Rules for submission, evaluation and selection of Expressions of Interest and Full Project Proposals

Context and scope

This document establishes the "Innovative Medicines Initiative Joint Undertaking" (IMI JU) rules for the expressions of interest and full project proposals submission, and the related evaluation, selection and award procedures (hereafter “the Rules”). It describes the procedures that the IMI JU will follow in accordance with IMI JU own Financial Rules (hereafter “Financial Rules”). These Rules will apply as of the 3rd IMI JU Call onwards.

These Rules do not apply to public procurement procedures.
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1. Introduction

The "Innovative Medicines Initiative Joint Undertaking" (IMI JU) opens Calls for proposals (“Calls”) based on topics stemming from the Scientific Priorities in the Annual Implementation Plan (see http://imi.europa.eu). Each topic is associated with a pre-determined group of pharmaceutical companies that are members of EFPIA (herein after the 'EFPIA Consortium'). EFPIA is the European Federation of Pharmaceutical Industries and Associations.

Applications for financial support under the IMI JU are made in the form of proposals submitted to the IMI JU in response to the Calls. Proposals set out details of planned work, indicative budget and planned composition of the consortium.

A two-stage submission and evaluation process is followed.

At stage 1 proposals submitted to IMI JU will be in the form of expressions of interest from consortia including research organisations, universities, SMEs, patient organisations and any legal entity which is not a pharmaceutical company that is a member of EFPIA, referred to as ‘Applicant Consortia’. At stage 2, full project proposals are submitted by the Applicant Consortia selected from stage 1, jointly with the corresponding EFPIA Consortia, to form public-private collaborations.

Both Stage 1 and Stage 2 include peer review evaluation.

The IMI JU evaluates expressions of interest and full project proposals in order to identify those whose quality is sufficiently high for possible funding. The expressions of interest and full project proposals are evaluated by independent experts (hereafter referred to as "experts").

The IMI JU enters into a negotiation with the coordinators of full project proposals that successfully pass the final evaluation stage.

If negotiations are successfully concluded, the project is selected for support and a grant agreement is established between the IMI JU and the participants. Prior to signature of a grant agreement, a project agreement must be signed among the participants of the Full Consortium.
These Rules rest on a number of well-established principles:

(i) **Excellence.** Projects selected for funding must demonstrate high quality in the context of the topics and criteria set out in the Calls.

(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 proposals.

(iii) **Fairness and impartiality.** All proposals submitted to a Call are treated equally. They are evaluated 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 grant preparation 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))

Specific pre-defined evaluation criteria and/or further details on the application of the evaluation criteria are provided in the Calls.

The Calls and associated Guide for Applicants may spell out in more detail the way in which these rules and procedures will be implemented and, where relevant, which options are to be followed.

The various steps involved in the submission, evaluation and selection procedures are summarised in the following diagram:
How a Call for proposals is launched and how the winning consortia and projects are selected

Call definition and launch

- IMI Research Agenda (multi-annual plan) advice by IMI Scientific Committee approved by IMI Governing Board
- IMI Annual Implementation Plan approved by IMI Governing Board
  - Including scientific priorities proposed by EFPIA
- Definition of the research topics (Call topics) by EFPIA Consortium (= pharmaceutical companies)
- Detailed description of topic content by EFPIA Consortium + IMI Executive Office
- Launch of the Call by IMI Executive Office

Stage 1

Evaluation based on scientific excellence ~ 5 months

- Submission of Expressions of interest by Applicant Consortia (academics, SMEs, patients ...)
- 1st peer review: assessment + ranking by independent experts + EFPIA topics coordinators by independent experts
- Approval of the 1st ranked consortia by IMI Governing Board
- Invitation to submit Full Project Proposal to first ranked Applicant Consortium + EFPIA Consortium

Stage 2

Evaluation of feasibility and scientific excellence ~ 4 months

- Submission of Full Project Proposal best ranked Applicant Consortium + EFPIA Consortium = Full Project Consortium
- Evaluation through 2nd peer review, including ethical evaluation by independent experts
- Approval of the projects by IMI Governing Board

Contract negotiation ~ 2 months

- Preparation of the: Grant Agreement Full Project Consortium + IMI Executive Office (description of work)
  Project Agreement Full Project Consortium
- Signature of the Project Agreement Full Project Consortium
- Approval project budget by IMI Governing Board

Signature and official project kick-off

- Signature of the Grant Agreement Full Project Consortium + IMI Executive Office
The IMI JU appoints a “Call supervisor” among its staff for each Call. This person acts as a contact point for practical questions associated with the Call, and ensures the overall planning and organisation of the expressions of interest reception and evaluation process.

2. Submission

A two-stage submission and evaluation process is followed:
- Stage 1: expressions of interest
- Stage 2: full project proposals

Stage 1 – Expressions of interest

2.1 Calls for expressions of interest

Expressions of interest are submitted in response to Calls. The 'Call Documents' are published on the IMI JU website (see http://imi.europa.eu), and:
- include references to the topics against which expressions of interest are invited, indicative budgets, and deadlines for submission
- provide all the necessary information for those wishing to apply to Calls. In particular, a Guide for Applicants is available for every Call. This Guide explains the submission process, and how the applicants can seek assistance or information on any matter related to a Call.

The expressions of interest consist of outline proposals, as detailed in the Guide for Applicants.

Calls are considered 'open' until the specified deadline.

2.2 Submission of expressions of interest

Expressions of interest are submitted electronically via a web-based system specifically designed by the IMI JU for that purpose. Among the participants in an Applicant Consortium, only the Applicant Consortium Coordinator (identified by user id and password) is authorised to submit an expression of interest. The preparation and uploading of all the expression of interest data and the applicants’ agreement to the conditions of use of the system and of the evaluation must take place prior to the attempt to submit the expression of interest. Submission of an expression of interest is considered as a declaration of acceptance of these Rules and other Call relevant Documents by the participants of the Applicant Consortium.

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1 Note that the legal entity represented by the Coordinator of the Applicant consortium will normally be in charge of managing the IMI JU grant to the consortium if the proposal is retained for funding and will be given the title “Managing Entity for the IMI JU funding”.

2 The Call documents are available at http://www.imi.europa.eu/content/3rd-call-2010
The IMI JU web-based system verifies that entries are made to all required fields and alerts the applicant to anything missing. These checks do not replace the formal eligibility checks described in section 2.4 which take place after the Call deadline.

Submission is deemed to occur at the moment when the Applicant Consortium Coordinator finalizes the submission in the web-based system (please consult the relevant user guide).

The expressions of interest submitted via the IMI JU web-based system are entered into databases after the Call closure.

Versions of expressions of interest sent on removable electronic storage medium (e.g. CD-ROM, diskette), by email or by fax will not be regarded as having been received. The withdrawal of an expression of interest by its Applicant Consortium Coordinator is possible at any moment before the Call deadline. A withdrawn expression of interest will not subsequently be considered by the IMI JU. The expression of interest may be updated with new data online until Applicant Consortium Coordinator finalises and submits it before the Call deadline. Expressions of interest are archived under secure conditions at all times. After completion of the evaluation and any subsequent full project proposal submissions and negotiation, all copies are destroyed other than those required for archiving and/or auditing purposes.

2.3 Reception of expressions of interest by the IMI JU

The date and time of receipt of the submitted expressions of interest are recorded. After the Call closure, an acknowledgement of receipt is sent to the Applicant Consortium Coordinator by e-mail containing:
- Expression of interest title, acronym and unique identifier;
- Name of the topic and/or activity/research area and Call identifier to which the expression of interest was addressed;
- Date and time of receipt.

There is normally no further contact between the IMI JU and applicants on their expressions of interest until after completion of the evaluation. The IMI JU may, however, contact an Applicant Consortium (usually through its coordinator) in order to clarify matters such as eligibility (see section 2.4).

2.4 Eligibility check of expressions of interest

Expressions of interest must fulfil all of the eligibility criteria if they are to be retained for evaluation. These criteria are rigorously applied. The following eligibility criteria apply to all expressions of interest submitted under a Call:
- Receipt of the expressions of interest by the IMI JU before the deadline date and time established in the Call.
- Respect of the "minimum conditions", as referred to in the IMI Rules for Participation.
- Completeness of the expressions of interest: Submission of all administrative forms for each participant (Part A) and of the description of scientific work (Part B) of the expression of interest (N.B. The completeness of the information contained in the
expression of interest will be for the experts to evaluate; the eligibility checks only apply to the presence of the appropriate parts of the expression of interest).

- **Scope**: the content of the expression of interest must relate to the scope of one specific topic in the Call, and must address the scope of the topic to which it is submitted. An expression of interest will only be deemed ineligible on grounds of ‘scope’ in clear-cut cases.

If one or more of the eligibility criteria have not been fulfilled, the proposal is declared ineligible by the IMI JU, and is withdrawn from any further examination and is not submitted for evaluation. Where there is a doubt on the eligibility of an expression of interest, the IMI JU reserves the right to proceed with the evaluation, pending a final decision on eligibility. The fact that an expression of interest is evaluated in such circumstances does not constitute proof of its eligibility.

If the question of eligibility is not clear-cut and a more comprehensive review of the case is deemed necessary, 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 will notify the Applicant Consortia Coordinators who have submitted non-eligible expressions of interest. Eligible expressions of interest shall undergo peer-review evaluation in accordance with section 3 below based on the published evaluation criteria.

Any arrangements for clustering or merging expressions of interest are dealt with at the stage of the Full Project Proposals.

### Stage 2 – Full project proposals

#### 2.5 Submission of full project proposals

Only those Applicant Consortia whose expressions of interest were first-ranked at Stage 1 are invited to discuss with the corresponding EFPIA Consortia the feasibility of jointly developing a full project proposal for submission at stage 2.

The deadlines for submission are communicated by the IMI JU in a letter addressed to both the coordinators of Applicant Consortium and of the EFPIA Consortium, with all the necessary information. The "Call supervisor" of the IMI JU acts as a contact point for practical questions.

Full project proposals are submitted electronically via a web-based service of the IMI JU. The EFPIA Consortium coordinator will become the Full Consortium Coordinator, unless otherwise agreed by the participants of the Full Consortium and the IMI JU. Among the applicants, only the coordinators of the Full Consortia (identified by user id and password) are authorised to submit the full project proposals. Submission of a full project proposal is considered as a declaration of acceptance of these Rules and other Call relevant Documents by the participants of the Full Consortium.

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3 The Call documents are available at [http://www.imi.europa.eu/content/3rd-call-2010](http://www.imi.europa.eu/content/3rd-call-2010).
The IMI JU web-based system verifies that entries are made to all required fields and alerts the applicant to anything missing. These checks do not replace the formal eligibility checks described in section 2.7 which take place after the Call deadline.

The full project proposals submitted via the web-based system are entered into databases after the Call closure.

The full project proposal may be updated with new data online until the Full Consortium Coordinator finalises and submits it before a specified deadline. Full project proposals are archived under secure conditions at all times.

2.6 Reception of full project proposals by the IMI JU

The date and time of receipt of the submitted full project proposal are recorded. After the specified deadline for full project proposal submission, an acknowledgement of receipt is sent to the Full Consortium Coordinator by e-mail containing:

- Full proposal title, acronym and unique identifier;
- Name of the topic and/or activity/research area and Call identifier to which the full proposal was addressed;
- Date and time of receipt.

2.7 Eligibility check of full project proposals

Full project proposals must fulfil all of the eligibility criteria if they are to be retained for evaluation. These criteria are rigorously applied. The following eligibility criteria apply to all full project proposals submitted under a Call:

- Receipt of the full project proposals by the IMI JU before the deadline date and time established in the Call.
- Respect of the "minimum conditions", as referred to in the IMI Rules for Participation.
- Completeness of the full project proposal: submission of all administrative forms for each participant (Part A) and of the description of scientific work (Part B) of the full project proposal (N.B. The completeness of the information contained in the full project proposal will be for the experts to evaluate; the eligibility checks only apply to the presence of the appropriate parts of the full project proposal).

If one or more of the eligibility criteria have not been fulfilled, the proposal is declared ineligible by the IMI JU, and is withdrawn from any further examination and evaluation.

Where there is a doubt on the eligibility of a full project 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 fact that a full project proposal is evaluated in such circumstances does not constitute proof of its eligibility.

The IMI JU will notify the Full Consortia Coordinators who have submitted non-eligible full project proposals. Eligible full project proposals shall undergo peer-review evaluation in accordance with section 3 below based on the published evaluation criteria.
3. Evaluation process

Both the expressions of interest and the full project proposals are evaluated in accordance with the procedure described in this section. Applicable criteria, thresholds and weightings for both stages are those set out in the Call.

With a view to upholding the principle of equal treatment, full project proposals submitted to the second stage should not substantially deviate in their scope or their composition from the corresponding selected expressions of interest nor from the original objectives of the respective Call topic other than to fulfil any recommendation received from the IMI JU following the peer review evaluation. Any substantial deviation must be clearly justified in the Full Project Proposal.

The evaluation procedure at stage 2 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).

3.1 Role of experts

The IMI JU evaluates expressions of interest and full project proposals with the assistance of independent experts to ensure that only those of the highest quality are selected for funding.

The coordinators and deputy coordinators of the EFPIA Consortia are invited as experts for the evaluation of the expressions of interest that have been received for their respective topic. They do not sit for the evaluation of full project proposals.

Experts in ethics are invited at stage 2 for evaluation of the full project proposals as required e.g. where projects involve the use of animal or human subjects.

Experts may be invited to carry out the evaluation fully or partially at their home or place of work (“remote evaluation”), or on IMI JU premises.

3.2 Appointment of experts

Experts 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 or private sector in one or more of the following areas or activities: public sector research and activities in the relevant pillars, pharmaceutical R&D, the SME life science sector, regulatory issues, patient interests, technology transfer, intellectual property rights and innovation, ethics of human and animal research, knowledge management, education & training. Experts must be internationally recognised in their fields. 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 associated to the 7th Framework Programme.

To evaluate the expressions of interest and full project proposals submitted in response to a Call, the IMI JU draws up a list of appropriate experts on the basis of their specific expertise in each topic opened in the Call and using the above selection criteria from an expert database used by the IMI JU. The experts are appointed on a per topic basis for the duration of each specific Call process.

The names of the experts assigned to individual expressions of interest and/or full project proposals are not made public. However, once a year the names of experts who have taken part in the evaluation process are collectively published on the IMI JU web site.

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

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

The appointment letter binds the 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 experts, the IMI JU takes all necessary steps to ensure that they are not faced with a conflict of interest in relation to the expressions of interest and/or full project proposals on which they are required to give an opinion. To this end, they 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. In addition, all experts are required to reconfirm that they have no conflict of interest for each expression of interest or full project proposal that they are asked to examine at the moment of the evaluation.

The EFPIA Coordinators and Deputy Coordinators participating in the review of expressions of interest will have the capacity to consult their respective EFPIA Consortia during Stage 1. In that case, before the EFPIA Consortium is consulted, each member company of the EFPIA Consortium will need to sign with the IMI JU an appropriate non-disclosure agreement to be established by the IMI JU.

3.4 Observers

With a view to ensuring a high degree of transparency, the IMI JU may invite observers of the evaluation process from the point of view of its working and execution. These observers are independent from the IMI Founding Members and are not faced with a conflict of interest in relation to the applicants of an Expression of Interest or of a Full Project Proposal. Their role is to give independent advice to the IMI JU on the conduct and fairness of all phases of the evaluation sessions, on ways in which the expert evaluators apply the evaluation criteria, and on ways in which the procedures could be improved. As such, they shall verify that the procedures set out or referred to in these Rules are adhered to, and report their findings and recommendations to the IMI JU. They are also encouraged to enter into informal discussions.
with the IMI JU staff involved in the evaluation sessions and to suggest to the IMI JU any possible improvements that could be put into practice immediately. However, in the framework of their work, they should not express views on the expressions of interest and full project proposals under evaluation or the experts’ opinions on the proposals.

In addition, the IMI JU Executive Director may choose to invite observers from the IMI Founding Members.

Observers are requested to respect the same obligations as the experts with regard to confidentiality and avoidance of conflicts of interest, and they sign the same declaration to that effect.

### 3.5 Evaluation criteria

All eligible expressions of interest or full project proposals are evaluated to assess their merit with respect to the pre-defined evaluation criteria relevant to the Call. The detailed evaluation criteria, and associated weights and thresholds, are set out in the Call Documents.

### 3.6 Scoring

**Expressions of interest and Full project proposals**

Experts examine the issues to be considered comprising each evaluation criterion, and score these 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.

### 3.7 Thresholds and weighting

**Thresholds**

Thresholds are set for some or all of the criteria, such that any expressions of interest or full project 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 Call. If the expression of interest or full project proposal fails to achieve a threshold for a criterion, the evaluation of the expression of interest or full project proposal will be stopped, and the said expression of interest or full project 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 Call.

3.8 Detailed description of evaluation

(a) Briefing of the experts

The IMI JU is responsible for the briefing of experts before they conduct their individual evaluation, and before the consensus panel. The briefing of the experts covers the objectives and uniqueness of IMI, and the evaluation processes and procedures. It also covers the evaluation criteria to be applied, and the content and expected impacts of the research topics under consideration.

(b) Individual evaluation

Each expression of interest and full project proposal are evaluated by the appropriate selected experts.

Expressions of interest and full project proposals are evaluated by a minimum of five independent experts.

In Stage 1, in addition to the independent experts mentioned above, the EFPIA Coordinators and Deputy Coordinators participate as experts to the individual evaluation. They may consult, under appropriate non-disclosure agreement, their respective EFPIA Consortium on all expressions of interest submitted to their respective topic, in order to represent the views of their respective EFPIA Consortium.

Evaluation of full project proposals is, where feasible, performed by the same experts as for the related expressions of interest with the following three exceptions:

• experts from the EFPIA consortia do not participate in the full project proposal evaluation
• experts on ethics participate in the full project proposal evaluation when relevant
• there is a justified need to replace certain experts

In this phase of the evaluation, each expert works individually and gives scores and comments for each criterion as described in the Call.

When remote evaluation is used, the IMI JU provides to all experts access to the expressions of interest or full project proposals to be examined.

Experts may be asked to perform only the individual evaluation. In this case, their individual evaluation reports are presented by IMI JU (the moderator) to the experts attending the consensus 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 experts have completed their individual assessments and communicated them to the IMI JU, the evaluation progresses to a consensus assessment, representing their common views. This normally entails a consensus panel meeting (or electronic forum) to reach a consensus on the scores awarded and any comments or recommendations. The consensus panels must be composed of a minimum of five experts (excluding ethical experts).

In addition, at Stage 1, the EFPIA Consortium Coordinator and Deputy Coordinator participate throughout the consensus panel’s evaluation discussions on each expression of interest submitted to their respective topic. However, they do not participate to the consensus numerical scoring and to the overall ranking of the expressions of interest.

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 experts without any prejudice for or against particular expressions of interest or full project proposals or the organisations involved, and to ensure a fair and equitable evaluation of each expression of interest or full project proposal according to the required evaluation criteria.

The moderators will designate at least one of the independent experts attending the consensus panel ("the rapporteur") to be responsible for drafting the consensus evaluation reports and recommendations for each expression of interest. The rapporteur(s) for each full project proposal is/are, as far as possible, the same as for the corresponding expression of interest.

The experts attempt to agree on a consensus score for each of the criteria that have been evaluated and suitable comments to justify the scores. Comments should be suitable for feedback to the respective Applicant Consortium Coordinator. Scores, comments and recommendations are set out in a consensus report.

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 expression of interest or full project proposal.
The moderators may request hearings of the coordinators of some expressions of interest or of full project proposals if deemed necessary.

**Outcome of consensus**

The outcome of the consensus step is the Consensus Evaluation Report, signed (possibly electronically) by the moderator and all the experts (except the EFPIA Coordinator and Deputy Coordinator), or 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 for the second stage or during negotiation for grant award.

The IMI JU takes the necessary steps to assure 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 expressions of interest is established by the IMI JU at the end of Stage 1 and a simple list of full project proposals at the end of Stage 2.

**4 Feedback to applicants**

**4.1 Feedback to applicants of expressions of interest**

The Applicant Consortia Coordinators of rejected expressions of interest are informed in writing. The letter informing them also includes the respective Consensus Evaluation Report. For those expressions of interest rejected after failing an evaluation threshold, the comments contained in the Consensus Evaluation Report are completed only up until the point where a threshold is not met.

The Applicant Consortium Coordinators of the highest ranked expression of interest for each topic are sent the Consensus Evaluation Report and a letter inviting them to discuss with the relevant EFPIA Consortium the feasibility of jointly developing a full project proposal for submission at stage 2. The deadline for submission of the full project proposal is indicated in the letter.

The Applicant Consortium Coordinators of the second and third-ranked expressions of interest may be invited for preliminary discussions with the EFPIA Consortium if the preliminary discussions with the higher ranked expressions of interest and the EFPIA Consortium fail. Such contacts should be done in priority order, i.e. the second ranked expressions of interest should be contacted only after failure of pre-discussions with the first ranked, and the third after the second ranked.

The EFPIA Consortium Coordinator shall be responsible for notifying the IMI JU if the possibility for preparing a full project proposal with the highest ranked expression of interest is not feasible. This notification must be accompanied with a report clearly stating the reasons for this decision. After acknowledgement by the IMI JU, the EFPIA Coordinator may contact the Applicant Consortium Coordinator of the next-ranked expression of interest. The report
will be sent to the Applicant Consortium Coordinator of the expression of interest in question by the IMI JU together with a rejection letter.

4.2 Feedback to applicants of full project proposals

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

The Full Consortium Coordinators of rejected full project proposal(s) are informed in writing. The letter informing them also includes the Consensus Evaluation Report.

The Full Consortium coordinators of successful full project proposals are sent the Consensus Evaluation Report by the IMI JU and a letter inviting them to enter into negotiations for a Grant Agreement with the IMI JU.

4.3 Rejection decisions

Those expressions of interest or full project 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. The IMI JU may also reject full project proposals on ethical grounds following the ethical review done by the experts at stage 2.

Following receipt of a rejection letter, the Applicant Consortium, through its Coordinator, would have 20 calendar days from the date of sending of rejection 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 evaluate the proposal and consequently will not call into question the judgement of an appropriately qualified group of experts) and will answer within 14 calendar days from the date of reception of the letter of complaint. During this time the Call process will continue.

5. Negotiation and Award

5.1 Negotiation of full project proposals

The Full Consortium Coordinators of the successful full project proposals are invited to begin negotiations with the IMI JU.

The IMI JU may be assisted by experts during the negotiation, possibly by the rapporteurs of the full project proposal involved during the evaluation stage.

The IMI JU ensures that recommendations, including ethical issues, addressed in the invitation letter to enter into negotiations for the conclusion of the grant agreement are taken into account during the negotiation phase.
In addition to any points raised in the evaluation report, the applicants may receive requests for further administrative, legal, technical and financial information necessary for the preparation of a grant agreement. The IMI JU may request changes, possibly including modifications to the budget. The IMI JU will justify all requested changes.

The legal aspects would cover, in particular, the verification of the existence and legal status of the participants, review of any special clauses in the grant agreement, or conditions required for the project, and other aspects relating to the development of the final grant agreement (including date of start of project, timing of reports and other legal requirements). The financial aspects would cover the establishment of the IMI JU contribution, up to a set maximum, the amount of the pre-financing, the estimated breakdown of budget and IMI JU financial contribution per activity and per participant, and the assessment of the financial capacity of the Managing Entity for the IMI JU funding and any other participants, if needed.

Grants may not be awarded to potential participants who are, at the time of a 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 potential participant who has committed an irregularity in the implementation of any other action under a Community or Union Programme may be excluded from the selection procedure at any time, with due regard being given to the principle of proportionality.

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

The IMI JU may terminate negotiations if the Full Consortium Coordinator proposes to modify the project in terms of its objectives, science & technology content, consortium composition or other aspects, to the extent that it becomes significantly different from the full project proposal that was evaluated.

Any arrangements for clustering or merging full project proposals are also dealt with during the negotiation phase.

5.2 Project agreement

All participants in a full project proposal are requested to negotiate and sign a project agreement between them before the grant agreement is signed with the IMI JU.

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*. The project agreement sets out the

*To that end, Applicant Consortia are invited to read carefully the Guidance Note on the IMI IP Policy (www.imi.europa.eu) whose purpose is to explore ways to handle issues that participants may encounter during the preparation, negotiation and completion phases of the Grant Agreement and Project Agreement.
rights and obligations and fairly reflects the scientific and commercial interests of all participants. The project agreement is signed by all project participants. The IMI JU is not a signatory to the project agreement.

If the project participants cannot reach an agreement between them on the terms of the project agreement within a reasonable delay not exceeding the duration of the grant agreement negotiation, then the grant will not be awarded.

**5.3 Grant agreement**

If negotiations are successful (that is, once the details for preparing the grant agreement have been finalised with all the applicants and all the necessary checks carried out), and the project agreement signed between the participants, a grant for funding is awarded, by means of a formal grant agreement between the IMI JU, and the Full Consortium Coordinator, the Managing Entity of the IMI JU funding, and the other participants.