



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 submission of Expressions of Interest and Full Project Proposals, 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 special Financial Rules. These Rules will apply as of the 5th IMI JU Call onwards.

These Rules do not apply to public procurement procedures.



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1. Introduction

Executive Summary

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, the European Federation of Pharmaceutical Industries and Associations¹ (herein after the '**EFPIA Consortium**').

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

A two-stage submission and evaluation process is followed.

At Stage 1, proposals submitted to the IMI JU will be in the form of Expressions of Interest from consortia including research organisations, universities, small and medium sized enterprises (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, the Applicant Consortia selected from stage 1, join together with the corresponding EFPIA Consortia to form public-private collaborations ("**Full Consortium**") and submit Full Project Proposals.

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 final negotiations 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. A Project Agreement must be signed among the participants of the Full Consortium in parallel to the negotiation.

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

- Call Fiche, including the indicative budgets, and deadlines for submission;
- Call topics text: Detailed description of the topics for which proposals are invited;
- Evaluation Form: Specific pre-defined evaluation criteria;

¹ A list of the EFPIA member companies can be found on the EFPIA web site - <http://www.efpia.eu/content/default.asp?PageID=353>

- Rules for submission, evaluation and selection of Expressions of Interest and Full Project Proposals: explanation of the whole process and how the applicants can seek assistance or information on any matter related to the Call;
- Rules for Participation.

The above mentioned Call Documents are available at <http://www.imi.europa.eu/content/5th-call-2012>

Other documents should also be consulted before applying to a Call:

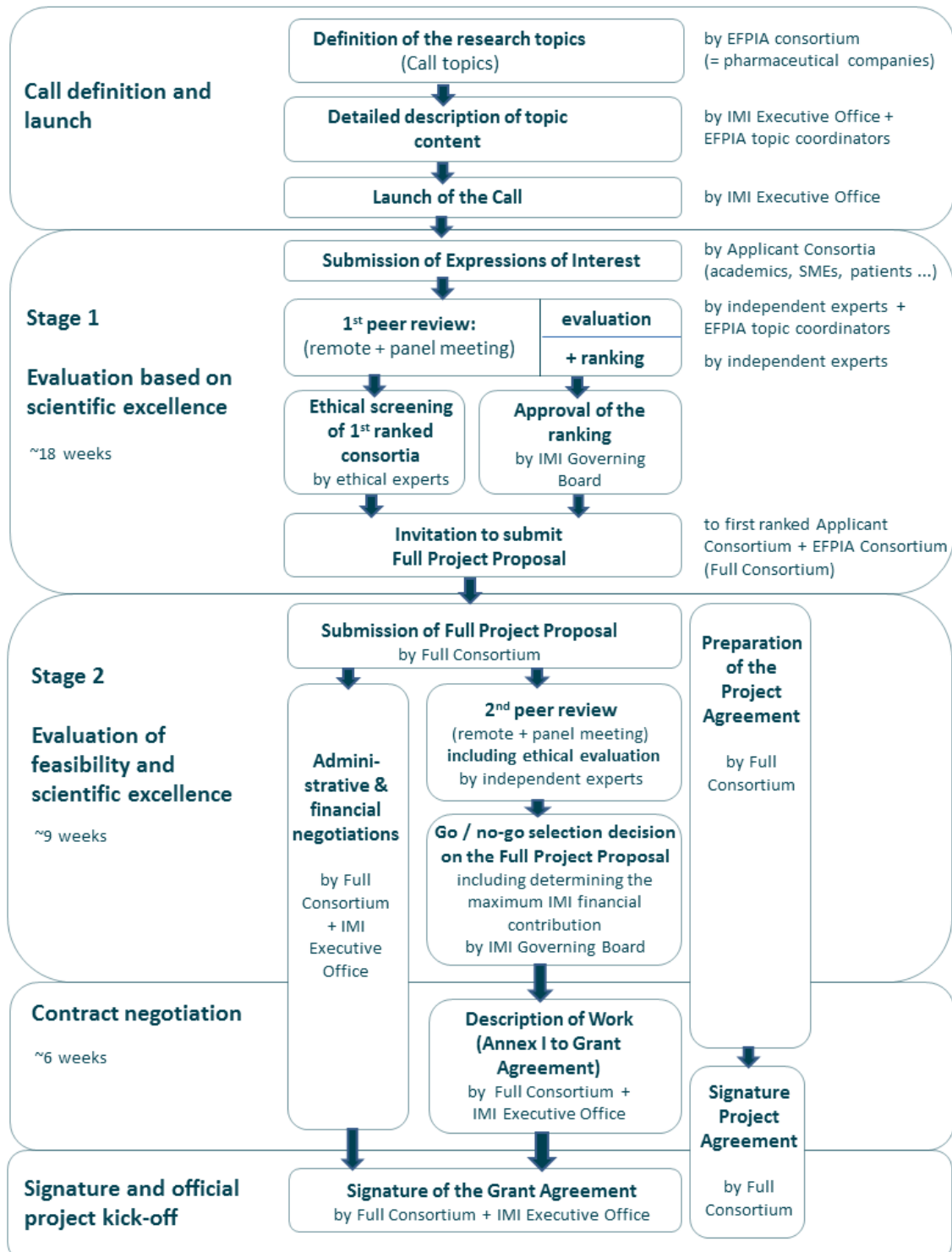
- Application forms for the Expression of Interest and Full Project Proposal together with the Guidelines for coordinators on how to prepare an Expression of Interest and Full Project Proposal.
- Model Grant Agreement² and the IMI Intellectual Property Policy³

The various steps involved in the submission, evaluation and selection procedures are summarised in the following diagram:

² The IMI model Grant Agreement is available at: http://www.imi.europa.eu/content/documents#grant_agreement

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

How a Call for proposals is launched and how the winning consortia and projects are selected



General principles

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 relevant Call.

(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))

(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)⁴, 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 concerned. Personal information will not be sent outside the [European Economic Area](#) unless the individual concerned 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.

Expressions of Interest and Full Project Proposals 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.

The IMI JU appoints a “Call supervisor” among its scientific staff for each Call. The Call supervisor acts as a contact point for practical questions associated with the Call, and ensures

⁴ 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 overall planning and organisation of the processes for the reception and evaluation of Expressions of Interest.

2. Submission

Applicants may only apply for topics opened under the Call referred to.

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 consist of administrative and scientific parts. An outline of the application for Expression of Interest as well as explanatory notes on how to fill it in can be found in the application forms available on the IMI website.

All parts/sections of the application forms will have to be completed by the Applicant Consortium.

Language: Expressions of Interest may be prepared in any official language of the European Union. If the Expression of Interest is not in English, an English translation would be of valuable assistance to the experts nominated to review it.

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

2.2 Submission of Expressions of Interest

The Coordinator⁵ of the Applicant Consortium will be responsible for submitting a complete Expression of Interest to the IMI JU before the deadline, as specified in the Call Fiche.

Expressions of Interest are submitted electronically via a dedicated IMI electronic submission tool (SOFIA: Submission OF Information Application) by Coordinators of the Applicant Consortia. Applicant Consortium coordinators will first be required to complete a Request for Access to the IMI online submission tool.

No other means of submission of the Expression of Interest will be accepted.

⁵ 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”.

Administrative data will be entered online while the scientific part will have to be uploaded as a pdf document. Further information on how to register and submit electronically can be found in the User Guide which is available in the submission tool itself.

Submission of an Expression of Interest is considered as a declaration of acceptance of the conditions of use of the web-based system, these Rules, other Call documents, the provisions of the Grant Agreement, and the IMI Intellectual Property Policy by the participants of the Applicant Consortium.

To complete the online submission of the Expression of Interest, the Applicant Consortium Coordinator has to finalise it by clicking on the “finalise” button in the web-based system. Submission is deemed to occur at the moment when the Applicant Consortium Coordinator finalises the submission in the web-based system (please consult the relevant User Guide). The Expression of Interest may be re-opened for changes online at any point until the submission deadline. The Applicant Consortium Coordinator will need nevertheless to ensure that they finalise it again (by clicking again on the “finalise’ button) before the submission deadline.

The dedicated IMI web-based system carries out basic verification checks, such as missing data, or excessive file size. However, these checks do not replace the formal eligibility checks described in paragraph 2.4 and cannot assure that the content of the files submitted respond to the requirements of the Call.

An Applicant Consortium Coordinator may withdraw an Expression of Interest at any moment before the Call submission deadline. A withdrawn Expression of Interest will not subsequently be considered by the IMI JU.

Expressions of Interest submitted via the IMI JU web-based system are entered into databases after the Call closure.

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.

Acknowledgement of receipt does not imply that the Expression of Interest meets the eligibility criteria (see section 2.4).

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 the Applicant Consortium Coordinator) in order to clarify matters such as eligibility (see section 2.4).

2.4 Eligibility check of Expressions of Interest

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

- Submission before the stage 1 Call deadline, i.e. date and time established in the Call Fiche.
- Respect of the "minimum conditions", as referred to in the IMI Rules for Participation.
- Completeness of the Expressions of Interest (both the administrative and scientific sections): the completeness also implies that the whole Expression of Interest shall be readable, accessible and printable.
- Scope: the content of the Expression of Interest must relate to 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.

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 Applicant Consortia Coordinators accordingly.

Where there is a doubt regarding the eligibility of an Expression of Interest, 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 an Expression of Interest is evaluated does not constitute evidence of its eligibility.

Eligible Expression of Interest shall undergo peer-review evaluation based on the published evaluation criteria (see section 3).

Stage 2 – Full Project Proposals

2.5 Submission of Full Project Proposals

Only the Applicant Consortium whose Expression of Interest was ranked first at Stage 1 is invited to first discuss with the corresponding EFPIA Consortium the feasibility of jointly developing a Full Project Proposal, and then submit it for Stage 2. The EFPIA Consortium Coordinator will become the Full Consortium Coordinator, unless otherwise agreed by the participants of the Full Consortium and the IMI JU.

With a view to upholding the principle of equal treatment, the Full Project Proposals 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 address any recommendations received from the IMI JU following the peer review evaluation at stage 1. Any substantial deviation must be clearly justified in the Full Project Proposal.

The deadline for submission is communicated by the IMI JU to both the coordinators of Applicant Consortium and of the EFPIA Consortium, with all the necessary information.

The Full Project Proposal consists of administrative and scientific parts. An outline of the application for Full Project Proposal as well as explanatory notes on how to fill it in, can be found in the application form available on the IMI website.

The Full Consortium Coordinator will be responsible for submitting a complete Full Project Proposal to the IMI JU before the deadline, as specified in the Call Fiche.

Full Project Proposals are submitted electronically via the same IMI JU web-based system as used for the submission of the Expression of Interest (the Full Consortium Coordinator will be identified by a user ID and password).

Submission of a Full Project Proposal is considered as a declaration of acceptance of the conditions of use of the web-based system, these Rules, other Call documents, the provisions of the Grant Agreement, and the IMI Intellectual Property Policy by the participants of the Full Consortium.

The Full Project Proposal may be changed/updated online up until the submission deadline, even if the Full Consortium Coordinator has already finalised it. Each time the Full Project Proposal is updated, the Coordinator should click on the “finalise” button in the web-based system to complete the submission process.

Full Project Proposals submitted via the dedicated IMI web-based system are entered into databases after the submission closure.

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.

Acknowledgement of receipt does not imply that the Full Project Proposal meets the eligibility criteria (see section 2.7).

2.7 Eligibility check of Full Project Proposals

To be retained for evaluation, Full Project Proposals must fulfil all of the eligibility criteria:

- Submission of the Full Project Proposal before the deadline date and time established by the IMI JU.
- Respect of the "minimum conditions", as referred to in the Rules for Participation.
- Completeness of the Full Project Proposal: (administrative section and scientific section): the term “completeness” implies that the entire Full Project Proposal shall be readable, accessible and printable.

These criteria are rigorously applied.

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

Where there is a doubt regarding 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 IMI JU reserves the right to proceed with the evaluation, pending a final decision on eligibility.

The fact that a Full Project Proposal is evaluated does not constitute evidence of its eligibility.

Eligible Full Project Proposals shall undergo peer-review evaluation based on the published evaluation criteria (see section 3).

3. Evaluation process

Both the Expressions of Interest and the Full Project Proposals are evaluated in accordance with the procedure described in this section.

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.

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

Experts in ethics may be invited for evaluation of the Expressions of Interest and Full Project Proposals as required e.g. where projects involve the use of animal or human subjects. The objective 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).

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

3.2 Appointment of experts

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.

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 and/or private sector in one or more of the following areas or activities: public sector research and activities in the relevant pillars, pharmaceutical research and development (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 countries associated to the 7th Framework Programme.

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 re-confirm 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. Each member company of the EFPIA Consortium will need to sign beforehand with the IMI JU an appropriate non-disclosure agreement established by the IMI JU.

3.4 Observers

With a view to ensuring a high degree of transparency, the IMI JU may invite observers to the evaluation process. These observers are independent from the IMI JU 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 experts 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 JU 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 an appointment letter 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 when applicable associated weights and thresholds, are set out in the Evaluation Form.

3.6 Scoring

For each evaluation criterion, a score on a scale from 0 to 5 is given by the experts. 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 Evaluation Form. If the Expression of Interest or Full Project Proposal fails to achieve a threshold for a criterion, the evaluation will not continue from that point, 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 Evaluation Form.

3.8 Detailed description of evaluation

(a) Briefing of the experts

The IMI JU is responsible for the briefing of appointed experts before they conduct the evaluation. The briefing of the experts covers the objectives and characteristics of the Call under consideration, 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 expert works individually and gives scores and comments for each criterion as described in the Call.

Each Expression of Interest and Full Project Proposal is evaluated by a minimum of five independent experts.

In Stage 2, evaluation of Full Project Proposals is performed by a panel of independent experts. This panel may be composed of independent experts already involved at Stage 1, and when relevant, experts on ethics.

When remote evaluation is used, the IMI JU provides all experts with 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 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 the 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 evaluations 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 in the consensus panel's discussions on each Expression of Interest submitted in response to their respective topic. However, they do not participate in 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 provide suitable comments to justify the scores. Comments should be suitable for feedback to the respective Coordinator. Scores, comments and recommendations are set out in a consensus report. In the evaluation of Expressions of Interest, the experts will also discuss to provide recommendations for the priority order of the Expressions of Interest 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 Expression of Interest or Full Project Proposal.

The IMI JU may organise hearings during the consensus panel meetings with the Coordinators of up to the four highest-scored Expressions of Interest and of the Full Project Proposals, if deemed necessary by the independent experts. In such instances the Coordinator 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 for the second stage or during the 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 Expressions of Interest is established by the IMI JU at the end of

Stage 1 and a list of Full Project Proposals passing all evaluation thresholds at the end of Stage 2.

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

(d) Ethical screening

In addition to the ethical review which may be performed at stage 2, an ethical screening may be performed at the end of stage 1 for those top-ranked expressions of interest. Any recommendations from the experts about issues to be considered for the preparation of the Full Project Proposal will be sent to the Applicant Consortium invited to stage 2 (see section 4.1).

4. Feedback to applicants

The IMI JU may send an information letter to the Coordinator of each evaluated Expression of Interest and Full Project Proposal. The aim is to give the consortia 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.

Upon the decision by the IMI JU on the outcome of the evaluation, the Coordinator of each evaluated Expression of Interest and Full Project Proposal will receive a formal decision letter, together with the Consensus Evaluation Report.

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 ranking below a certain level, 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.

For those proposals 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.

4.1 Feedback to applicants of Expressions of Interest

The Applicant Consortium Coordinators of the highest-ranked Expression of Interest for each topic are sent the Consensus Evaluation Report. The accompanying formal decision letter invites them to discuss with the relevant EFPIA Consortium the feasibility of jointly developing a Full Project Proposal to be submitted before the deadline indicated by the IMI JU.

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 preparation of 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 Full Consortium Coordinators of successful Full Project Proposals are sent the Consensus Evaluation Report by the IMI JU and the formal decision letter inviting them to enter into final negotiations for a Grant Agreement with the IMI JU (see section 5).

4.3 Appeal procedure

The Applicant Consortium, through its 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. Negotiations and Award

5.1 Negotiations of Full Project Proposals

The Full Consortium Coordinators of the successful Full Project Proposals are invited by the IMI JU to finalise the scientific-technical and administrative-financial-legal details of the project needed for preparing a Grant Agreement (“**negotiation phase**”).

The IMI JU may be assisted by experts during this negotiation phase, possibly by the rapporteurs involved in the evaluation of the Full Project Proposal.

The IMI JU therefore ensures that recommendations, including ethical issues, raised in the Consensus Evaluation Report are taken into account. In addition, 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 the date of the 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 the budget and the IMI JU financial contribution per activity and per participant, and the assessment of the financial capacity of the Managing Entity of 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 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 phase, 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 and 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

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 Agreement⁶. The Project Agreement sets out the rights and obligations and fairly reflects the scientific and commercial interests of all participants.

The Project Agreement is mandatory and shall be signed by all participants. The IMI JU is not a signatory to the project agreement.

All participants in a Full Project Proposal are requested to start negotiation on the Project Agreement between them in parallel to the preparation of the Full Project Proposal.

⁶ To that end, Applicant and Full 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.

The Full Consortium shall ensure that the negotiation of the project agreement is completed no later than the finalisation of the full project Description of Work.

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), the formal Grant Agreement between the IMI JU, the Full Consortium Coordinator, the Managing Entity of the IMI JU funding, and the other participants is issued.