

**IMI2 Call 8 – Ebola and other filoviral haemorrhagic fevers
(Ebola+) programme: future outbreaks**

Call ID:

IMI-2 – Call 8 Ebola + first cut-off 16th March 2016

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1. Background

This report provides the findings of the Independent Observer following completion of the Consensus Panel meetings of the first cut-off date of IMI2 Call 8 held in Brussels from the 13th to the 14th April 2016.

The 8th Call for proposals is the second Call under the Ebola+ programme. This call for proposals is continuously open for a period of two years with 5 cut-off dates for submission of proposals. Proposals submitted at each cut-off date are evaluated and ranked in one single list.

The proposals are evaluated against the specific IMI2 evaluation criteria (Excellence, Impact and Quality and efficiency of the implementation)¹. Best-ranked proposals, in the framework of the available budget, will be invited to prepare a Grant Agreement.

The deadline for the submission of proposals to the electronic submission tool (SOFIA) for the first cut-off date was 16 March 2016 – 17:00:00 Brussels time.

Guidelines to submit proposals included the scope, expected key deliverables and expected impact.

The scope includes aspects of pre-clinical development and/or Phase 1, 2, and 3 clinical developments of vaccines (in particular multivalent), treatments and diagnosis of Ebola or other filovirus infections. Manufacturing strategies, vaccine stability during transport and storage, and/or deployment of vaccines and treatments are also in scope. Proposals for the development of adaptable platforms, which can address multiple other priority pathogens in addition to filoviruses are also eligible.

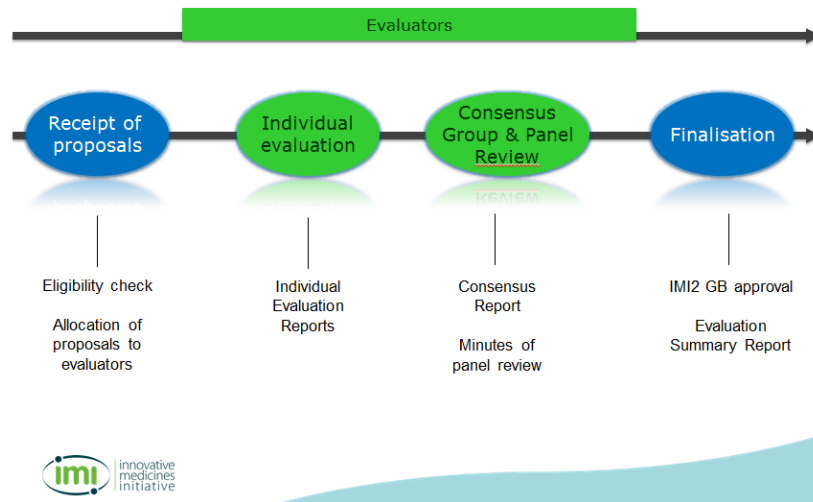
For the “expected impact” it was underlined *that applicants must pay particular attention to exploiting support from different stakeholders, including the mobilization of funds through the inclusion of contributing partners under the IMI programme of public-private consortia. Such contributing partners might include EFPIA companies or organizations associated to EFPIA, and Associated Partners to IMI2 JU7. The budgeted cost for the participation of such partners is expected to account for at least 40% of the total project cost.*

For the applicant it was mentioned “*that the threshold for evaluation criterion ‘Impact’ is 4 in a single-stage Call process. It is therefore considered highly unlikely if not impossible for your proposal to score above threshold if no contributing partner under the IMI scheme of public-private consortia is included*”.

The overview of the evaluation process is illustrated in the next graph:

¹http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_Evaluation-Form_RIA-IA_en.pdf

Overview of the Evaluation Process



Four proposals were submitted and remotely evaluated over a two week period prior to the 13 April 2016, by 7 Independent Experts (IE). The independent Observer (IO) had also remote access to the four submitted proposals.

The consensus group met for the panel meeting in Brussels from 13-14 April 2016.

All eligible proposals were discussed to assess their merit with respect to the pre-defined evaluation criteria relevant to the Call.

General discussion on the merits of each application, consensus scores and drafting of the final Evaluation Summary Reports were conducted by an IMI moderator.

All the rules for submission, evaluation, selection and evaluation criteria were clearly described during the briefing that took place at the beginning of the first day.

The detailed evaluation criteria (scoring, thresholds and weighting) are also fully described in the publicly available document²

²

http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2_SubmissionManual_De c2015.pdf

2. The role of the Independent Observer

In order to fulfil the IMI2 evaluation rules based on transparency, an independent observer was invited to follow all the evaluation process.

3. Overall observations

As stated in the “IMI2 *MANUAL FOR SUBMISSION, EVALUATION AND GRANT AWARD*’ 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.

The IO spoke individually with all the IEs and several IMI employees. These included the Scientific Officers who acted as moderators, the supporting Secretariat and IMI lawyers.

4. Overall observations

For IEs, the online submission and evaluation system, SOFIA was of easy use and worked perfectly well. In the view of the IO the tool functioned well during the remote evaluation and the writing of the Consensus Reports and minutes of the panel review.

The IO observed that despite the SOFIA system functioned well, the saving during the writing of the Consensus Reports is not optimal. The saving /finalize steps and uploading the new version in the system takes too long.

An on-site briefing for IEs took place before the panel sessions, with an overview of the process and the obligations of both the IE and the IMI Team as a whole, being set out clearly by an IMI Scientific Officer. The on-site briefing was also the opportunity for the IO to get introduced to the Evaluators.

The IO observed that one IE (out of 7) was not present during the briefing due to the strike at the Brussels City airport but arrived the next day (He attended the first day of

the consensus group panel through a phone call). One IE did also not attend the panel meeting and acted only through the remote evaluation.

The on-site evaluation and review process was conducted in accordance with the plan set out during the briefing, and the meeting ran smoothly in line with the pre-defined Agenda.

The IO observed that the IMI is following a set of core principles for good practice in peer review that are Gold Standards as stated by the European Science Foundation in the European Peer Review guide published in March 2011³ :

Excellence: for each proposal, the excellence of the proposals was based on the assessment performed by high quality experts. The minimal number of expert considered by IMI is 3, but all of the proposals of the Call 8 were assessed by 7 experts.

Impartiality: All proposals were treated equally and were evaluated on their merits, irrespective of their origin or the identity of the applicants.

Transparency: decisions and scoring were based on clearly described rules and procedures that were published in the public applicants and evaluators guides

Confidentiality: All proposals and related data, intellectual property and other documents have been treated in confidence by experts and IMI personal involved in the process. Particular attention was taken not to leave documents (proposals or evaluation reports) unattended in an empty office.

Ethical and integrity considerations were taken into account as part of the assessment of the proposals but by an independent group.

Conflict of interest: The prevention and management of conflicts of interest are the most important ingredients for ensuring equity and integrity in peer review, and to preserve the credibility of the process. IMI distinguish conditions that would automatically disqualify an expert, and those that may be considered as such, thus requiring the assessment of the IMI office taking into account all the relevant factors.

In the IO's opinion:

- The well-defined evaluation procedures, the high scientific level of IE and the skilled Scientific Officers supported by a very competent staff allowed the proposals to benefit of an outstanding quality assessment.
- There were no violations against the rules of the published evaluation guidelines.
- The choice of IE from different scientific fields and including experts from Regulatory Bodies was of high value during the discussion
- IEs were of a high quality and possessed all the relevant expertise for the evaluation of each proposal.
- All participants approached their tasks with commitment and professionally.
- Evaluation of the proposals, panel discussions were fair and transparent. A consensus was reached by the IEs on the scoring of all proposals.

³ European Peer Review Guide – Integrating Policies and Practices into Coherent Procedures :
<http://www.esf.org/publications.html>

- The final Evaluation Summary Reports were drafted with active participation of all Panel members and reviewed collectively, under the guidance of the IMI scientific officers. They faithfully represent the consensus opinion of the Panels.
- The fact that comments are written first before the score are given is of great importance to ensure that comments and recommendations are aligned with the scores.
- The IMI scientific officer guidance was also very important to ensure that the comments are in the correct section according to IMI rules.
- The presence of 2 IMI scientific officers, one acting as moderator, ensured the efficacy and the quality of the in-house evaluation panel meeting throughout the review session.

5. Observations

The following sections record IO observations on the evaluation process and collate comments received from participants over the two days of the meeting.

The overall opinion is that the evaluation process was carefully and fairly implemented, of excellent quality and conformed to international standards of peer review.

All IEs were not involved in any applicant consortia and were not subject to any kind of conflict of interest.

All IEs took an active role in the discussion held during the Panel meetings and drafting of the final Evaluation Summary Reports. The view of the IE that acted only on remote evaluation was taken into account by each proposal rapporteur.

The IO observed that 2 proposals that were reported of high scientific value by the IEs were not considered for funding because they scored lower than the threshold for the evaluation criterion 'Impact'. The absence of a contributing private partner accounting for at least 40% of the total project cost prevented the specific proposal from achieving the expected impact as outlined in the call topic text. Two IEs suggested that the lack of sufficient contributing private partner should disqualify the proposal before evaluation by the IEs. The IEs have regretted the time wasted.

6. Overall Conclusions and Comments

There were no apparent violations of the published Guidelines and the evaluations, and discussions were fair and transparent.

All evaluation IMI procedures have been fully respected.

The evaluation was conducted by the IMI staff in a very professional way. The evaluation involved important logistics preparation of the meetings (travels, hotel booking, printing evaluation reports, call documents, applicant proposals, IT system etc..). No complaint of any expert was expressed.

It should be emphasized that the IMI assessment procedures have reached a very high level of quality directly connected to the expertise, professionalism and competence of its employees.

7. Acknowledgements

The IO thanks the IEs and IMI staff for being amenable to being “observed” and for the formal and informal conversations that helped formulate this report.

The IO particularly thanks the IMI staff for their help, competence and hospitality.