



Innovative Medicines Initiative

IMI2

MANUAL FOR SUBMISSION, EVALUATION AND GRANT AWARD



efpia

Innovative Medicines Initiative

Postal mail: IMI JU, TO 56, Office 6/5 1049 Brussels
Visiting address: Avenue de la Toison d'Or, 56-60, 1060 Brussels
tel: +32 (0)2-221 81 81 – fax: +32 (0)2-221 81 74
www.imi.europa.eu

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I. Submit a proposal

Differences to IMI1

- ✘ recommendations of experts limited
- ✘ 'negotiation' replaced by 'grant preparation'

Summary

This section explains how you can:

- submit a proposal

Key points

- We will treat your proposal **confidentially**, as well as any related information, data, and documents we receive from you.

We will ensure that the process of handling and evaluating proposals is carried out in a confidential manner.

Experts are also bound by an obligation of confidentiality.

You should also avoid taking any actions that could jeopardise confidentiality. You must not attempt to discuss your proposal with persons you believe may act as expert evaluators.

- Your proposal is archived under **secure** conditions at all times. After the evaluation and signature of any subsequent grant agreement, all copies are destroyed except those required for archiving or auditing purposes.
- We will process **personal data** in accordance with Regulation No 45/2001¹ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 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 (OJ L 8, 12.01.2001, p. 1). and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the IMI2 JU (publicly accessible in the IMI2 DPO register).
- Once the coordinator (or sole applicant) has submitted a proposal, you will not hear from us until the proposal has been evaluated, unless:
 - we need to contact you (usually through the coordinator) to clarify matters such as eligibility or to request additional information;
 - we need more information, or supporting documents, for ethics screening, legal entity validation, financial capacity check (see sections II.3.1, of this Manual)
 - you have made an enquiry or a complaint (see below); or
 - the evaluation process involves hearings (see below).
- For details on your call see the call topic information.
- There is a help desk available to deal with issues relating to the electronic submission system: sofia@imi.europa.eu

For information on how to register concerns or enquiries, please use only the following email address: sofia@imi.europa.eu

¹ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 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 (OJ L 8, 12.01.2001, p. 1).

I.1 Before proposal submission

Draft proposals

The coordinator can enter draft proposals in the Electronic Submission System [*link to SOFIA tool*], using the forms and templates provided there.

Mock evaluation

As part of the topic information for your call, you will find a link to the forms similar to those used by our experts for the evaluation of your proposal.

It is strongly recommended that you use these forms to assess the strengths and weaknesses of your proposal before you submit it. Ideally, ask a disinterested colleague to carry out a mock evaluation.

Checklist for submission

Before the coordinator (or sole applicant) officially submits the proposal, check that:

- your proposal fulfils the conditions set out in the call;
- the proposal (both the administrative forms and technical annex] is complete, readable, accessible and printable.
- the requested declarations have been made; and
- all consortium members have:
 - obtained access to the Electronic Submission System
 - registered in the Beneficiary Register;

Access by the IMI2 JU

We have no access to the proposal before the call deadline. However, so that we can plan the evaluation process and meet the deadline for informing you of the outcome, we will ask you consent to access certain information before the call deadline:

- the call title and the topic for which the proposal is submitted,
- the title of the proposal, summary information, keywords, and
- the identity codes of your organisation(s),

 A disclaimer will inform you that we will be accessing this information and we will give you the opportunity to refuse access.

 Some calls allowing for **continuous submission** may indicate that proposals will be evaluated individually as they arrive. They will be ranked after the closure date specified in the call. In those cases, we may access your proposal from the moment of submission.

Rules:

- × Art 15 RfP
- × WP/call

Specific schemes:

- × two-stage submission schemes
- × continuous submission schemes
- × multi-step evaluation schemes

I.2 Proposal submission

Submitting your proposal

Proposals must be submitted by the coordinator **on-line** via the Electronic Submission System before the call deadline.

We will record the date and time the coordinator submits the proposal, and immediately send a confirmation e-mail to all applicants.

⚠ If you have not received this e-mail, it is because the proposal has not been submitted.

⚠ If you miss the call deadline, it will not be possible to submit your proposal.

Specific cases:

For **two-stage submission schemes**, you must submit a ‘short outline proposal’ for the first stage and you will be invited to submit your ‘full proposal’ for the second stage, if you pass the first-stage evaluation.

⚠ The full proposal must be consistent with the short outline proposal and may not differ substantially.

Some calls may be **continuously open for submission** at any time.

In these cases, the call will set intermediate or final closure dates and specify whether:

- the evaluation of proposals will be carried out within one month of that date;
- proposals will be evaluated individually as they arrive and ranked after the next intermediate or final closure date.

⚠ If you miss an intermediate closure date, the proposal will be evaluated in the next evaluation session.

The system carries out basic verification checks for completeness of the proposal, internal data consistency, virus infection file types, size limitations etc.

⚠ The system will check page limits in specific parts of the proposal and, if necessary, suggest that you shorten it. After the deadline, unless otherwise indicated in the call, any excess pages will be overprinted with a ‘watermark’, indicating to evaluators that these pages must be disregarded.

Before the call deadline, the coordinator may replace the proposal with new proposals. We will only keep for evaluation the most recent version submitted.

After the call deadline, changes or additions are no longer possible, unless we ask you to clarify any obvious clerical errors on your part.

After the call deadline (or intermediate or final closure date for continuous submission schemes), the system will issue an e-receipt by email to all participants.

- the full proposal incl. proposal title, acronym and unique proposal identifier (proposal number);

- the call and topic identifiers; and
- the date and time of receipt (i.e. the call deadline).

 If during the final days of the submission process there is a fault in the system, we may decide to extend the call deadline accordingly.

Withdrawing a proposal

The coordinator can subsequently withdraw your proposal.

Multiple proposals

If the coordinator submits a number of similar proposals, we may ask him to choose one or more of them to be withdrawn.

Admissibility check

We will check your proposal for admissibility (against the general conditions on admissibility (including page limits) set out in the call and, if relevant the specific conditions on admissibility set out in the work plan for your call).

The work plan gives the standard admissibility conditions. To be considered admissible, a proposal must be:

- submitted in the Electronic Submission System before the deadline given in the call conditions;
- readable, accessible and printable.

Incomplete proposals may be considered inadmissible. This includes the requested administrative data, the proposal description, and any supporting documents specified in the call. The Call documents list the necessary supporting documents.

In case of an 'obvious clerical error' (*e.g. omission to submit evidence or information on a non-substantial element of the proposal*), we may first ask you to provide the missing information or supporting documents.

 If the missing information or document would substantially change the proposal, it will not be taken into account.

Rejection of inadmissible proposals

If your proposal is inadmissible, we will inform the coordinator by email.

I.3 How to file a complaint

If you believe that submission failed due to a fault in the Electronic Submission System, the coordinator should immediately file a complaint via sofia@imi.europa.eu, explaining the circumstances and attaching a copy of the proposal.

The method of filing a complaint over other aspects of submission will be explained in the information you receive via the Electronic Submission System.

II. From evaluation to grant signature

Rules:

- × Art 131(2) FR
- × Art 201 RAP
- × Art 7-10 RfP
- × Art 1 IMI2 Delegated Regulation
- × WP/call

II.1 Proposal eligibility check

Summary

This section explains how and why IMI2 JU:

- checks eligibility of the proposal

Eligibility check

We will check your proposal for eligibility (against the general and specific eligibility criteria set out in the IMI2 annual work plan and the Call Documents).

Example:

Research & innovation actions require, for instance, a minimum of three independent legal entities established in different Member States or associated countries².

 Your proposal must also correspond to the topic description for your call.

 For more information on participation of applicants from non-EU countries, see the Horizon 2020 Online Manual (available on the [Participant Portal](#)).

Specific cases:

In the case of two-stage submission schemes, an eligibility check is carried out at first stage. At second stage, we will check that the eligibility conditions are still complied with.

Rejection of ineligible proposals

If your proposal is ineligible, we will send the coordinator a proposal rejection letter, together with the reasons why and how to appeal.

² Further conditions may be set out in the IMI2 annual work plan.

II.2 Evaluation of proposals and operational capacity check

Rules:
X Art 15(7), 40 RfP

Summary

This section explains how the IMI2 JU

- chooses its experts
- evaluates your operational capacity
- evaluates your proposal
- establishes its ranked list

Key points

- We will evaluate your proposal with the help of independent external experts.
- We will be guided by the following:
 - Excellence. Projects must demonstrate high quality in relation to the topics and criteria set out in the calls.
 - Transparency. Funding decisions must be based on clearly described rules and procedures, and applicants should receive adequate feedback on the outcome of the evaluation.
 - Fairness and impartiality. All proposals submitted in response to a call are treated equally and evaluated impartially on their merits, irrespective of their origin or the identity of the applicants.
 - Efficiency and speed. Evaluation, award and grant preparation should be done as quickly as possible without compromising quality or neglecting the rules.
- If a proposal fails to achieve the threshold for a criterion, the evaluation of the proposal will be stopped.

II.2.1 Evaluation by experts

In order to ensure that only proposals of the highest quality are selected for funding, we rely on **independent experts** for the evaluation of proposals ('evaluators').

How are the evaluators selected? We appoint independent evaluators for each topic in a call from the database of experts. When selecting evaluators, we look for:

- a high level of skill, experience and knowledge in the relevant areas, *e.g. project management, innovation, exploitation, dissemination and communication*;
- provided the above condition can be satisfied, a balance in terms of:
 - skills, experience and knowledge;
 - geographical diversity;
 - gender;
 - where appropriate, the private and public sectors, and
 - an appropriate turnover from year to year.

In principle, your proposal will be examined initially by at least three experts (in many cases, five or more).

Exception: For the first stage in two-stage submission schemes and for low-value grants, it may be that only two experts are used.

Additional experts will be appointed for the ethics review.

In addition, the evaluation process may be followed by one or more **independent observers**:

- to observe the practical workings of the evaluation process;
- to give independent advice on:
 - the conduct and fairness of the evaluation sessions;
 - the application of the award criteria;
 - ways in which the procedures could be improved, but

Observers do not express views on the proposals or the other experts' opinions.

 Experts that have a conflict of interests will be excluded by us.

We consider that a conflict of interest exists, if an expert:

- was involved in the preparation of a proposal;
- benefits directly or indirectly if a proposal is accepted;
- has a close family or personal relationship with any person representing an applicant;
- is a director, trustee or partner or is in any way involved in the management of an applicant;
- is employed or contracted by one of the applicants or any named subcontractors;
- is a member of governance body or an advisory group set up by the IMI2 JU to advise on the preparation of IMI2 annual work plan in an area related to the call;
- is a H2020 National Contact Point or is directly working for the Enterprise Europe Network;
- is a member of a H2020 programme committee; We decide whether a conflict of interest exists — taking account of the objective circumstances, available information and related risks — when an expert:
- was employed by one of the applicants in the last three years;
- is involved in a contract or grant agreement, grant decision, membership of management structures (*e.g. member of management or advisory board etc.*) or research collaboration with an applicant or a fellow researcher, or had been so in the last three years
- is in any other situation that could cast doubt on their ability to participate in the evaluation of the proposal impartially, or that could reasonably appear to do so in the eyes of an external third party.

We will publish on the internet site at least once a year the list of experts who have assisted us together with their area of expertise.

Industry participation

In Stage 1 only, in addition to the independent experts mentioned above, the industry coordinator and deputy coordinator participate in the evaluation. The latter may consult, under an appropriate non-disclosure agreement, their respective industry consortium. However, they do not participate in the consensus numerical scoring and to the overall ranking.

II.2.2 Evaluation of proposals and operational capacity check

Selection criteria

Rules:

- × Art 131(3), 132(1,2), 133 FR
- × Art 202, 203, 204 RAP
- × Art 15 RfP
- × WP/call

To evaluate your capability, the experts will give an opinion on your **operational capacity** to implement the action based on the information provided in your proposal.

Award criteria — Scoring — Thresholds

Your proposal will be evaluated against the following **award criteria**:

- excellence
- impact and
- quality and efficiency of implementation

and according to the weighting and thresholds that are set out in the Call Documents.

For each criterion, your proposal will be given scores of 0 to 5 (half marks are possible), as follows:

- 0 — The proposal fails to address the criterion or cannot be assessed due to missing or incomplete information (unless the result of an ‘obvious clerical error’);
- 1 — Poor: the criterion is inadequately addressed or there are serious inherent weaknesses;
- 2 — Fair: the proposal broadly addresses the criterion but there are significant weaknesses;
- 3 — Good: the proposal addresses the criterion well but with a number of shortcomings;
- 4 — Very good: the proposal addresses the criterion very well but with a small number of shortcomings;
- 5 — Excellent: the proposal successfully addresses all relevant aspects of the criterion; any shortcomings are minor.

The maximum overall score is therefore 15.

 Proposals will be evaluated on their own merit, and not their potential should certain changes be made. Proposals with an inflated budget are likely to receive a lower score.

In order to be considered for funding, your proposal must score above a certain threshold for each criterion, and above an overall threshold.

Thresholds may vary according to the call.

For two-stage submission schemes, thresholds and the maximum overall score may vary between the first and the second stage.

Evaluation process

If your proposal is admissible and eligible (or if admissibility and/or eligibility cannot immediately be determined), it will be evaluated by independent experts.

Specific cases:

For **two-stage submission schemes**, there is a first-stage and a second-stage evaluation (against the evaluation criteria for each stage).

 In a two-stage submission scheme, proposals must pass all thresholds to pass to the second stage.

For **continuous submission schemes**, there is normally an evaluation session after the intermediate or final closure dates (normally within a month). The call may provide for evaluation when the proposals arrive. In this case they are all ranked after the intermediate or final closure date and evaluation results are made available immediately.

If the call provides for a combination of continuous submission scheme and two-stage submission scheme, the first-stage short outline proposals may be evaluated on a continuous basis when they are received and the full proposal will be evaluated after the intermediate closure date for the second-stage evaluation.

For '**multi-step evaluations**' there are several steps and different experts may be examining the different criteria. Proposals failing a threshold score may not progress to the next step.

The **experts are briefed** on:

- the evaluation procedures (including selection and award criteria);
- the content of the topics under consideration;
- the terms of their contract (*e.g. confidentiality, impartiality, conflicts of interest, completing tasks and approving reports, penalties for non-compliance*);
- disregarding excess pages, and
- the need to evaluate proposals in their current state, rather than their potential should certain changes be made.

 Similarly to Horizon 2020, there will very limited scope for recommending improvements to proposals (including improvements on the budget). In particular, proposals with an inflated budget, taking into account cost efficiency considerations, should receive a lower score.

The evaluation process has **three phases**:

Phase 1 — Individual evaluation

Phase 2 — Consensus group

Phase 3 — Panel review

Phase 1 — Individual evaluation

Each expert carries out an evaluation and prepares an ‘**individual evaluation report (IER)**’ with comments and scores for each criterion.

They also indicate if the proposal:

- falls entirely outside the scope of the part of the call which they are evaluating

Phase 2 — Consensus group

The individual experts then form a ‘consensus group’ to come to a common view and agree on comments and scores (in a ‘**consensus report**’).

 Exceptionally and if foreseen in the call,

- an arithmetic average (i.e. median or mean value) of the individual scores may be taken as the consensus score.

The ‘mean’ is the total score of the experts, divided by the number of experts.

The ‘median’ is found by arranging all the scores from lowest value to highest value and picking the middle one (e.g., the median of {3, 5, 9} is 5).

- If there is an even number of experts, then there is no single middle value; the median is then the mean of the two middle scores (the median of {3, 5, 7, 9} is $(5 + 7) / 2 = 6$); the consensus report may consist in a collation of the individual evaluation reports or extracts from them.

 If you have previously submitted your proposal to the IMI2 JU or any other IMI JU call in the past two years, and if the work plan and criteria were comparable, the moderator of the consensus group may give a copy of the previous Evaluation Summary Report (see below) to the experts.

The group has an impartial ‘moderator’ (normally an IMI2 JU staff member), who:

- seeks a consensus and
- ensures that proposals are evaluated fairly, in line with the criteria.

If a consensus group cannot reach a common view, the consensus report will set out both the majority view and the dissenting views.

 In some cases we may ask additional experts to examine the proposal, to establish whether a clear majority view exists.

Phase 3 — Panel review

Finally, a panel will review all the proposals within a call, or part of a call, to:

- make sure that the consensus groups have been consistent in their evaluations;
- if necessary, propose a new set of marks or comments; and
- resolve cases where a minority view was recorded in the consensus report.

It may be possible to arrange for all the consensus group experts to examine all the proposals, and carry out their final review at the same time as they prepare the consensus reports. These experts are thus considered to constitute the panel.

 Exceptionally, in some cases, justified by the specific call circumstances, the outcome of the consensus group will constitute the final result of the evaluation, and there will be no Panel Review. These cases will be signalled in the guidance documents.

 A panel review may not take place if there are sufficient funds to support all the proposals that passed the relevant thresholds.

The panel review is guided by a ‘panel chairperson’ (normally an IMI2 JU staff member) who must ensure fair and equal treatment of the proposals. A rapporteur (who may also be the chair) may be appointed to draft the panel’s advice

As part of the panel deliberations, the IMI2 JU may organise **hearings with the applicants** to:

- clarify the proposals and help the panel establish their final assessment and scores or
- improve the experts’ understanding of the proposal.

The call documents will indicate if hearings will be organised.

Invitations to hearings are sent only to the coordinators of proposals with consensus scores above the individual and overall thresholds and, in some cases, also to those whose proposals passed the individual thresholds, but fell short of the overall threshold.

Hearings may not be used to modify proposals.

You may only provide explanations and clarifications in response to questions submitted to you in advance.

 You may choose not to attend the hearing and to reply only in writing.

The panel may invite additional experts to clarify particular issues requiring specific expertise.

These experts may not take position on the proposal as a whole.

Hearings are usually held in Brussels, but may also be conducted by a written procedure, via telephone, or by video-conference.

The ‘**panel report**’ includes the ‘**evaluation summary report (ESR)**’ for each proposal (based on the consensus report, including comments and scores, and taking into account the panel’s deliberations and any new scores or comments considered necessary), with explanations and a list of proposals passing all thresholds, along with a final score, (‘**panel ranked list**’) and, where necessary, the panel’s recommendations for priority order in the event of equal scores, using the procedure set out in the work plan.

 Phases 2 and 3 may be merged.

For both phases, should a proposal fails to achieve the threshold for a criterion, the evaluation of the proposal will be stopped.

Rules:

- × Art 128(2) FR
- × Art 204(4,5) RAP
- × Art 15(6), 16, 20 RfP

II.2.3 IMI2 JU ranked list — Reserve list — Information on the

IMI2 JU ranked list

We will rank the proposals that passed the thresholds according to the results of the evaluation by the experts.

Award of the grants will be made on the basis of this ranking, and the available budget.

Information on the outcome of the evaluation — Rejection of proposals that are not on the list

If your proposal is successfully evaluated, we will send an ‘**evaluation information letter**’ to the coordinator, to inform you of the results of the evaluation and to invite you to take part in the grant agreement preparation phase.

Exception: For two-stage submission schemes, if you successfully pass the first stage, you will receive the information letter at the end of the second stage; at the end of the first stage, you will be informed that your short outline proposal has been successfully evaluated and only be invited to submit the full proposal.

 This is not a commitment that we will fund your project.

If your proposal has not been retained on the ranked list, we will send the coordinator a **proposal rejection letter**, together with the reasons why and how to appeal.

Reserve list

We may keep a number of proposals in reserve in case proposals are withdrawn, excluded or extra funding becomes available.

If your proposal is put on a reserve list, we will inform the coordinator and let him/her know of any subsequent change.

II.3 Grant preparation

II.3.1 Ethics pre-screening and ethics review

Rules:
✘ Art 16 H2020 FP Reg
✘ Art 13(2,3), 14 RfP

Summary

This section explains how and why the IMI2 JU makes an:

- ethics pre-screening and if necessary an:
- ethics screening
- ethics assessment

Key points

- We will check if your proposal **complies with ethical principles** (including research integrity).

The ethics review has **2 stages**:

- Stage 1— Ethics screening
- Stage 2 — Ethics assessment

Proposals raising serious ethical issues must undergo an ethics assessment.

Proposals involving the use of human embryonic stems cells (hESCs) always undergo an ethics assessment.

① For more information on ethics, see also the [H2020 Online Manual on the Participant Portal](#)

In parallel to the evaluation, we will check if your proposal complies with ethical principles and relevant legislation.

Although the main focus is on the ethical dimension (e.g. ethics, human rights and protection of human beings, animal protection and welfare, data protection and privacy, environmental protection, malevolent use of research results), we may also look at ‘research integrity’ issues (e.g. fabrication, falsification or plagiarism, including misrepresenting credentials and authorship improprieties).

 Proposals that contravene ethical principles may be excluded at any time.

All proposals considered for funding will go through an ethics review process made of one or more consecutive steps depending on whether or not ethical issues are confirmed, whether they are adequately addressed as well as their severity and complexity.

If so, we will carry out an ethics review with the help of independent experts.

The ethics review has two stages:

Stage 1 — Ethics screening, starting with the pre-screening (on the basis of your ‘ethics self-assessment’) to see if it raises ‘ethical issues’ and whether they are adequately handled.

Stage 2 — Ethics assessment; for proposals raising serious ethical issues (e.g. severe intervention on humans, lack of appropriate ethics framework in the country where the research will be conducted, etc.) a more detailed analysis is made.

Exception: Proposals involving the use of human embryonic stems cells (hESCs) must always undergo an ethics assessment (without ethics screening).

It is normally started during the evaluation or soon after and culminates in one or more **ethics reports** (one for the ethics screening and one for the ethics assessment, if necessary).

These ethics reports may:

- grant **ethics clearance**;
- grant **conditional ethics clearance** subject to ‘ethics requirements’ to be included in the grant agreement, *e.g.*:
 - *regular reporting*;
 - *appointing an independent ethics advisor or board*;
 - *an ethics check or audit*;
 - *submission of further information*;
- recommend an **ethics assessment** (as a conclusion of the screening), or
- **refuse** ethics clearance.

 During an ethics assessment, the experts may request a **second ethics assessment**, if they consider that the elements submitted do not allow them to provide an opinion.

Information on the outcome of the ethics review — Rejection of projects where clearance is refused

If the report is **positive** (clearance or conditional clearance), it will be sent to your coordinator.

If the report is **negative**, your coordinator will receive a **letter** (together with the report), giving the reasons and explaining how to appeal.

II.3.2 How to file a complaint

If you consider that we unduly rejected your proposal, the coordinator may file a **complaint** by email to the IMI2 Programme Office.

If the complaint is justified, we will continue to evaluate the proposal and inform the coordinator.

If the complaint is not justified, we will inform the coordinator, together with the reasons why.

For specific complaints concerning the **evaluation of your proposal** (see section IV.2), the coordinator may — within **30 days** of receiving the proposal rejection letter — file a **request for an evaluation review**, using the on-line forms referred to in the proposal rejection letter.

 The review covers only the procedural aspects of the evaluation, not the merits of the proposal.

If the complaint is justified, we will arrange for a re-evaluation and inform the coordinator.

If the complaint is not justified, we will inform the coordinator, together with the reasons why.