



IMI JU RULES FOR PARTICIPATION

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1. Definitions

'EFPIA' means the European Federation of Pharmaceutical Industries and Associations.

'IMI JU' means the Innovative Medicines Initiative Joint Undertaking set up under the Council Regulation no 73/2008 of 20 December 2007.

'Legal entity' means any natural person, or any legal person created under the national law of its place of establishment, or under Community or Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations. In the case of natural persons, references to establishment are deemed to refer to habitual residence.

'Project participant' means a legal entity that participates in the project as defined in the grant agreement. Contributions from third parties such as subcontractors do not constitute participation.

'Qualified patient organisation' means an organisation representing the interests of certain patient groups and which complies with the guiding principles with regards to transparency established by the European Union Health Policy Forum: (http://ec.europa.eu/health/ph_overview/health_forum/policy_forum_en.htm).

'SMEs' mean micro, small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC in the version of 6 May 2003.

2. Participation in an IMI JU collaborative project

2.1 General provisions

Any company, university, research organization, or other entity, carrying out activities relevant to the objectives of the IMI JU in European Member States or countries associated with the Seventh Framework Programme can participate in an IMI JU collaborative project.

Any other entities who do not meet the conditions laid down above may participate if so agreed by the IMI JU.

Active participation of European patient organisations is welcome.

2.2 Eligible consortia

IMI JU research support is sought by building a consortium in order to submit a project proposal in response to a call.

A two-stage submission and evaluation process is followed. At stage 1, expressions of interest are submitted to the IMI JU by applicant consortia consisting of research organisations, universities, SMEs, patient organisations and any legal entity which is not a research-based pharmaceutical company that is a member of EFPIA. At stage 2, the applicant consortia of the

best expressions of interest are invited to form joint consortia with pre-established EFPIA consortia already associated with the topics and to submit full project proposals.

To be eligible for participation and unless otherwise specified in the call, these consortia, whatever their size, must fulfil the following **minimum conditions**:

- at stage 1:

- (a) at least two legal entities who are eligible to receive IMI JU funding (see section 3 below) must participate.
- (b) these two legal entities must be independent of each other and of the research based pharmaceutical companies that are members of EFPIA, within the meaning of section 2.3 below, and must carry out activities relevant to the objectives of the IMI JU in a Member State or in a country associated to the Seventh Framework Programme.

- at stage 2:

- (a) at least two legal entities who are research based pharmaceutical companies that are members of EFPIA must participate together with two legal entities, whose proposal has been selected at stage 1, who are not research based pharmaceutical companies that are members of EFPIA and who are eligible to receive IMI JU funding (see section 3 below).
- (b) the minimum number of participants is therefore four legal entities, all of whom must be independent of each other within the meaning of section 2.3 below, and must carry out activities relevant to the objectives of the IMI JU in a Member State or in a country associated to the Seventh Framework Programme.

2.3 Independence

Legal entities are regarded as independent of each other when neither is under the direct or indirect control of the other, or under the same direct or indirect control as the other.

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.

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. Eligibility to receive IMI JU funding

The following legal entities **only** are eligible for funding by IMI JU provided they carry out activities relevant to the objectives of the IMI JU in a Member State or country associated to the Seventh Framework Programme:

- (a) SMEs within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises;
- (b) legal entities established as non-profit public bodies under national law;
- (c) intergovernmental organisations, which have legal personality under international public law, as well as any specialised agencies set up by such intergovernmental organisations;
- (d) legal entities established under Community law;
- (e) legal entities established as non-profit organisations which carry out research or technological development as one of their main objectives; For the purpose of the IMI JU Regulation, "non profit public bodies" include those that may make profit but are not permitted to distribute such profits otherwise than in the furtherance of public interest purposes and which carry out scientific and technological research among their main activities;
- (f) secondary and higher education establishments;
- (g) non-profit qualified patients' organisations.

Any other legal entities, who do not meet the conditions laid down above, will bear their own costs for participating in an IMI JU project.

4. Funding Principles

4.1 Funding scheme

IMI JU collaborative projects are implemented through a co-financing scheme. The IMI JU grants financial support to the eligible entities (see conditions above), while the other entities (including the research based pharmaceutical companies that are members of EFPIA) participate in the project with their own resources.

4.2 Eligible project costs

4.2.1 Participants eligible for funding

Eligible project costs will be calculated under the conditions laid out in the Grant Agreement, and taking into account the provisions of the IMI Financial Rules (Article 100)¹. They will be based on the following principles:

¹ See <http://www.imi.europa.eu/content/documents>

a) Eligible project costs are determined according to the usual accounting and management principles of the participants in a manner consistent with the principles of economy, efficiency and effectiveness. Costs must be actual, incurred by the participant who is claiming it, during the project (with the exception of the final reports within the time limit set forth in accordance to the grant agreement), in European Member States or countries associated to the Seventh Framework Programme, and for the sole purpose of achieving the objectives of the project. They must be recorded in the accounts of the participant who is claiming them.

b) Non-eligible costs include identifiable indirect taxes including value added tax, duties, interest owed, provisions for possible future losses or charges, exchange losses, costs related to return on capital, costs declared, incurred, or reimbursed in respect of another project funded by the European Communities, debt and debt service charges, excessive or reckless expenditure, and any other costs that do not meet the conditions of eligibility laid down above.

c) The total eligible costs comprise the direct eligible costs incurred by the project participants in accordance with the above principles, with a flat rate of 20% of the direct eligible cost (excluding subcontracting costs and the costs of resources made available by third parties) to cover the indirect costs².

4.2.2 Participants not eligible for IMI JU funding

Costs incurred by research based pharmaceutical companies that are members of EFPIA are considered as "in kind contributions" to the project. "In-kind contributions" will be calculated under the conditions laid out in the Grant Agreement³ based on the same principles detailed in 4.2.1 above. Note that costs incurred by research based pharmaceutical companies that are members of EFPIA for the project outside European Member States or countries associated to the Seventh Framework Programme can be acknowledged as "in kind contributions", but will not be counted towards the matching IMI JU financial contribution.

Financial contributions from a research based pharmaceutical company that is a member of EFPIA to a participant eligible for IMI JU funding in order to cover part of the eligible project costs of the latter can also be included in the in kind contributions of this company. Such financial contributions must also be declared by the participant eligible for IMI JU funding who received them as receipts to the project, and must cover costs of work performed, without added profit.

4.3 Eligible costs activities

The following cost activities apply to all project participants (research based pharmaceutical companies that are members of EFPIA, research organisations, universities, SMEs, patient organisations, or any other type of legal entity):

² Funding rules related to indirect costs are currently under discussion. Therefore, the applicable rules might be subject to a modification following a decision of the IMI Governing Board in this regard.

³ "In-kind contribution" are currently under discussion. Therefore, the applicable rules will be subject to a modification following a decision of the IMI Governing Board in this regard.

<i>Direct eligible costs</i>			<i>Indirect eligible costs⁴</i>
Activities	Indicative type of eligible costs		
Research activities	Personnel	Costs for personnel allocated to the project	Flat rate of 20% of Direct eligible costs, excluding subcontracting or reimbursement of third party costs
	Equipment	Purchase & depreciation (or leasing), in proportion of its use for the project	
	Consumables & Materials	Purchase	
	Subcontracting for services	See 4.3 for general conditions	
Other activities	Management activities	Costs for personnel allocated for activities related to management of the project; certificates on the financial statements; meetings, travel and subsistence for management purposes	
	Training activities	Fees, travel and subsistence for participants in training activities; facilities & equipments; salary costs of those providing the training (salary costs of those being trained are not eligible)	
	Other	Dissemination (<i>e.g. establishment of website, presentation to conferences</i>); networking; intellectual property (<i>e.g. filing and prosecution of patent applications, patent searches and legal advice</i>), studies	

4.4 Subcontracting

The following principles apply to subcontracting:

- Only services, such as data processing for example, may be sub-contracted by project participants. Such services may only be subcontracted if it is a more efficient means for that participant to deliver the required service.
- Subcontracting must ensure best value for money (best price/quality ratio), under conditions of transparency and equal treatment.
- Any subcontracted work must be conducted in European Member States or countries associated to the Seventh Framework Programme. Exceptions may only be accepted on a case-by-case basis, based on scientific or technical justification.
- The project participant remains legally responsible of the performance of the subcontracted work, and of all related management and financial aspects.
- Costs for subcontracting are reported by the project participant in accordance with the reporting principles.

⁴ See footnote 2

- The identity of subcontractor(s) is communicated to all participants.
- The relevance of the proposed subcontracting is evaluated as part of the whole evaluation/selection process of applications.
- However, if a need for subcontracting is identified during the course of a project, the tasks may be reassigned among the participants, or subcontracted following agreement among the participants on condition that this does not increase the project costs.
- Subcontractors are **not** parties to the Grant Agreement signed between the IMI JU and project participants, and as such do not receive any right with regard to the intellectual property of the IMI JU Project, as granted to project participants.

4.5 Forms of grants and calculation of the IMI JU contribution for entities eligible for IMI JU funding

IMI JU's standard form of grant for its financial contribution is the **reimbursement of a percentage of the eligible costs**, direct and indirect, incurred by participants eligible for funding. For indirect costs (overheads), a flat rate of 20 % of total eligible direct costs (excluding subcontracting costs and the costs of resources made available by third parties) applies⁵.

For participating entities eligible for IMI JU funding, the **maximum** IMI JU financial contribution covers:

- 75% of eligible costs for research activities.
- 100% of eligible costs for other activities including management and training activities.

The IMI JU contribution is based on the reported costs of each Project Participant.

The IMI JU financial contribution must not give rise to a profit. Receipts are taken into consideration for the payment of the grant.

⁵ See footnote 2

5. Ethical requirements

The IMI JU will not support Projects which are contrary to fundamental ethical principles and those recalled in article 6 of the 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).