needs to address points 1.1.2, 1.2.2, parts of 1.2.3 and parts of 1.3.1 of partial general approach of Horizon 2020
<b>Monitoring JU operations</b>		
Selection of projects and allocation of funding	Time-to-grant	270 days
	Time-to-pay	30 days
	Level of adherence to time schedule	Budget committed and calls launched accordingly
	Level of SME participation and benefits	From the beginning 20% IMI2 funding going to SMEs, benefit to SMEs monitored as from 2 <sup>nd</sup> year: at least 70% of SME respondents stating that they benefit from the expertise of industry and/or academic partners; 80% of SMEs stating that objectives could not have been met without IMI2 support.
Efficiency of research programme	Number of publications	On average 20 publications per €10 million funding
	Impact factor of journals where articles are published	Average impact factor 10% above EU average
	Impact of publications	Citations 20% above average for EU publications
	Number of patents	On average 2 patent applications per €10 million funding

1.5. **Grounds for the proposal/initiative**

1.5.1. *Requirement(s) to be met in the short or long term*

IMI2 JU shall contribute to achieving smart, sustainable and inclusive growth.

1.5.2. *Added value of EU involvement*

This issue is addressed in the Impact Assessment document attached to this proposal.

### 1.5.3. *Lessons learned from similar experiences in the past*

The ongoing Innovative Medicines Initiative has achieved a significant mobilisation of resources, bringing together a large number of partners from the pharmaceutical industry, academia, SMEs, patient organisations and regulators in focused projects that mobilise significant resources (average project size €32 million). The large pharmaceutical industry participates strongly in IMI (50% of resources, 30% of staff – total commitment to projects by large industry of €715 million until end 2012), whereas its participation in European research programmes outside IMI is very low (0.78% of participations in FP7 Health, total contribution to all of FP7 about €80 million, ¼ of which to FP7 Health).

IMI has significantly contributed to strengthening the links between the different stakeholders in the health research and innovation field by opening access to other partner's expertise and increasing collaboration between the pharmaceutical industry and other stakeholders in Europe.

IMI also achieves focusing and developing strategic research agendas and horizontal policy coordination, the former having a structuring effect on European life science research, notably in neuropsychiatric diseases, in antimicrobial resistance, and other areas, the latter by coordinating the involvement of patient organisations and - in projects addressing regulatory sciences - of regulatory agencies, which was considered a rare achievement in the interim evaluation.

The ongoing Innovative Medicines Initiative has demonstrated that bringing together relevant partners can lead to a new model of innovation and can address key bottlenecks in biomedical and pharmaceutical research.

Areas for improvement concern especially the administrative set-up, where simplification is required and the opening of the partnership by the expanding the scope to all areas of life science research and innovation and consequently involving a broader range of partners. A particular issue that needs to be addressed is to open the partnership to industrial participants who are neither EFPIA companies nor SMEs under the EU definition.

### 1.5.4. *Compatibility and possible synergy with other appropriate instruments*

The societal challenge of the ageing population is so large that the PPP under Horizon 2020 cannot address it alone. The future IMI will be complementary to the Ambient Assisted Living Article 185 initiative, which is focused on deploying technology solutions for helping elderly citizens live independently. The European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) under the Innovation Union flagship initiative, aims at increasing by two the number of healthy life years of European citizens by 2020 through the coordination of many different activities. Results from IMI2 will support this EIP on AHA. Research actions conducted under IMI2 will be tightly coordinated with research funded from the 'Health, demographic change and wellbeing challenge'. Finally, this initiative aligns with the proposed EU Regulation on Clinical Trials, which addresses current shortcomings in Europe resulting from too different national legislations hampering product development.

## 1.6. **Duration and financial impact**

Proposal/initiative of **limited duration**

Proposal/initiative in effect from 01/01/2014 to 31/12/2024

Financial impact from 01/01/2014 to 31/12/2020 for commitment appropriations

Financial impact from 01/01/2014 to 31/12/2024 for payment appropriations

Proposal/initiative of **unlimited duration**

- Implementation with a start-up period from YYYY to YYYY,
- followed by full-scale operation.

### 1.7. Management mode(s) envisaged<sup>25</sup>

**Direct management** by the Commission through:

executive agencies

**Shared management** with Member States:

**Indirect management** by entrusting budget implementation tasks to:

international organisations and their agencies (please specify);

the EIB and the European Investment Bank;

bodies referred to in Article 209 FR;

public law bodies;

bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU and identified in the relevant basic act.

## 2. MANAGEMENT MEASURES

### 2.1. Monitoring and reporting rules

*Specify frequency and conditions.*

The IMI Joint Undertaking will be monitored through intermediary contacts and as provided in Articles 6 and 16 of the Statutes.

A set of quantitative and qualitative performance indicators will be established to monitor the implementation of IMI2. These performance indicators will measure the impact of the JU on EU competitiveness and on achieving the objectives of advancing health research to bring biomedical innovations to patients.

The top-level monitoring will fall upon the Governing Board of the JU, in which the Commission will be represented according to its share of the overall budget. The Executive Management will monitor the operations of the JU internally.

In support of the European Research Area objective, the organisation of the annual Stakeholder forum will continue, in order to report on the progress of IMI2 operations, to contribute to the exchange of information and to help coordinating activities between the JTI, other EU initiatives, and national, regional and private actions.

Quantitative indicators will be measured in a comparative and systematic manner, and qualitative analyses will be performed annually.

An interim evaluation will be carried out by 31.12.2017 and a final evaluation within 6 months after the end of IMI2.

<sup>25</sup>

Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: [http://www.cc.cec/budg/man/budgmanag/budgmanag\\_en.html](http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html)

## 2.2. Management and control system

### 2.2.1. Internal control framework

The Commission (DG RTD) through the Authorising Officer by Delegation will ensure that the rules applicable to the IMI JTI JU fully comply with the requirements of Article 60 and 61 of the Financial Regulation. Monitoring arrangements, including membership of the Governing Board, of the IMI JTI JU and reporting arrangements will ensure that the Commission services can meet the accountability requirements both to the College and to the Budgetary Authority.

The internal control framework for the IMI JTI JU is built on:

- the implementation of the Internal Control Standards offering at least equivalent guarantees to those of the Commission;
- procedures for selecting the best projects through independent evaluation, and for translating them into legal instruments;
- project and contract management throughout the lifetime of every project;
- ex-ante checks on 100% of claims, including receipt of audit certificates and ex-ante certification of cost methodologies;
- ex-post audits on a sample of claims as part of the Horizon 2020 ex-post audits;
- and scientific evaluation of project results.

Various measures have been established to mitigate the inherent risk of conflict of interest within the IMI JTI JU, especially equal votes for the Commission and for industrial partners in the Governing Board, selection of the Director by the Governing Board based on a proposal by the Commission, independence of staff, evaluations by independent experts based on published selection criteria together with appeal mechanisms and full declarations of any interests. The establishment of ethical and organisational values will be one of the key roles of the JTI JU, and will be monitored by the Commission.

### 2.2.2. Costs and benefits of controls

The Commission's internal auditor shall exercise the same powers over the Joint Undertaking as those exercised in respect of the Commission. Moreover, the Governing Board may arrange, as appropriate, for the establishment of an internal audit capability of the Joint Undertaking.

The Executive Director of the IMI JTI JU, as Authorising Officer, will be required to introduce a cost-effective system of internal control and management. He/she will be required to report to the Commission on the internal control framework adopted.

The Commission will monitor the risk of non-compliance through the reporting system that it will develop, as well as by following the results of ex-post audits on the recipients of EU funds from the IMI JTI, as part of ex-post audits covering the whole of the Horizon 2020.

The control system established will need to take account of the strong feeling, amongst the recipients of EU funds as well as amongst the legislative authority, that the control burden required to attain an error limit of 2% has become too great. This runs the risk of lowering the attractiveness of the Union's Research programme, and so negatively affecting Union research and innovation.

The European Council of February 4th 2011 concluded that 'it is crucial that EU instruments aimed at fostering R&D&I be simplified in order to facilitate their take-up by the best scientists and the most innovative companies, in particular by agreeing between

the relevant institutions a new balance between trust and control and between risk taking and risk avoidance' (see EUCO 2/1/11 REV1, Brussels 8 March 2011).

The European Parliament, in its Resolution of 11 November 2010 (P7\_TA(2010)0401) on simplifying the implementation of the Research Framework Programmes explicitly supports a higher risk of errors for research funding and "expresses its concern that the current system and the practice of FP7 management are excessively control-oriented, thus leading to waste of resources, lower participation and less attractive research landscapes; notes with concern that the current management system of 'zero risk tolerance' seems to avoid, rather than to manage, risks".

There is therefore an acceptance among stakeholders and Institutions that the whole range of objectives and interests, especially the success of the Research policy, international competitiveness and scientific excellence, should be considered, along with the error rate. At the same time, there is a clear need to manage the budget in an efficient and effective manner, and to prevent fraud and waste.

As stated above, the Commission will monitor the risk of non-compliance through the reporting system that it will establish, as well as by following the results of ex-post audits on the recipients of EU funds from the IMI JTI JU, as part of the ex-post audits covering the whole of the Horizon 2020.

### 2.2.3. *Expected level of risk of non-compliance*

As the Commission reported in the Legislative Financial Statement for Horizon 2020, it remains the ultimate objective to achieve a residual error rate of less than 2% of total expenditure over the lifetime of the programme, and to that end, it has introduced a number of simplification measures. However, the other objectives set out above as well as the costs of controls need to be considered.

As the rules for participation of the IMI JTI JU are similar to those of Horizon 2020, and with a population of beneficiaries with a similar risk profile to those of the Commission, it can be expected that the level of error will be similar to that established by the Commission for Horizon 2020, i.e. to give reasonable assurance that the risk of error over the course of the multiannual expenditure period is, on an annual basis, within a range of 2-5 %, with the ultimate aim to achieve a residual level of error as close as possible to 2 % at the closure of the multi-annual programmes, once the financial impact of all audits, correction and recovery measures have been taken into account.

See the Legislative Financial Statement for Horizon 2020 for full details of the error rate expected with respect to participants.

### 2.3. **Measures to prevent fraud and irregularities**

The Commission will ensure that procedures to fight against fraud at all stages of the management process are applied by the IMI2 JTI JU. The proposals for Horizon 2020 have been subject to fraud proofing and an assessment of their impact. Overall the measures proposed should have a positive impact on the fight against fraud, especially the greater emphasis on risk based audit and reinforced scientific evaluation and control.

The Commission will ensure that appropriate measures are in place to ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and deterrent penalties.

The current IMI2 JTI JU already cooperates with the Commission services in matters relating to fraud and irregularity, the Commission will ensure that this will continue and be strengthened.

The accounts of the IMI2 Joint Undertaking shall be examined by an independent audit body as laid down in Article 60(5) of Regulation (EU, Euratom) No 966/2012. The accounts of the IMI2 Joint Undertaking shall not be subject to examination by the Court of Auditors. The Court of Auditors may conduct audits on those participants that have received funding from the IMI2 Joint Undertaking.

The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with an agreement or decision or a contract funded under this Regulation.

### 3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

#### 3.1. Heading of the multiannual financial framework and expenditure budget line affected

- New budget lines requested

*In order of multiannual financial framework headings and budget lines.*

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [H1a Competitiveness for growth and jobs]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
1a	08.020731 (mother line 08.020301)	[Diff]	YES	YES	YES	YES

### 3.2. Estimated impact on expenditure

#### 3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

<b>Heading of multiannual financial Framework:</b>	H1a	Competitiveness for growth and jobs
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IMI 2 Joint Undertaking			Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021-2024	TOTAL
Title 1 Staff expenditure	Commitments	(1)	0,239	0,378	0,555	0,648	2,534	2,585	12,999	0	<b>19,938</b>
	Payments	(2)	0,239	0,378	0,555	0,648	2,534	2,585	2,636	10,363	<b>19,938</b>
Title 2 Infrastructure and operating expenditure	Commitments	(1a)	0,496	0,672	0,706	0,717	3,243	3,192	15,886	0	<b>24,912</b>
	Payments	(2a)	0,496	0,672	0,706	0,717	3,243	3,192	3,140	12,746	<b>24,912</b>
Title 3 operational expenditure	Commitments	(3a)	207,300	211,000	214,800	190,850	276,200	293,000	287,000	0	<b>1.680,150</b>
	Payments	(3b)	16,600	65,950	105,000	146,000	191,000	209,200	245,000	701,400	<b>1.680,150</b>
<b>TOTAL appropriations for [IMI 2 JU]</b>	Commitments	=1+1a +3a	208,035	212,050	216,061	192,215	281,977	298,777	315,885	0	<b>1.725,000</b>
	Payments	=2+2a +3b	17,335	67,000	106,261	147,365	196,777	214,977	250,776	724,509	<b>1.725,000</b>

<sup>1</sup> In addition EUR 15.8 million (including EFTA) has been frontloaded in 2013 for the IMI running cost related to the completion of its activities under FP7.

The annual split of these appropriations as well as the corresponding industry contribution are presented in the table under point 3.2.3.3.d.

<b>Heading of multiannual financial framework:</b>	<b>1A</b>	Competitiveness for growth and jobs
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EUR million (to three decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021-2024	TOTAL
DG: RTD										
• Human resources		0,559	0,570	0,582	0,593	0,605	0,617	0,630		<b>4,156</b>
• Other administrative expenditure		0	0	0	0	0	0	0	0	<b>0</b>
<b>TOTAL DG RTD</b>	Appropriations	0,559	0,570	0,582	0,593	0,605	0,617	0,630		<b>4,156</b>

<b>TOTAL appropriations under HEADING 1A</b> of the multiannual financial framework	(Total commitments = Total payments)	0,559	0,570	0,582	0,593	0,605	0,617	0,630		<b>4,156</b>
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EUR million (to three decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021-2024	TOTAL
<b>TOTAL appropriations under HEADINGS 1 to 5</b> of the multiannual financial framework	Commitments	208,594	212,620	216,643	192,808	282,582	299,394	316,515		1.729,156
	Payments	17,894	67,570	106,843	147,958	197,382	215,594	251,406	724,509	1.729,156

### 3.2.2. Estimated impact on IMI 2 JU's appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as described below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ↓			Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	TOTAL								
	OUTPUTS																	
	Type <sup>26</sup>	Average cost	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Total number	Total cost
SPECIFIC OBJECTIVE NO 1 <sup>27</sup> supporting grants for collaborative projects led by EFPIA																		
- Output	Grants	~€17,5m	10	179,500	10	182,700	11	186,000	9	165,100	14	239,200	15	254,000	14	248,650	83	1.455,150
Subtotal for specific objective N°1			10	179,500	10	182,700	11	186,000	9	165,100	14	239,200	15	254,000	14	248,650	83	1.455,150
SPECIFIC OBJECTIVE No 2 supporting grants for collaborative projects led by other industries																		
- Output	Grants	~€13,2m	2	27,800	2	28,300	2	28,800	2	25,600	3	37,000	3	39,300	3	38,200	17	225,000
Subtotal for specific objective No 2			2	27,800	2	28,300	2	28,800	2	25,600	3	37,000	3	39,300	3	38,200	17	225,000
- Output	Participation in investment projects																	
Subtotal for specific objective No 3																		
<b>TOTAL COST</b>			12	207,300	12	211,000	13	214,800	11	190,700	17	276,200	18	293,300	17	286,850	100	1.680,150

<sup>26</sup> Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

<sup>27</sup> As described in point 1.4.2. 'Specific objective(s)'.

### 3.2.3. Estimated impact on IMI 2 JU's human resources

#### 3.2.3.1. Summary

- X The proposal/initiative does not require the use of appropriations of an administrative nature
- The proposal/initiative requires the use of appropriations of an administrative nature, as described below:

Staffing numbers (in headcounts / FTE)<sup>28</sup>

	Year 2014 <sup>29</sup>	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021	Year 2022	Year 2023	Year 2024
Officials (AD Grades)	0	0	0	0	0	0	0	0	0	0	0
Officials (AST Grades)	0	0	0	0	0	0	0	0	0	0	0
Contract agents	8	9	9	10	10	10	10	9	9	9	8
Temporary agents (AD only)	33	35	38	39	39	39	39	38	37	37	35
Seconded National Experts <sup>30</sup>	0	0	0	0	0	0	0	0	0	0	0
<b>TOTAL</b>	<b>41</b>	<b>44</b>	<b>47</b>	<b>49</b>	<b>49</b>	<b>49</b>	<b>49</b>	<b>47</b>	<b>46</b>	<b>46</b>	<b>43</b>

EUR million (to three decimal places)

	Year 2014 <sup>31</sup>	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020	Year 2021	Year 2022	Year 2023	Year 2024
Officials (AD Grades)	0	0	0	0	0	0	0	0	0	0	0
Officials (AST Grades)	0	0	0	0	0	0	0	0	0	0	0
Contract agents	0,376	0,431	0,440	0,499	0,509	0,519	0,529	0,486	0,496	0,506	0,458
Temporary agents	3,564	3,856	4,270	4,470	4,559	4,650	4,743	4,714	4,682	4,776	4,608
Seconded National Experts	0	0	0	0	0	0	0	0	0	0	0

These amounts consider costs until 2024 including the phasing out costs.

<b>TOTAL</b>	<b>3,940</b>	<b>4,287</b>	<b>4,710</b>	<b>4,969</b>	<b>5,068</b>	<b>5,169</b>	<b>5,273</b>	<b>5,200</b>	<b>5,178</b>	<b>5,281</b>	<b>5,066</b>
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<sup>28</sup> In the case of EU PPP bodies under Article 209 FR, this table is included for information purposes.

<sup>29</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>30</sup> In accordance with Article 7 of the Council Regulation, the IMI2 Joint Undertaking may make use of seconded national experts and trainees not employed by the Joint Undertaking. Staff numbers for temporary agents will be reduced if IMI2 employs ENDS.

<sup>31</sup> Year N is the year in which implementation of the proposal/initiative starts.

### 3.2.3.2. Estimated requirements of human resources for the parent DG

- The proposal/initiative does not require the use of human resources.
- The proposal/initiative requires the use of human resources, as described below:

Estimate to be expressed in full number

	Year 2014 <sup>32</sup>	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020*
<b>• Establishment plan posts (officials and temporary staff)</b>							
XX 01 01 01 (Headquarters and Commission's Representation Offices)	0	0	0	0	0	0	0
XX 01 01 02 (Delegations)	0	0	0	0	0	0	0
08 01 05 01 (Indirect research)	4	4	4	4	4	4	4
10 01 05 01 (Direct research)	0	0	0	0	0	0	0
<b>• External staff (in Full Time Equivalent: FTE)<sup>33</sup></b>							
XX 01 02 01 (CA, SNE, INT from the 'global envelope')	0	0	0	0	0	0	0
XX 01 02 02 (CA, LA, SNE, INT and JED in the delegations)	0	0	0	0	0	0	0
<b>XX 01 04 yy<sup>34</sup></b>	- at Headquarters <sup>35</sup>		0	0	0	0	0
	- in delegations		0	0	0	0	0
08 01 05 02 (CA, SNE, INT - Indirect research)	0.5	0.5	0.5	0.5	0.5	0.5	0.5
10 01 05 02 (CA, SNE, INT- Direct research)	0	0	0	0	0	0	0
Other budget lines (specify)	0	0	0	0	0	0	0
<b>TOTAL</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>	<b>4.5</b>

\*Staff number for the period after 2020 will be decided at the later stage.

<sup>32</sup> Year N is the year in which implementation of the proposal/initiative starts.

<sup>33</sup> CA= Contract Agent; LA = Local Agent; SNE = Seconded National Expert; INT= agency staff ('Intérimaire').

<sup>34</sup> Sub-ceiling for external staff covered by operational appropriations (former "BA" lines).

<sup>35</sup> Mainly for the Structural Funds, the European Agricultural Fund for Rural Development (EAFRD) and the European Fisheries Fund (EFF).

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	The tasks of Commission staff in conjunction with the implementation of the IMI JU are to assure the correct budget implementation and supervision of the operations of the IMI JU. Senior managers from Commission services will serve on the IMI2 JU Governing Board.  Commission staff members will contribute to the work of the advisory groups of IMI2 that may be established by the Governing Board. It is estimated that 4 advisory groups will be established, each requiring 0.25 FTE of work from Commission staff members for the entire period of establishment of IMI.
External staff	External staff will support officials and temporary staff in assuring the correct budget implementation and supervision of the operations of the IMI JU.

Description of the calculation of cost for FTE equivalent should be included in the Annex, section 3.

### 3.2.3.3. a. Estimated requirements of human resources for the IMI 2 JU<sup>36</sup>

- The proposal/initiative does not require the use of human resources.
- The proposal/initiative requires the use of human resources, as described below:

### b. Estimated requirements of human resources to be financed from appropriations under 2014-2020 Multiannual Financial Framework

Estimate to be expressed in full in numbers

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020*
<b>• Establishment plan posts (officials and temporary staff)</b>							
XX XX XX XX (PPP body)							
Temporary (AD grades)	0	0	0	0	0	0	0
Temporary (AST grades)	0	0	0	0	0	0	0
IMI JU (PPP body)							
TA	4	6	9	10	39	39	39
CA	1	2	2	3	10	10	10
SNE	0	0	0	0	0	0	0
INT	0	0	0	0	0	0	0
<b>TOTAL</b>	<b>5</b>	<b>8</b>	<b>11</b>	<b>13</b>	<b>49</b>	<b>49</b>	<b>49</b>

\*for years 2021 to 2024 please refer to table 3.2.3.1

Description of tasks to be carried out:

Officials and temporary staff	The tasks are described in Article 1 of the Statutes annexed to the Council Regulation. The tasks of the Executive Director of IMI2 are described in Article 6 of the Statutes.
External staff	External staff shall assist the temporary staff of the IMI JU in carrying out their tasks.

<sup>36</sup> In the case of EU PPP bodies under Article 209 FR, this section is included for information purposes.

c. Human resources financed from appropriations under 2007-2013 Multiannual Financial Framework<sup>37</sup>

Estimate to be expressed in full numbers (of FTE)

	Year 2014	Year 2015	Year 2016	Year 2017
<b>• Establishment plan posts (officials and temporary staff)</b>				
IMI JU (PPP body)				
Temporary (AD grades)	0	0	0	0
Temporary (AST grades)	0	0	0	0
<b>• External staff (in Full Time Equivalent: FTE)<sup>38</sup></b>				
IMI JU (PPP body)				
TA	29	29	29	29
CA	7	7	7	7
SNE	0	0	0	0
INT	0	0	0	0
<b>TOTAL</b>	<b>36</b>	<b>36</b>	<b>36</b>	<b>36</b>

d. Contribution to the running costs for the phasing out of the PPP body under the Multiannual Financial Framework 2007-2013

EUR million (to 3 decimal places)

	Year 2014	Year 2015	Year 2016	Year 2017	Total <sup>39</sup>
Contribution in cash from the EU	3,950	3,950	3,950	3,950	15,800
Contribution in cash from third parties	3,950	3,950	3,950	3,950	15,800
<b>TOTAL</b>	<b>7,900</b>	<b>7,900</b>	<b>7,900</b>	<b>7,900</b>	<b>31,600</b>

3.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible the current multiannual financial framework.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. [Not applicable]

<sup>37</sup> In the case of EU PPP bodies under Article 209 FR, this table is included for information purposes.

<sup>38</sup> CA = Contract Agent; LA = Local Agent; SNE = Seconded National Expert; INT = agency staff ('Intérimaire').

<sup>39</sup> The total for the EU cash contribution should equal the amount front-loaded in the 2013 budget for the completion of the 2007-2013 activities of the body.

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework<sup>40</sup>.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.  
[Not applicable]

### 3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties.
- The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to three decimal places)

	Year 2014*	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020 and later	TOTAL
European Federation of Pharmaceutical Industries and Associations – <i>contribution in cash to administrative costs</i>	0,735	1,050	1,260	1,366	5,777	5,777	28,885	44,850
Associated partners, future members and participants to the co-investment scheme - <i>contribution in cash to administrative costs</i>	0	0	0	0	0	0	0	0
<i>contribution in cash to the operational costs - amount currently not specified; is expected to be made</i>								
TOTAL appropriations cofinanced by EFPIA								
Total appropriations cofinanced by associated partners or future members of the PPP or participations in the co-investment scheme	0,735	1,050	1,260	1,366	5,777	5,777	28,885	44,850

The total contribution from members other than the Union are laid down by Article 4 of the Council Regulation of the IMI2 Joint Undertaking.

#### Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
  - on own resources
  - on miscellaneous revenue

<sup>40</sup> See points 19 and 24 of the Inter-institutional Agreement.