



# Rules for submission, evaluation and selection of Expressions of Interest and proposals

## ***Context and scope***

*This document establishes the "Innovative Medicines Initiative Joint Undertaking" (IMI JU) rules for the expressions of interest and 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 do not apply to public procurement procedures.*

## 1. Introduction

The "Innovative Medicines Initiative Joint Undertaking" (**IMI JU**) opens calls for proposals based on topics stemming from its annual implementation plan ([www.imi.europa.eu/...](http://www.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, which set out details of planned work, budget and participants.

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 academic research organisations and universities, SMEs, and patient organisations, 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 "**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 and a grant agreement is established between the IMI JU and the applicants.

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.

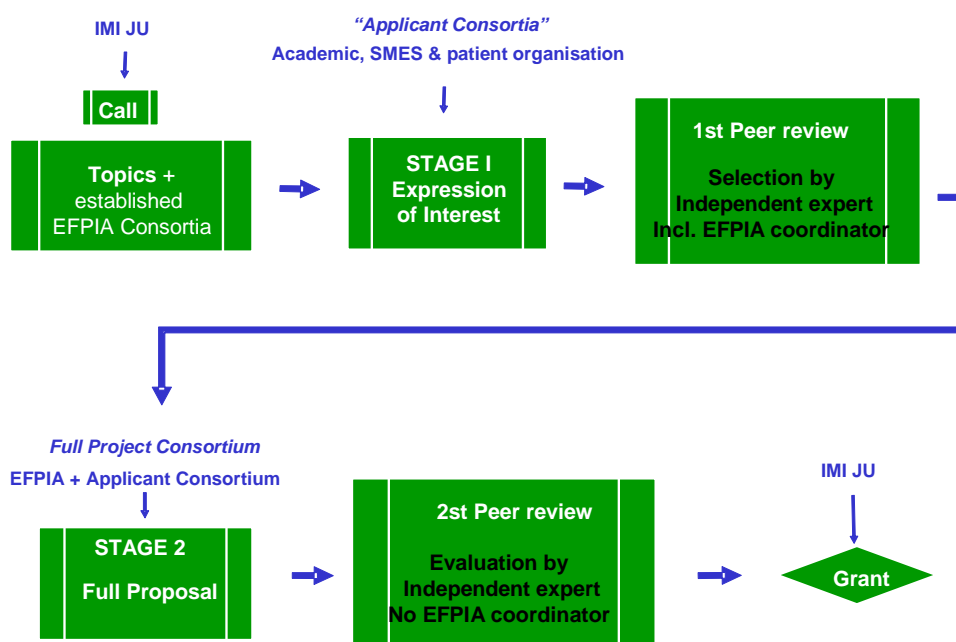
(v) **Efficiency and speed.** Evaluation, award and grant preparation are as rapid as possible, commensurate with maintaining the quality of the evaluation, and respecting the legal framework.

(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 evaluation criteria and/or further details on the application of the evaluation criteria are provided in the calls for proposals.

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:



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## **2. Submission**

A two-stage submission procedure 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 for expressions of interest (“**calls**”). The content and timing of calls are set out in IMI JU Annual Implementation Plan. The 'call texts' are published on the IMI JU website ([www.imi.europa.eu](http://www.imi.europa.eu).....), and include references to the topics against which expressions of interest are invited, indicative budgets, and deadlines for submission. This website provides access to 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.

Calls are considered 'open' until the specified deadline.

The IMI JU appoints a “call coordinator” for every 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.

#### **2.2 Submission of expressions of interest**

Expressions of interest are submitted electronically via a web-based service specifically designed by the IMI JU for that purpose. Among the applicants in an Applicant Consortium, only the coordinator<sup>1</sup> (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.

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.

The expressions of interest submitted via the IMI JU web-based system are entered into databases after the call closure. The IMI JU has no access to the expressions of interest until the call deadline has passed.

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<sup>1</sup> Note that the Coordinator of the Applicant consortium will be in charge of managing the IMI JU grant to the consortium if the proposal is retained for funding

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 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 the call deadline, and only the most recent eligible version is evaluated. 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 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 (usually through the coordinator) in order to clarify matters such as eligibility (see section 2.4).

## **2.4 Eligibility check of expressions of interest**

Expression 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.
- Minimum conditions (such as number of participants), as referred to in the IMI JU Rules for Participation.
- Completeness of the expression of interest, i.e. the presence of all requested administrative forms and the descriptive parts (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 proposal).
- Scope of the call: the content of the expressions of interest must relate to the topic(s) open in the call. An expression of interest will only be deemed ineligible on grounds of 'scope' in clear-cut cases. If it becomes clear before, during or after the evaluation phase that 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. 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 coordinators of Applicant Consortia 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.

## **Stage 2 – Full project proposals**

### **2.5 Submission of full project proposals**

Only those Applicant Consortia whose expressions of interest were evaluated positively at stage 1 are invited to contact the corresponding EFPIA Consortia in order to submit full project proposals 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 coordinator" 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. Among the applicants, only the coordinators of the EFPIA Consortia, acting as full proposal coordinators (identified by user id and password) are authorised to submit the full project proposals (including a draft Project Agreement, see section 5.2).

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 a specified deadline, and only the most recent eligible version is evaluated. 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 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.
- Minimum conditions (such as number of participants), as referred to in the IMI JU Rules for Participation.
- Completeness of the full project proposals, i.e. the presence of all requested administrative forms and the descriptive parts (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).

## 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 may be excluded if their scope or the composition of the Applicant Consortia deviate substantially from the corresponding selected expressions of interest otherwise than to fulfil any recommendation received from the IMI JU following the peer review evaluation.

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 of the EFPIA Consortia are invited as experts for the evaluation of the expressions of interest that have been received for the topic they are concerned with. 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. 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 other than the Member States or countries associated to the 7<sup>th</sup> Framework Programme.

To evaluate the 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. The experts are appointed on a per topic basis for the duration of each specific call process<sup>2</sup>. The lists of experts are drawn up primarily using the above selection criteria from the expert database established by the Commission.

The names of the experts assigned to individual expression of interest and/or full project proposals are not made public. However, once a year the names of experts who have taken part to 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, 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 to remove the conflict of interest. In addition, all experts are required to 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.

## **3.4 Independent observers**

With a view to ensuring a high degree of transparency, the IMI JU may invite observers (hereafter "observers") of the evaluation process from the point of view of its working and execution. Their role is to give independent advice to the IMI JU on the conduct and fairness

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<sup>2</sup> For future calls, the establishment of four Standing Peer Review Committees (one per pillar) is foreseen.



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 proposals under evaluation or the experts' opinions on the proposals.

### **3.5 Evaluation criteria**

All eligible expressions of interest or full project proposals are evaluated to assess their merit with respect to the evaluation criteria relevant to the call. The detailed evaluation criteria, and associated weights and thresholds, are set out in the calls and associated Guide for Applicants.

### **3.6 Scoring**

#### **Expressions of interest**

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.*

#### **Full project proposals**

Full project proposals are evaluated against each evaluation criterion and are marked as either Excellent, Acceptable subject to adjustment to any points raised in the evaluation report, and Non-acceptable.

### **3.7 Thresholds and weighting**

These apply only to expressions of interest

#### **Thresholds**

Thresholds are set for some or all of the criteria, such that any expressions of interest 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 fails to achieve a threshold for a criterion, the evaluation of the proposal may be stopped.

### **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 evaluation sessions. The briefing of the experts covers the evaluation processes and procedures as well as 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 is evaluated by the appropriate selected experts.

Expressions of interest or proposals are evaluated by a minimum of five experts.

Evaluation of full project proposals is performed by the same experts as for the related expressions of interest with the following two 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

Two rapporteurs are designated for each expression of interest. The rapporteurs for each full project proposal are the same as for the corresponding expression of interest.

In the initial 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 access to the expressions of interest or full project proposals to be examined to the experts.

Review time does not exceed three weeks.

### 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. In the case of remote evaluation, the results are communicated to the IMI JU.

The expert's individual evaluation report may not subsequently be changed. In signing 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**

Once all the experts have completed their individual assessments, the evaluation progresses to a consensus assessment, representing their common views. This normally entails a consensus meeting (or electronic forum) to discuss the scores awarded and to prepare comments.

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 moderator may designate an expert to be responsible for drafting the consensus evaluation reports and recommendations.

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 proposal coordinator. Scores and comments are set out in a consensus report.

If during the consensus discussion it is found to be impossible to bring all the experts to a common point of view, the IMI JU may ask up to three additional experts to examine the expression of interest or full project proposal.

The moderator may request hearings of the coordinators of some expressions of interest if deemed necessary.

### Outcome of consensus

The outcome of the consensus step is the evaluation report, signed (possibly electronically) by the moderator and all the experts, or as a minimum, by the moderator and the "rapporteurs". The moderator is responsible for ensuring that the consensus report reflects the consensus reached, expressed in scores and comments. The 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 reports, with particular attention given to clarity, consistency and appropriate level of detail.

Based on the result of the peer review evaluation and associated 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 evaluation report.

The Applicant Consortium coordinators of the most highly ranked expression of interest for each topic are sent the evaluation report and a letter inviting them to contact the coordinators of the relevant EFPIA Consortium to develop and submit a full project proposal. The deadline for submission of the full project proposal is indicated in the letter.

Exceptionally, there may be more than one consortium invited to submit a full project proposal for any one topic with the understanding that the funds allocated to the topic shall be divided between them in the event that their full project proposal is accepted.

A number of expressions of interest may be kept in reserve to allow for eventualities such as the failure of negotiations on full project proposals between the EFPIA consortium and the Applicant Consortium. In such cases, the Applicant Consortia coordinator receive information that negotiations with EFPIA Consortium with a view to preparing a full project proposal may be offered. This information also indicates a date after which no further offers of negotiations for full project proposals are likely to be made.

### **4.2 Feedback to applicants of full project proposals**

The coordinators of rejected full project proposal are informed in writing. The letter informing them also includes the evaluation report.

The successful full project proposals are sent the evaluation report by the IMI JU and a letter inviting them to enter into negotiations for a Grant Agreement with the IMI JU.

The IMI JU ensures that any recommendations given by the experts are taken into account during the grant negotiations.

### **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 proposals on ethical grounds following the ethical review done by the experts at stage 2.

## **5. Negotiation and Award**

### **5.1 Negotiation of full project proposals**

The coordinators of full project proposals that have not been rejected are invited to begin negotiations.

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.

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 co-ordinator of the Applicant Consortium 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 Regulation (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 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 co-ordinator proposes to modify the project in terms of its objectives, S&T content, consortium composition or other aspects, to the extent that it becomes significantly different from the proposal that was evaluated.

### **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 rights and obligations and fairly reflects the scientific and commercial interests of all participants. The project agreement is signed by all project participants. IMI 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 of the grant agreement have been finalised with 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 project coordinators and the other participants.