



Innovative Medicines Initiative

IMI-GB-DEC-2012-12

RULES FOR PARTICIPATION IN THE IMI JU COLLABORATIVE PROJECTS

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1. Definitions

‘Beneficiary’ means a *participant* eligible to receive *IMI JU* financial contribution in accordance with the *IMI JU* Statutes annexed to Council Regulation (EC) No 73/2008 on the establishment of the *IMI JU* of 20 December 2007.

‘EFPIA’ means the European Federation of Pharmaceutical Industries and Associations.

‘EFPIA company’ means a legal entity which is a research-based pharmaceutical company that is a member of EFPIA.

‘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.

‘Participant’ means a legal entity forming part of the consortium, contributing to the project and having rights and obligations with regard to the *IMI JU* under the terms of the grant agreement.

‘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 and regulatory agencies 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 an EFPIA company. At stage 2, the applicant consortia of the first ranked 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 any EFPIA company, 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 EFPIA companies must participate together with two beneficiaries (see section 3 below), whose proposal has been selected at stage 1.
- (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 Programme¹.

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:

¹ The minimum number of participants, as specified in this document, is also applied for the purpose of distribution of the pre-financing by the Managing Entity to beneficiaries (Article 6 of the model IMI JU Grant Agreement)

- (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 and Union 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 collaborative 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 EFPIA companies) participate in the project with their own resources.

4.2 Eligible project costs

4.2.1 Eligible project costs incurred by the beneficiaries

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)². They will be based on the following principles:

² See <http://www.imi.europa.eu/content/documents>

a) Eligible project costs are determined according to the usual accounting and management principles and practices of the beneficiary in a manner consistent with the principles of economy, efficiency and effectiveness. Costs must be actual, incurred by the beneficiary who is claiming them, during the project (with the exception of the final reports within the time limit set forth in accordance with 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 Union, 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 beneficiary in accordance with the above principles and the indirect eligible costs. The beneficiaries may opt for one of the following indirect costs methods:

1. *actual indirect costs*

2. *simplified method*

Simplified method is a modality of the actual indirect costs for organisations which do not aggregate their indirect costs at a detailed level, but can aggregate them at the level of the legal entity.

3. *a flat rate of 20%* of the direct eligible costs (excluding subcontracting costs and costs of other third parties which are incurred outside the premises of the beneficiary).

The beneficiary shall apply the same indirect costs method in all IMI JU grant agreements in which the beneficiary will participate.

4.2.2 Eligible project costs incurred by the participants not eligible for IMI JU funding

Costs incurred by EFPIA companies are considered as "in kind contribution" to the project. "In kind contribution" will be calculated under the conditions laid out in Article II.13.4 of the IMI JU grant agreement (notably based on usual accounting and management principles and practices). Costs incurred by EFPIA companies outside European Member States or countries associated to the Seventh Framework Programme shall not be considered as "in kind contribution", except when otherwise agreed by IMI JU Governing Board based on one of the following approaches. :

- General approach: A maximum limit of 10% per project applies within a global cap at programme level of 5% of the total committed EFPIA in kind contribution.
- For special projects derived from topics of interest for EU citizens that will benefit European academics and SMEs, where there are few EFPIA research capacities in Europe while academic research is strong or substantially developed in Europe and, in particular research into rare diseases or disease areas of high public interest where creation of a critical mass of research is needed. There is no maximum limit of 10% per project but a global cap at the IMI programme level of 30% of the total committed EFPIA in kind contribution shall apply.

The Call documents shall clearly identify the cases where in-kind contribution in special projects applies.

Financial contributions from an EFPIA company to a beneficiary, or a participant which is neither a beneficiary nor an EFPIA company, in order to cover part of the eligible project costs of the latter may also be included in the "in kind contribution" of this company.

Any financial contributions must cover costs of work performed without added profit, and be declared by the concerned beneficiary as receipts to the project. Also a participant which is neither a beneficiary nor an EFPIA company must declare financial contributions.

4.3 Eligible cost activities

The following cost activities apply to all project participants (EFPIA companies, beneficiaries, or any other type of legal entity):

1) Direct eligible costs

Activities	Indicative type of direct eligible costs	
Research activities	Personnel	Costs of personnel allocated to the project
	Equipment	Purchase & depreciation (or leasing), in proportion of its use for the project
	Consumables & Materials	Purchase
	Subcontracting for services	See 4.4 for general conditions
Other activities	Management activities	Costs of personnel allocated for activities related to management of the project; meetings, travel and subsistence for management purposes; subcontracting for management purposes, such as certificates on the financial statements.
	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 at conferences</i>); networking; intellectual property (<i>e.g. filing and prosecution of patent applications, patent searches and legal advice</i>), studies.

2) Indirect eligible costs

See sections 4.2.1.c) and 4.2.2 above.

4.4 Subcontracting

The following principles apply to subcontracting:

- Only services, such as data processing for example, may be subcontracted by 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 participant remains legally responsible for the performance of the subcontracted work, and for all related management and financial aspects.
- Costs of subcontracting are reported by the participant in accordance with the reporting principles.
- 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 total costs.
- Subcontractors are **not** parties to the Grant Agreement signed between the IMI JU and participants, and as such do not receive any rights with regard to the intellectual property of the IMI JU project, as granted to participants.
- Public entities must follow the procurement principles established by their national authorities. For subcontracts exceeding certain amounts, the directive on public procurement of services applies and the publication of a call for tenders is mandatory. However, they must in any case comply with the terms of the Grant Agreement.

4.5 Forms of grants and calculation of the IMI JU contribution for beneficiaries

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 the beneficiary. 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) applies for those beneficiaries who do not declare their actual indirect costs, see section 4.2.1.

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 accepted costs for each participant eligible for IMI JU funding.

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

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).