



Innovative Medicines Initiative

Rules for submission, evaluation and selection of proposals to explore new scientific opportunities in on-going IMI JU collaborative projects

Context and scope

This document establishes the "Innovative Medicines Initiative Joint Undertaking" (IMI JU) rules for the submission of proposals to explore new scientific opportunities in on-going IMI JU collaborative projects, and the related evaluation, selection and award procedures (hereafter "the Rules"). It describes the procedures that IMI Consortia and the IMI JU will follow in accordance with IMI JU special Financial Rules.



TABLE OF CONTENTS

1. Executive Summary	3
General principles	4
2. Submission of proposals	5
2.1. Calls for proposals	5
2.2 Reception of proposals by the IMI JU	6
2.3 Eligibility check of proposals	6
3. Evaluation process	7
3.1 Appointment of the independent experts	7
3.2 Terms of appointment, Code of conduct and Conflict of interest	7
3.3 Evaluation criteria	8
3.4 Scoring, thresholds and weighting	8
3.5 Detailed description of evaluation	9
(a) Briefing by the IMI JU	9
(b) Individual evaluation	9
Justification of scoring	9
Outcome of the individual evaluation	9
(c) Consensus panel	9
Outcome of consensus	10
4 Feedback to applicants	11
4.1. Feedback on the evaluation process	11
4.2 Appeal procedure	11
5. Negotiation and Award	11
5.1 Negotiation	11
5.2 Project agreement	12
5.3 Amendment to the grant agreement	12

1. Executive Summary

During the implementation of the IMI JU collaborative projects for which a grant agreement has been already signed with the IMI JU, Consortia may apply to:

- carry out new activities demonstrating significant added value to on-going IMI projects considering promising results deserving additional activities, or major changes occurred in the field after the start of their project, or new needs generated by the activities of their project;
- create synergies or complementarities with other IMI projects, which provide significant added value beyond the initial project objectives;
- build on IMI projects' results (Foreground) that offer a potential interest for further investigations going beyond the initial project objectives;
- explore ways to ensure the sustainability of IMI projects' achievements;
- involving new partner(s) conducting excellent research in the same area than IMI projects and capable of major contributions to such IMI projects.

The proposals - which may also imply the involvement of **new** beneficiary(ies) - must relate to the objectives of the IMI JU and should demonstrate an added value to the IMI collaborative project concerned, while they could not be accommodated with the current available budget of the project. The proposal implying an increase the IMI JU financial contribution to the beneficiaries shall be concomitant with an at least equal increase in EFPIA in kind contribution.

The Call for proposals to explore new scientific opportunities in on-going IMI JU collaborative projects is a continuous submission process, with several cut-off-dates, from the date of publication of the Call until the final submission deadline. Proposals received by a given cut-off date will be evaluated together and proposals are selected based on the available budget.

All the necessary information for those wishing to apply are provided in the Call Documents relevant for that specific Call, which are:

- Call Fiche, including the indicative budgets, and deadlines for submission;
- Evaluation Form: Specific pre-defined evaluation criteria and further details on the application of the evaluation criteria;
- Rules for submission, evaluation and selection of proposals to explore new scientific opportunities in on-going IMI JU collaborative projects: explanation of the whole process and how the applicants can seek assistance or information on any matter related to the Call;
- Rules for Participation in the IMI JU collaborative projects.

The above mentioned Call Documents are available at <http://www.imi.europa.eu/content/call-proposals>.

General principles

The Call rests on a number of well-established principles:

- (i) **Excellence:** Proposals must demonstrate high quality.
- (ii) **Transparency:** Funding decisions are based on the described rules and procedures, and applicants receive adequate feedback on the outcome of the evaluation of their proposal.
- (iii) **Fairness and impartiality:** All proposals submitted to the Call are treated equally. They are evaluated competitively and impartially on their merits, irrespective of their origin or the identity of the applicants.
- (iv) **Confidentiality:** All proposals and related data, knowledge and documents communicated to the IMI JU are treated in confidence.
- (v) **Efficiency and speed:** Evaluation, communication, award and amendment to the grant agreement are as rapid as possible, commensurate with maintaining the quality of the evaluation, and respecting the legal framework.
- (vi) **Ethical considerations:** Any proposals which contravene fundamental ethical principles are excluded at any time from the process of evaluation, selection and award (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)).
- (vii) **Data protection:** In accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council (OJ L8 of 12.01.2001, p1)¹ the data will only be used for the specific purposes for which it was collected and will not be disclosed to other parties without the consent of the individual whom it is about. Personal information will not be sent outside the European Economic Area unless the individual whom it is about has consented or adequate protection is in place. Applicants may, on written request, gain access to their personal data and correct any information that is inaccurate or incomplete. They should address any questions regarding the processing of their personal data to the IMI JU. Applicants may lodge a complaint against the processing of their personal data with the European Data Protection Supervisor at any time.

Proposals are archived under secure conditions at all times. After completion of the evaluation and negotiation, all copies are destroyed other than those required for archiving and/or auditing purposes.

¹ Regulation (EC) No 45/2001 of the European Parliament and of the Council (OJ L8 of 12.01.2001, p1) on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data

The IMI JU appoints a “Call supervisor” among its scientific staff. This identified person acts as a contact point for practical questions associated with the Call, and ensures the overall planning and organisation of the proposals reception and evaluation process.

2. Submission of proposals

2.1. Calls for proposals

The Coordinator of an on-going IMI collaborative project, acting on behalf and the consent of the entire Consortium, is responsible for submitting a complete proposal (see below) via electronic mail as a pdf-file to the IMI JU (infodesk@imi.europa.eu).

Proposals may be submitted continuously from the date of publication of the Call until 15 December 2013 at 5 P.M. CET time (“final Call deadline”), and will be evaluated and selected based on two specific cut-off-dates per year as set out in the Call Fiche.

Proposals consist of administrative and scientific parts. Outline of the application as well as explanatory notes on how to fill it can be found in the submission forms available on the IMI website.

All parts/sections of the application forms will have to be completed and submitted.

Proposal language: Proposals may be prepared in any official language of the European Union. If the proposal is not in English, an English translation would be a valuable assistance to the experts nominated to review the said request.

Format: To allow a fair evaluation, the space allowed in each section of the Submission Form is limited and must be completed using Times New Roman - 12 point.

Submission of a proposal is considered as a declaration of acceptance by the Consortium of these Rules, other Call Documents, the provisions of the grant agreement² and the Project Agreement, and the IMI Intellectual Property Policy³.

The Coordinator may withdraw the proposal at any moment until the relevant cut-off-date. A withdrawn proposal will not subsequently be considered by the IMI JU.

There is no limit on the number of separate proposals that each consortium may submit, as far as the above conditions are fulfilled. However, only one proposal per IMI collaborative project can be under evaluation at any one time (i.e. per cut-off date).

² The IMI model Grant Agreement is available at

http://www.imi.europa.eu/content/documents#calls_for_proposals

³ The IMI Intellectual Property Policy is available at http://www.imi.europa.eu/content/documents#ip_policy

2.2 Reception of proposals by the IMI JU

The date and time of receipt of the submitted proposal(s) are recorded, and an acknowledgement of receipt is sent to the Coordinator by e-mail.

The acknowledgement of receipt does not replace the formal eligibility checks carried out by the IMI JU, as described in paragraph 2.4.

There is normally no further contact between the IMI JU and applicants until after completion of the evaluation. The IMI JU may, however, contact the Consortium (through the Coordinator) in order to clarify matters such as for the eligibility, and/or in case the independent experts request a hearing with the Consortium (see section 3.4).

2.3 Eligibility check of proposals

To be retained for evaluation, proposals must fulfil all of the following eligibility criteria:

- Call deadline: Proposals must be received before the final Call deadline;
- Completeness: Proposals shall be complete, i.e. contains all parts/sections and forms mentioned in Section 2.1. Please note that the completeness criterion also implies that all parts of the request shall be readable, accessible and printable;
- Scope: The proposals must address one of the Call objectives as outlined in the Call Fiche;
- Proposals are submitted for an on-going IMI project for which a grant agreement has been already concluded with the IMI JU, having started from at least one (1) year from the proposal submission and ending at least 6 months after the relevant cut-off-date;
- Proposals should be accompanied by a formal endorsement from the EFPIA Research Directors Group confirming that the additional funding for IMI JU beneficiaries would at a minimum be matched by additional EFPIA in kind contribution for that same IMI project.

These criteria are rigorously applied.

If one or more of the eligibility criteria have not been fulfilled, the proposal is declared ineligible by the IMI JU, and is not considered for evaluation. The IMI JU will notify the Coordinator accordingly.

Where there is a doubt on the eligibility of a proposal, the IMI JU may convene an internal eligibility review committee. The committee's role is to ensure a coherent legal interpretation of such cases and equal treatment of applicants. The IMI JU reserves the right to proceed with the evaluation, pending a final decision on eligibility.

The fact that a proposal is evaluated does not constitute evidence of its eligibility.

3. Evaluation process

Eligible proposals submitted at each cut-off-date shall undergo peer-review evaluation based on the published evaluation criteria.

A one-stage submission and evaluation process is followed.

With a view to upholding the principle of equal treatment, proposals should not substantially deviate from the original overall key objectives of the respective IMI JU collaborative project. Any substantial deviation must be clearly justified and demonstrate the added value to the IMI collaborative project concerned. In any case, the proposal should relate to the objectives of the IMI JU.

3.1 Appointment of the independent experts

The IMI JU evaluates proposals with the assistance of duly appointed independent experts to ensure that only those of the highest quality are selected for funding.

Independent experts may be drawn from the panel which took part in the original evaluation.

Experts in ethics may be invited for evaluation of the proposals as required e.g. where projects involve the use of animal or human subjects.

Independent experts involved in the evaluation are required to have skills and knowledge appropriate to the areas of activity in which they are asked to assist. They must also have a high level of professional experience in the public and/or private sector and be internationally recognised in their field of expertise. They are selected based on their individual merits and not as official representatives of sectors, organisations or societies. They may be citizens of countries other than the EU Member States or countries associated to the 7th Framework Programme.

The names of the independent experts assigned to individual proposals are not made public. However, once a year the names of independent experts, who have taken part in any of the IMI evaluation processes are published on the IMI JU web site.

3.2 Terms of appointment, Code of conduct and Conflict of interest

The IMI JU shall conclude an appointment letter with each independent expert.

The appointment letter binds each independent expert to a code of conduct, establishes the essential provisions regarding confidentiality, and specifies, in particular, the description of work, the conditions of payment, and reimbursement of expenses.

When appointing the independent experts, the IMI JU takes all necessary steps to avoid conflicts of interest. To this end, independent experts are required to sign a declaration that no such conflict of interest exists at the time of their appointment and that they undertake to inform the IMI JU if one should arise in the course of their duties. When so informed, the IMI JU takes all necessary actions before and during the evaluation.

Experts may be invited to carry out the evaluation fully or partially remotely (“**remote evaluation**”) and/or on IMI JU premises.

3.3 Evaluation criteria

All eligible proposals submitted within one cut-off date will compete against each other and are evaluated with respect to the pre-defined evaluation criteria relevant to the Call as set out in the Evaluation Form (see Call Documents).

The evaluation procedure includes a check of ethical issues raised by the proposals. The objective of this ethical review is to make sure that the IMI JU does not support research which would be 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).

The detailed evaluation criteria, and when applicable associated weights and thresholds, are set out in the Evaluation Form.

3.4 Scoring, thresholds and weighting

Scoring

Independent experts score each evaluation criterion on a scale from 0 to 5. Half point scores may be given. For each criterion under examination, score values indicate the following assessments:

0 - Fails to address the criterion under examination or cannot be judged due to missing or incomplete information.

1 - Very poor. The criterion is addressed in a cursory and unsatisfactory manner.

2 - Poor. There are serious inherent weaknesses in relation to the criterion in question.

3 - Fair. Broadly addresses the criterion, with significant weaknesses that need correcting.

4 - Good. Addresses the criterion well, although certain improvements are possible.

5 - Excellent. Successfully addresses all relevant aspects of the criterion in question. Any shortcomings are minor.

Thresholds

Thresholds are set for some or all of the criteria, such that any proposal failing to achieve the threshold scores will be rejected. In addition, an overall threshold may also be set. The thresholds to be applied to each criterion as well as any overall threshold are set out in the Evaluation Form. If the proposal fails to achieve a threshold for a criterion, the evaluation will not continue from that point, and the said proposal immediately categorised as rejected.

Weighting

It may be decided to weight the criteria. The weightings to be applied to each criterion are set out in the Evaluation Form.

3.5 Detailed description of evaluation

Proposals are evaluated by a minimum of three independent experts.

(a) Briefing by the IMI JU

The IMI JU is responsible for the briefing of appointed independent experts before they conduct the evaluation. The briefing covers the objectives and characteristics of the Call, and the evaluation processes and procedures. It also covers the evaluation criteria to be applied.

(b) Individual evaluation

In this phase of the evaluation, each independent expert works individually and gives comments for each criterion as described in the Evaluation Form (see Call Documents).

The IMI JU provides to all independent experts access to the proposal(s) to be examined. The independent experts are also provided with the last approved version of the Annex 1 (Description of Work) of the grant agreement of the relevant IMI collaborative project(s).

Experts may be asked to perform only the individual evaluation. In this case, their individual evaluation reports are presented by the IMI JU (the moderator) to the experts attending the consensus panel meeting so that it is taken into account during the discussions and in the preparation of the consensus reports.

Justification of scoring

Experts are required to provide comments to accompany each of their scores. These comments must be consistent with any scores awarded and serve as input to any consensus discussion and related consensus report.

Outcome of the individual evaluation

The expert completes an individual evaluation report confirming his/her individual reading and assessment, and communicates it to the IMI JU. The expert's individual evaluation report may not subsequently be changed. In validating the individual evaluation report, each expert confirms that he/she has no conflict of interest with respect to the evaluation of that particular expression of interest or full project proposal.

(c) Consensus panel

Once all the independent experts have completed their individual evaluations and communicated them to the IMI JU, the evaluation progresses to a consensus assessment, representing their common views. This entails a unique consensus panel meeting (preferably held via an electronic forum) to reach a consensus on any comments or recommendations. The unique consensus panel must be composed of a minimum of three independent experts and, where necessary, ethical experts.

The consensus discussion is moderated by a chairperson from the IMI JU ("the moderator"). The role of the moderator is to seek a consensus between the individual views of independent experts without any prejudice for or against (a) particular proposal(s) or the organisations involved, and to ensure a fair and equitable evaluation of each proposal according to the defined evaluation criteria.

The moderator will designate one of the independent experts participating in/attending the consensus panel ("the **rapporteur**") to be responsible for drafting the Consensus Evaluation Report(s) and recommendations for proposal.

The independent experts shall agree on consensus scores and comments for each of the criteria including ethics that have been evaluated to justify their assessment and recommendations. Comments should be suitable for feedback to the respective Coordinator(s). Comments and recommendations are set out in a Consensus Evaluation Report.

In the evaluation of proposals the experts will also discuss to provide recommendations for priority order of the proposals that pass the evaluation thresholds (overall ranking).

If during the consensus discussion it is found that, despite all reasonable efforts to reach consensus, it is impossible to bring all the experts to a common point of view, the moderator may propose actions to reach resolution which may include decision by a two-thirds majority vote. In exceptional cases, the IMI JU may ask up to three additional experts to examine the proposal.

The IMI JU may organise hearings during the consensus panel meeting of the Coordinator(s) of the top-ranked proposals, if deemed necessary by the independent experts. In such instances, the Coordinator(s) will be provided beforehand with a list of questions.

Outcome of consensus

The outcome of the consensus step is the Consensus Evaluation Report, signed (possibly electronically), as a minimum, by the moderator and the "rapporteur(s)".

The moderator is responsible for ensuring that the Consensus Evaluation Report reflects the consensus reached, expressed in scores and comments. The Consensus Evaluation Report may also provide recommendations and/or conditions to be fulfilled during negotiation phase for grant award.

The IMI JU assures the quality of the Consensus Evaluation Reports, with particular attention given to clarity, consistency and appropriate level of detail.

Based on the result of the peer review evaluation and associated Consensus Evaluation Reports, a ranked list of proposals is established by the IMI JU.

The number of selected proposals in the list depends upon the available budget for the relevant cut-off-date.

As a general rule, the IMI JU follows the priority order of proposals suggested by the experts. In exceptional cases, a proposal may be placed in a different order than the one suggested by experts if duly justified.

Budget cuts are possible, but will not be made for the purpose of supporting additional proposals that would not otherwise be funded.

4 Feedback to applicants

4.1. Feedback on the evaluation process

The IMI JU may send an information letter, together with the Consensus Evaluation Report, to the Coordinator of each evaluated proposal. The aim is to give the Consortium a prompt indication of how the proposal fared in the evaluation. However, at this stage, the IMI JU cannot make a commitment with regard to possible selection and funding.

Upon decision by the IMI JU on the outcome of the evaluation, the Coordinator of each proposal will receive a formal decision letter, together with the Consensus Evaluation Report.

Those proposals found to be ineligible (whether before, or during the course of the evaluation), failing any of the thresholds for evaluation criteria or below certain rank are formally rejected by the IMI JU.

Proposals positively evaluated but falling outside the budget availability for the relevant cut-off-date will be rejected.

The IMI JU may also reject proposals on ethical grounds following the ethical review.

4.2 Appeal procedure

The Coordinator has 20 calendar days from the date of sending of the formal decision letter by the IMI JU to submit a complaint to the IMI JU. The IMI JU will check if all review procedures have been fully respected (the IMI JU does not re-evaluate the proposal and consequently will not call into question the judgement of an appropriately qualified group of experts) and will answer within 20 calendar days from the date of reception of the letter of complaint. In the exceptional case where IMI JU is not in position to provide a final answer within this timeframe, the Applicant Consortium will be at least informed by when such an answer will be provided. During this time the Call process will continue.

5. Negotiation and Award

5.1 Negotiation

Each Consortium of a successful proposal is invited by the IMI JU to finalize the scientific-technical and administrative-financial-legal details of the project needed for preparing an amendment to the existing grant agreement (“negotiation phase”).

The Consortium should consider in parallel if the existing Project Agreement (See Section 5.2 below) need to be amended.

The IMI JU may be assisted by independent experts if needed, during the negotiation, possibly by the rapporteurs involved during the evaluation stage.

The IMI JU therefore ensures that recommendations, including ethical issues, raised in the Consensus Evaluation Report are taken into account. In addition, the Consortium and new beneficiaries may receive requests for further administrative, legal, technical and financial information necessary for the amendment of the grant agreement. The IMI JU will justify all requested changes.

Grants may not be awarded to legal entities eligible for IMI funding who are, at the time of a new grant award procedure, in one of the situations referred to in articles 81 (1), 82 and 83 of the IMI JU Financial Rules (relating, for example, to bankruptcy, convictions, grave professional misconduct, social security obligations, other illegal activities, previous break of contract, conflicts of interest, misrepresentation).

Any legal entity who has committed an irregularity in the implementation of any other action under a Community or Union Programme may be excluded from the procedure at any time, with due regard being given to the principle of proportionality.

Negotiations are completed once the details for preparing the amendment to the grant agreement have been finalised with all the participants and all the necessary checks carried out.

If it proves impossible to reach agreement within a reasonable deadline that the IMI JU may impose on any matter covered during the negotiation phase, negotiations may be terminated and the additional funding rejected by IMI JU decision.

The IMI JU may terminate negotiations if the Consortium proposes to modify the IMI collaborative project in terms of its objectives, or other aspects to the extent that it becomes significantly different from the relevant IMI JU collaborative project and/or the proposal.

5.2 Project agreement

The project agreement⁴ may need to be updated in order to reflect all modifications in the description of work, consortium composition or IP rights which result from the negotiation of the proposal.

When additional participant(s) is (are) joining the IMI JU collaborative project it(they) is(are) requested to adhere to the project agreement, in accordance with the procedures and provisions foreseen by the Consortium.

5.3 Amendment to the grant agreement

If negotiations are successful, a grant corresponding to the additional funding is awarded by the IMI JU by means of a formal amendment to the existing grant agreement (including Annex I - Description of Work).

⁴ The project agreement is the legal document that governs the relationship between the project participants, including detailed intellectual property rights based on the IMI JU intellectual property rights policy included in the grant agreement.