Innovative Medicines Initiative

SUMMARY OF THE MOST RELEVANT PROVISIONS FOR PARTICIPATING IN IMI2 ACTIONS

Version 1.2

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1- What kind of actions are supported by IMI2

Article 2 of the Council Regulation establishing the Innovative Medicines Initiative 2 Joint Undertaking (EU) No 557/2014 H2020 Regulation (EU) No 1291/2013

1. IMI2 JU supports the development and implementation of pre-competitive research and innovation actions and any relevant accompanying measures to improve European citizens' health and well-being.
2. The research and innovation actions primarily consist of activities aiming to establish new knowledge and/or to explore the feasibility of a new or improved technology, product, process, service or solution. For this purpose they may include basic and applied research, technology development and integration, testing and validation on a small-scale prototype in a laboratory or simulated environment. Such projects may contain closely connected but limited demonstration or pilot activities aiming to show technical feasibility in a near to operational environment.
3. IMI2 initiates competitive calls for proposals and any other necessary procedure for funding, evaluates proposals, awards funding to projects according to the applicable rules, within the limits of available funds[1].
4. The relevant IMI2 Annual Work Plan and/or the Call for Proposals will specify the type of action and the applicable procedure.

2- Who may participate to IMI2 actions

Article 7 of H2020 Regulation (EU) No 1290/2013

1. Any legal entity, regardless of its place of establishment, or international organisation carrying out activities relevant to the objectives of the IMI2 JU may participate in an action provided that the conditions laid down in the H2020 Rules for participation, and Commission Delegated Regulation have been met, together with any conditions laid down in the relevant IMI2 Annual Work Plan.
2. The relevant IMI2 Annual Work Plan may restrict the participation of legal entities established in third countries where conditions for the participation of legal entities from Member States, or of their affiliated entities established in a third country, in the third country's research and innovation programmes are considered to be prejudicial to the Union's interests.
3. The JRC may participate in actions with the same rights and obligations as a legal entity established in a Member State.

[1] Funding may take one or several of the forms provided for by Regulation (EU, Euratom) No 966/2012, in particular grants, prizes, procurement or financial instruments (article 10 of H2020 Regulation)

3- Who is eligible for IMI2 funding

Article 1 of the Commission Delegated Regulation No 622/2014 of 14 February 2014 Article 10.3 of H2020 Regulation (EU) No 1290/2013

1. The following participants are eligible for funding:

(a) independent[2] legal entities established in a Member State or an Associated Country, or created under Union law; and

(b) which fall within one of the following categories:

(i) micro, small and medium-sized enterprises and other companies with an annual turnover of EUR 500 million or less, the latter not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities'[3] within the meaning of Article 2(1)(2) of Regulation (EU) No 1290/2013 shall apply mutatis mutandis;

(ii) secondary and higher education establishments;

(iii) non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organisations.

(c) the Joint Research Centre;

(d) international European interest organisations.

2. EU funding may be granted to international organisations and legal entity established in a third country provided that at least one of the following conditions is fulfilled:

(a) the participation is deemed essential for carrying out the IMI2 JU action;

(b) such funding is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and the international organisation or, for entities established in third countries, the country in which the legal entity is established.

4- Minimum conditions for participation in IMI2 actions

Article 9 of H2020 Regulation (EU) No 1290/2013

1. The following minimum conditions shall apply:

(a) at least three legal entities shall participate in an action;

(b) three legal entities shall each be established in a different Member State or Associated Country; and

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[2] Article 8 of Regulation (EU) No 1290 /2013:

1.Two legal entities shall be regarded as independent of each other where neither is under the direct or indirect control of the other or under the same direct or indirect control as the other.

2. Control may, in particular, take either of the following forms:

a) the direct or indirect holding of more than 50 % of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;

b) the direct or indirect holding, in fact or in law, of decision making powers in the legal entity concerned.

3. However, the following relationships between legal entities are not in themselves deemed to constitute controlling relationships:

a) the same public investment corporation, institutional investor or venture-capital company having a direct or indirect holding of more than 50 % of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;

b) the legal entities concerned being owned or supervised by the same public body.

[3] Article 2(1)(2) of Regulation (EU) No 1290 /2013: *'Affiliated entity' means any legal entity that is under the direct or indirect control of a participant, or under the same direct or indirect control as the participant, or that is directly or indirectly controlling a participant. Control may take any of the forms set out in Article 8(2),* see above.

(c) the three legal entities referred to in point (b) shall be independent of each other within the meaning of Article 8 of Regulation (EU) No 1290/2013.
2. Where appropriate and duly justified, the Annual Work Plan may provide for additional conditions according to specific policy requirements or to the nature and objectives of the action, including inter alia conditions regarding the number of participants, the type of participant and the place of establishment.

5- IMI2 funding rates

Articles 28 and 29 of H2020 Regulation (EU) No 1290/2013

1. A single reimbursement rate of maximum 100 % of the eligible costs shall be applied per action for all activities funded in Research and Innovation actions[4] . The maximum rate shall be fixed in the IMI2 Annual Work Plan. The IMI2 Annual Work Plan will specify when use of unit costs applies.
2. Grants shall not exceed the eligible costs.
3. Indirect eligible costs shall be determined by applying a flat rate of 25 % of the total direct eligible costs, excluding direct eligible costs for subcontracting and the costs of resources made available by third parties, which are not used on the premises of the beneficiary, as well as financial support to third parties. By way of derogation, indirect costs may be declared in the form of a lump sum or unit costs when provided for in the IMI2 Annual Work Plan.

6- Eligible/Non-eligible costs in IMI2 actions for beneficiaries receing EU funding

Article 126 of Financial Regulation (EU, Euratom) No 966/2012 Article 6 of the IMI2 model Grant Agreement

1. Eligible costs are costs actually incurred by the beneficiary of a grant which meet all of the following criteria: [5]
(a) they are incurred during the duration of the action, with the exception of costs relating to final reports and audit certificates;
(b) they are indicated in the estimated overall budget of the action;
(c) they are necessary for the implementation of the action which is the subject of the grant;
(d) they are identifiable and verifiable, in particular being recorded in the accounting records of the beneficiary and determined according to the applicable accounting standards of the country where the beneficiary is established and according to the usual cost accounting practices of the beneficiary;
(e) they comply with the requirements of applicable tax and social legislation;
(f) they are reasonable, justified, and comply with the principle of sound financial management, in particular regarding economy and efficiency.
Costs incurred by third parties under the action may be eligible when in compliance with the relevant legal provisions.

[4] For Innovation actions, the grant shall be limited to 70% of the total eligible costs for beneficiaries other than non-profit legal entities (paragraph 5 of Article 28 of H2020 Regulation (EU) No 1290/2013)
[5] Specific categories of costs declared as unit costs are eligible in accordance with the Commission decision, such as the *'COMMISSION DECISION of 7.3.2014 authorising the use of reimbursement on the basis of unit costs for actions requiring the conduct of clinical studies under 'Societal Challenge 1: Health, Demographic Change and Wellbeing' of the Horizon 2020 Framework Programme'*, and foreseen in the grant agreement.

2. Ineligible costs are those not complying with the conditions of paragraph 1, including, in particular, provisions for possible future losses or charges, exchange losses, costs related to return on capital, costs reimbursed in respect of another Union action or programme, debt and debt service charges and excessive or reckless expenditure.

7- What is the industry contribution in IMI2 actions

Article 4 of the Council Regulation establishing the Innovative Medicines Initiative 2 Joint Undertaking (EU) No 557/2014 and Article 13 of the annexed Statutes

1. In kind contributions are the 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 less the contribution of the IMI2 Joint Undertaking and any other Union financial contribution to those costs.
2. In kind contributions consisting of costs incurred in third countries other than countries associated to Horizon 2020 shall be justified and relevant to the objectives of the IMI2 JU. It shall not exceed 30% at the level of the IMI2 programme of the eligible costs incurred by the Members other than the Union and the Associated Partners.
3. Financial contributions 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 (1).

8- Time to Grant

Article 20 of H2020 Regulation (EU) No 1290/2013

The call for proposals shall specify the planned date by which all applicants shall be informed of the outcome of the evaluation of their application and the indicative date for the signature of grant agreements or the notification of grant decisions. This shall be based on the following periods:
(a) for informing all applicants of the outcome of the scientific evaluation of their application, a maximum period of five months from the final date for submission of complete proposals;
(b) for signing grant agreements with applicants or notifying grant decisions to them, a maximum period of three months from the date of informing applicants they have been successful.

9- Ethics

Article 19 of the Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 - the Framework Programme for Research and Innovation (2014-2020)

1. All the IMI2 research and innovation activities shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.
2. Any proposal considered for funding will go through an ethics review process.

10- Intellectual Property provisions

Articles 1.3 (c) and 41 to 49 of H2020 Regulation (EU) No 1290/2013 Articles 2 to 7 of the Commission Delegated Regulation N°622/2014 of 14 February 2014

1. Specific operating needs have been identified regarding intellectual property rules in the context of the Innovative Medicines Initiative 2 objectives, in order to achieve an open innovation model, a dynamic system of knowledge sharing providing wider possibilities to create and exploit the knowledge resulted from the IMI projects and wide access of participants, affiliates and third parties to this knowledge, with the ultimate goal of speeding up the development of diagnostics and medical intervention for patients' benefit, including by stimulating clinical, translational research and clinical trials, in particular in the areas of public health interest and high unmet medical need, as identified in the World Health Organisation priority medicines report issued on 9 July 2013.
2. The IMI2 IP provisions provide specific rules on the following:
- ownership and access to data, knowledge and information which are outside of the objectives of an action and which are not needed for implementing and exploiting the action (referred to as sideground) ;
- ownership and access rights to the background of a beneficiary, and associated restrictions;
- transfer of ownership, and licensing, of background and results by a beneficiary to another beneficiary or a third party, including extension of such to affiliated entities, purchasers and any successor entity without the consent of the other beneficiary(ies);
- exploitation by another beneficiary, its affiliated entities and third parties as licensee, of background and results for all purposes other than implementing the action and direct exploitation (developing results for commercialisation or commercialising results themselves), referred to as research use;
- access rights to background and results for direct exploitation of a beneficiary's results, whether by a beneficiary or a third party;
- dissemination and protection of results, while taking into account the legitimate interests of the beneficiaries.
3. The entities participating to IMI2 actions shall have understood the intellectual property provisions and abide by them.

11- Open Access

Articles 43 of H2020 Regulation (EU) No 1290/2013

Open access must be granted to all scientific publications resulting from IMI2 actions and proposals must refer to measures envisaged.
Where relevant, proposals should also provide information on how the participants will manage the research data generated and/or collected during the project, such as details on what types of data the project will generate, whether and how this data will be exploited or made accessible for verification and re-use, and how it will be curated and preserved.