

IMI2

MANUAL FOR SUBMISSION, EVALUATION AND GRANT AWARD

Note: This version 1.4 of the Manual for submission, evaluation and grant award should be used by applicants from IMI 2 – 10th Call for proposals 10 onwards. Applicants of earlier IMI 2 Calls for proposals (including future cut-off dates of IMI 2 – 8th Call for proposals, the open Call on Ebola and related diseases) should use the previous version of the manual applicable to their Call.

History of changes

Version	Date	Change	Page
1.0	09 July 2014	First version	
1.1	15 September 2015	revised to ensure clarity regarding how hearings are held as part of panel deliberations	13
1.2	01 December 2015	revised ethics review section to ensure alignment with H2020	15-17
1.3	11 April 2016	Page limits Updated 'key points' Industry participation Evaluation info letter to stage1successful consortium.	6 9 10 15
1.4	28 October 2016	General alignment with the H2020 manual for submission, evaluation and grant award Clarification on the IMI2 two-stage submission scheme Industry representatives SOFIA IT submission tool replaced by H2020 electronic submission tool	5- 15 12

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Differences to IMI1

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

I. Submit a proposal

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 for the IMI2 JU. Furthermore, under a two-stage evaluation procedure, you must not attempt to discuss your proposal with any member of the industry consortium pre-identified in the respective call topic until the results of the stage 1 evaluation are communicated to the applicants.
- 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 (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 refer information including the [Call for proposals information](#).
- There is a [Helpdesk](#) available to deal with issues relating to the H2020 Electronic Submission System. For information on how to register concerns or enquiries, please use only the following email address: [Participant Portal](#)
- To contact us please use only the electronic exchange system (i.e. the 'My Area' section of the Participant Portal). For information on the Call, please contact IMI, at Infodesk@imi.europa.eu.

I. 1 Before proposal submission

1.1 Draft proposals

The coordinator can enter draft proposals in H2020 'Electronic Submission Service' of the Participant Portal (accessible via the topic page of your call), using the forms and [templates](#) provided there.

- For tips on the ethics self-assessment, see [How to complete your ethics self-assessment](#).¹

1.2 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.

1.3 Checklist for submission

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

- the proposal fulfils the conditions set out in the IMI2 Annual Work Plan(AWP)/Call for Proposals (Call);
- the proposal (both the administrative forms and technical annex) is complete, readable, accessible and printable.
- the requested declarations have been made;
- all consortium members have:
 - obtained access to the Electronic Submission System;
 - registered in the Beneficiary Register.

¹ In a two-stage submission scheme, the ethics self-assessment has to be submitted at stage 2.

I. 2 Proposal submission

2.1 Submitting your proposal

Rules:

- ✗ Art 15 RfP
- ✗ AWP/Call

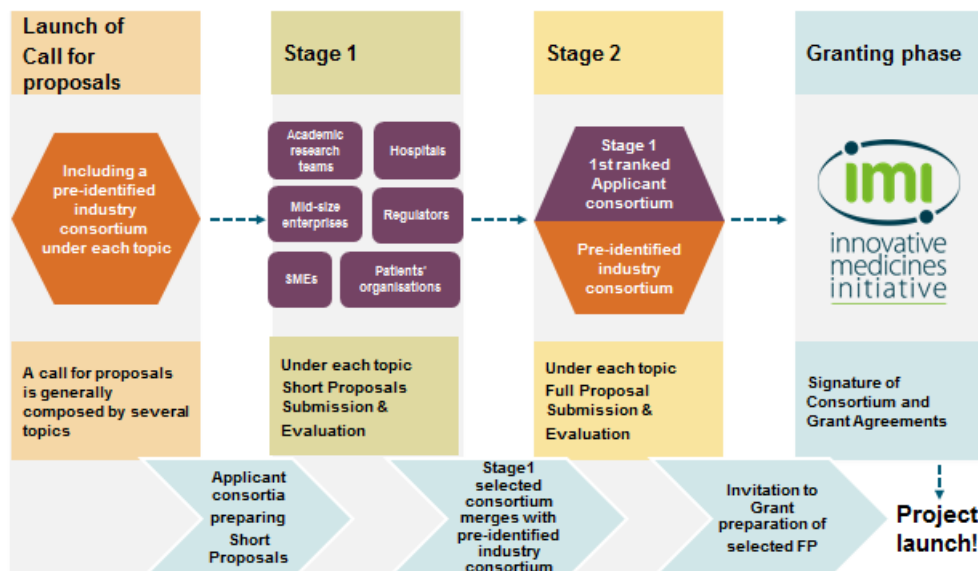
Specific schemes:

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

Proposals must be submitted by the coordinator **on-line** via the Electronic Submission System of the Participant Portal and before the Call deadline.

Under the IMI2, the **two-stage submission scheme** is the most commonly used: you must submit a 'short proposal (SP)' for the stage1 evaluation. SPs must involve all applicant organisations requesting JU funding. At the end of stage 1 evaluation, under each topic, only the applicant consortium of the first ranked SP will be invited to prepare and submit a 'full proposal (FP)' for the stage 2 together with the 'pre-identified industry consortium' for the relevant topic (see Two-stage procedure below).

IMI2 calls: Two stage procedure




⚠ The full proposal must be consistent with the short proposal, taking into account the stage 1 evaluation outcome, and may not differ substantially apart from integration of the 'pre-defined industry consortium'.


A **single-stage submission scheme** may be used for some particular topics. In this case, there is a single submission and evaluation and there is no pre-defined industry consortium. The applicants which may include one or several industry partners must submit a proposal which will be checked for admissibility and eligibility and assessed by independent experts against the award criteria for 'excellence', 'impact' and "quality and efficiency of the implementation". The proposals above threshold may be invited to enter into Grant preparation according to the ranked list and within the available budget.

Some Calls, which are normally single stage, may be **continuously open for submission** at any time. In these cases, the Call will set intermediate or final closure dates (cut-off dates) and specify that there will be an evaluation session after each cut-off date, and the final closure date. The evaluation of proposals will be carried out within one month of after each cut-off date. After each cut-off date, the submitted proposals will be grouped, evaluated and ranked together. 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 you miss an intermediate closure date, the proposal will be evaluated in the next evaluation session.

In all cases, we will record the date and time the coordinator submits the proposal, and immediately we will 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.

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. It will contain:

- 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.

I. 3 After proposal submission

3.1 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 for 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;
 - 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.

3.2 Withdrawing a proposal

The coordinator can subsequently withdraw the proposal.

3.3 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.

3.4 Complaints

If you think that the submission of your proposal was not entirely successful due to a technical error on the side of the IMI2 JU/EC, the coordinator may lodge a complaint through the IT Helpdesk on the Participant Portal. For the complaint to be admissible it must be filed within 4 calendar days following that of the Call closure. You will receive an acknowledgement of receipt the same or next working day.

You should secure a PDF version of all the B-parts and annexes of your proposal holding a time stamp (file attributes listing the date and time of creation and last modification) that is prior to the Call deadline dd/mm/yyyy:hh:mm , as well as any proof of the alleged failure (e.g. screen shots). Later in the procedure you may be requested by the IT Helpdesk to provide these items. Please, note that any information regarding the proposal will be treated in a strictly confidential manner.

In order that a complaint would be upheld, the IT audit trail (application log files and access log files of the EC IT-systems involved) must show that there was indeed a technical problem at the IMI2 JU/EC side which prevented you from submitting (or resubmitting) the proposal using the electronic submission system.

You will be notified about the outcome of the treatment of your complaint as soon as possible and at latest within the time indicated in the acknowledgment of receipt. If a decision cannot be reached in this term you will receive a holding reply.

If your complaint is upheld, the secured files (provided by you to the IT helpdesk), for which the investigation has demonstrated that technical problems at the IMI2 JU/EC side prevented (re)submitting, will be used as a reference for accepting the proposal for subsequent evaluation. In absence of such documents, the version present in the IT system will be evaluated.

II. Evaluation process

II. 1 Proposal admissibility & eligibility

Summary

This section explains how and why IMI2 JU:

- checks eligibility of the proposal

Rules:

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

1.1 Admissibility & eligibility check

We will check your proposal for admissibility (against the general conditions on admissibility, including page limits) set out in the IMI2 Annual Work Plan (AWP)/Call and, if relevant the specific conditions on admissibility set out in the AWP for your Call).

The IMI2 AWP 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.

We will also check your proposal for eligibility (against the general and specific eligibility criteria set out in the IMI2 AWP 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.

① 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.

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

1.2 Proposals page limit

Unless stated otherwise in the AWP applicable to a specific Call, in a two-stage submission and evaluation process the page limit for a stage 1 – short proposal is maximum 30 pages.

The page limit for a single stage/stage 2 – full proposal is maximum 70 pages.

1.3 Outcome of the admissibility & eligibility check

If the **proposal** is considered **inadmissible** or **ineligible**, we will inform the coordinator (via a 'proposal rejection letter' sent through the electronic exchange system), together with the reasons why and how to appeal.

If the proposal is (for the moment) eligible, but you are not, we will inform you and the coordinator (via an '**applicant rejection letter**' sent through the electronic exchange system).

II. 2 Evaluation of proposals

- × Rules: Art 128(2), 131(3), 132(1,2), 133 FR
- × Art 202, 203, 204 RAP
- × Art 15, 40 RfP
- × AWP/Call

Summary

This section explains how the IMI2 JU:

- chooses its experts
- evaluates your operational capacity
- evaluates your proposal (on its scientific merit)
- 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;
 - Ethics and security. Proposals must not contravene fundamental ethical principles or relevant security procedures.

2.1 Evaluation and operational capacity

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

All proposal submitted under a Call (or within a coherent part of the Call, i.e. a topic) are evaluated together.

At the single stage or stage 2 of a two-stage evaluation, the experts will give an opinion on your operational capacity to implement the action based on the information provided in your proposal.

2.2 Evaluation by independent 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. Scientific area, 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 of independent experts 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

- not to 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;

Such an expert may, however, exceptionally be invited to take part in the evaluation session, if all of the following apply:

- the expert works in a different department/laboratory/institute from where the action is to be carried out;
- the bodies operate with a high degree of autonomy; and
- such a role is justified by the requirement to appoint the best available experts and by the limited size of the pool of qualified experts (and this is documented).
- 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 IMI2 website at least once a year the list of experts who have assisted us together with their area of expertise.

2.3 Industry representatives

At **Stage 1 of a two-stage evaluation only**, two representatives of the industry pre-defined consortium are invited to provide industry views and expectations to the panel of the independent experts carrying out the evaluation. This occurs before the panel proceeds with consensus numerical scoring and the overall ranking of the evaluated proposals. The industry representatives do not participate nor assist in the consensus numerical scoring and to the overall ranking. Prior to meeting with the panel, the industry representatives may consult, under an appropriate non-disclosure agreement, with their respective industry consortium.

2.4 Award criteria — Scoring — Thresholds

Proposals 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 and relevant IMI2 AWP.

Thresholds may vary according to the IMI2 AWP /Call.

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


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

- 0.point/s** 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.point/s** **Poor**: the criterion is inadequately addressed or there are serious inherent weaknesses;
- 2.point/s** **Fair**: the proposal broadly addresses the criterion but there are significant weaknesses;
- 3.point/s** **Good**: the proposal addresses the criterion well but with a number of shortcomings;
- 4.point/s** **Very good**: the proposal addresses the criterion very well but with a small number of shortcomings;
- 5.point/s** **Excellent**: the proposal successfully addresses all relevant aspects of the criterion; any shortcomings are minor.

The maximum overall score is therefore 15.

In order to be considered for funding, proposals must score above the relevant threshold set for the criteria, and/or above an overall threshold, if any.

Please note that in IMI2 two-stage evaluation procedures only one short proposal per topic will be retained for stage 2. Indeed, on the basis of the outcome of the stage 1, only the applicant consortium of the highest ranked short proposal (stage 1) for each topic will be invited to discuss with the relevant industry consortium the feasibility of jointly developing a full proposal (stage 2).

 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.

2.5 Evaluation process

The evaluation process has **three phases**:


Phase 1 — Individual evaluation

Phase 2 — Consensus group

Phase 3 — Panel review

Before starting the evaluation process, the **experts are briefed** on:

- the evaluation process and 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.

 In Horizon 2020, there will be no 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. However experts may identify shortcomings, and formulate remarks which may be of assistance to the consortium if the proposal proceeds to the next stage (i.e. stage 2 and grant preparation).

2.5.1 Phase 1 — Individual evaluation

For a given topic, 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 topic which they are evaluating.

2.5.2 Phase 2 — Consensus group

For a given topic 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 IMI 2 JU WP/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, Horizon 2020 or any other programme in the past two years, and if the Annual Work Plan topics 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.

2.5.3 Phase 3 — Panel review

Finally, a panel will review all the proposals under each topic (or within a call, or part of a call, when specifically mentioned in the AWP/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.

There will be no panel review:

- if the IMI2 AWP/Call provides for an exception;
- if there is sufficient funds to support all the proposals that passed the relevant thresholds;
- if the same consensus group has examined all the proposals. In this case their final review will be done together with the consensus reports. This is considered to constitute the panel review:

Ex. In IMI the consensus group (phase 2) and panel review (phase 3) are normally merged in one meeting when the same consensus group has examined all the proposals submitted for a topic of the Call and there is a separate budget per topic.

In the case where a panel takes place, 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 report.

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 may be organised.

Hearings are held if deemed necessary by the panel of independent experts, in particular:

- In stage 1 of a two stages evaluation, invitations to hearings may be sent to the coordinators of up to the four highest-scored short proposals;
- In stage 2 of a two stages evaluation, an invitation to a hearing may be sent to the coordinator of Full Proposal;
- In a single stage evaluation, invitations to hearings may be sent to all the proposals that have passed the individual thresholds (even if they fell short of the overall threshold).

In such instances the consortia Coordinator will be provided beforehand with a list of questions.

Hearings may not be used to modify proposals. You may only provide explanations and clarifications in response to questions provided by the panel 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 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 IMI2 AWP.

2.6 IMI2 JU ranked list – Information on the outcome of the evaluation

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.

Please note that under an IMI2 two-stage evaluation procedure, at the end of stage 1, for each topic only one short proposal – the highest ranked – will be retained for stage 2 and invited to prepare a full proposal together with the pre-identified industry consortium. The applicant consortia of the second and third-ranked short proposals (stage 1) for each topic may be invited, in priority order, for preliminary discussions with the industry consortium if the preliminary discussions with the higher ranked proposal and the industry consortium fail.

Under a single stage evaluation procedure, the outcome will be a ranked list consisting of:

- a main list (proposals proposed for funding);
- normally also a reserve list (in case proposals are withdrawn, excluded or extra funding becomes available);
- a list of proposals that cannot be funded because of insufficient budget.

In addition, we will make a list of proposals that didn't pass the thresholds or has been found to be ineligible (e.g. out of scope).

If your proposal is successfully evaluated:

- at the end of the stage 1 of a two-stage evaluation, you will be informed that your short proposal has been successfully evaluated and be invited to submit your full proposal together with the pre-identified industry consortium;

- at the end of a single stage or stage 2 of a two stage we will **invite you to the grant preparation stage** (via a 'grant information letter' sent through the electronic exchange system).
 - This is not a commitment that we will fund your project.

You will receive this letter within 5 months of the Call submission deadline.

If your proposal is:

- second or third-ranked in stage 1 under a two stage evaluation process, or
- put on a reserve list;

we will inform the coordinator and let him/her know of any subsequent change.

If your proposal has not been retained for funding or invited to the following stage, we will inform the coordinator (via a proposal rejection letter sent through the electronic exchange system), together with the reasons why and how to appeal.

If the proposal is retained for funding, but one organisation may not participate (e.g. because it is found to have insufficient operational capacity or to be ineligible), we will inform that organisation and the coordinator (via an 'applicant rejection letter' sent through the electronic exchange system).

Following each evaluation stage, applicants will receive an ESR (Evaluation Summary Report) regarding the respective evaluated proposal.

II.3 Ethics review

Rules:

- × Art 19 H2020 FP Reg
- × Art 13(2,3), 14 RfP

Summary

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

- ethics review

Key points

During proposal submission you are asked to fill out the “ethics self-assessment” for your proposal.

This consists of:

- The “ethics issue table” in Part A of the proposal template; and
- The “ethics self-assessment” in Part B of the proposal template, a description of how the identified ethics issue is addressed and how it complies with applicable laws.

We will check if your proposal complies with ethical principles (including research integrity) and applicable international, EU and national law.

All proposals will be screened for ethics issues (“ethics screening”).

The ethics review has **2 stages**:

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

Proposals raising serious ethical issues must undergo an ethics assessment (*e.g. proposals involving the use of human embryonic stems cells (hESCs); significant research integrity issues*).

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

- The IMI2 JU carries out the ethics pre-screening, the ethics screening, and the ethics assessment of proposal. These procedures are equivalent to those of the Commission for H2020. For proposals involving hESCs, the IMI2 JU requests the DG RTD Ethics Department to perform the ethics assessment.

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

3.1 Ethics review

In parallel to the evaluation, we will check – with the help of independent ethics experts – if your proposal complies with ethical principles and relevant legislation.

3.2 Ethics issues

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).

3.3 Ethics review process

The ethics review process has one or two stages:

- Stage 1 – Ethics screening
- Stage 2 – Ethics assessment

All proposals considered for funding will go through an ethics review process (made up 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).

We will start the ethics screening by flagging any ethics issues that are not already indicated in the ethics self-assessment of your proposal and then examine whether they are adequately handled.

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

Example (ethics issues): *impact on human beings, environment or animal welfare; processing of personal data; fabrication and falsification of data (plagiarism).*

If a proposal raises serious or complex ethics issues, it will undergo an ethics assessment (i.e. more in-depth analysis)

Example (serious ethics issues that require ethics assessment): *severe intervention on humans; multiple and interconnected ethics issues; lack of appropriate ethics framework in the country where the research will be conducted, etc.*

- We may contact you during the ethics review, if we need more information or supporting documents.

3.4 Outcome of the ethics review: Ethics opinion

The ethics review culminates in one or more **ethics reports** (one for the ethics screening and one for the ethics assessment, if necessary) with an **ethics opinion**.


These ethics reports may:

- grant ethics clearance (for proposals that are “ethics ready”, i.e. respect ethical principles and applicable law);

- grant conditional ethics clearance (for proposals here the experts make the clearance subject to conditions (i.e. “ethics requirements”) to be fulfilled before the signature of the grant agreement or to be included in the grant agreement);

These conditions may include:

- regular reporting;
 - appointing an independent ethics advisor or board (that may notably be tasked to report to the EC/IMI2 JU on the compliance with the ethics requirements);
 - an ethics check or audit;
 - submission of further information;
 - necessary adaptation of the methodology to comply with ethical principles and relevant legislation.
- recommend an **ethics assessment**, 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.

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.4 How to file a complaint

If you consider that we unduly rejected your proposal, the coordinator may file a complaint with 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**, 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.