

IMI – 10th Call 2013

Evaluation of Stage 1

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Independent Observers' Report

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Abbreviations:

EFPIA - European Federation of Pharmaceutical Industries and Associations

EoI - Expression of Interest IMI Innovative Medicines Initiative

IO- Independent Observer

IE – Independent Expert

1. Background

This is the report of the independent observer (IO) for Stage 1 of the 10th Call for proposals by the Innovation Medicines Initiative (IMI)

The IMI 10th Call contained only one topic: “Immunological Assay Standardisation and Development for Use in Assessments of Correlates of Protection for Influenza Vaccines” and was launched on 29 October 2013. Expressions of Interest (EoIs) could be submitted in response to the Call until the deadline for submission of 28 January 2014 at 17:00 hours Brussels time (CET).via the IMI web-based submission tool.

The eligible EoI was then remotely evaluated from 31 January until 19 February 2014, both by independent experts (IEs) and by representatives of the companies (topic coordinator and co-coordinator) from the planned EFPIA consortium for the Call topic. The independent experts, along with the coordinator and co-coordinator of the Call-generating EFPIA consortium, were then brought together in Brussels from 25 to 26 February 2014 to finish the Stage 1 evaluation process. This consisted of a series of plenary, panel discussions, a telecom hearing, scoring and ranking of the EoI by the IEs only, and resulted in a consensus evaluation of the single eligible EoI that was submitted for this Call topic. The results of the evaluation will be communicated to applicants following IMI Board approval, concluding Stage 1 of the 10th Call for proposals.

2. Overall Observations

The IO found that the Stage 1 evaluation was conducted professionally and fairly.

All participants were highly dedicated to ensuring an impartial and thoughtful evaluation of the submitted EoI. The IMI team performed an excellent job in publishing and publicizing the Call, organizing the EoIs submission and evaluation process, contacting highly professional and well-qualified independent experts and in putting together the onsite evaluation meeting.

The clarity of the onsite briefing for independent experts was well appreciated as well as the excellent organization and coordination of the process.

The IO can further acknowledge that the 1.5 day process was set up according to the plan and the panel of experts run smoothly and according to the proposed agenda.

The IO observed that IMI rules for evaluation¹ follow a set of core principles for good practice in peer-review that are Gold Standards as previously stated in the ESF – European Peer Review Guide published in March 2011:²

Excellence: the excellence of the proposal was assessed by a panel of highly qualified independent experts (9 experts in total including EFPIA coordinator and co-coordinator).

Impartiality: the proposal was evaluated based on its merit, irrespective of its origin or identity of the consortium.

Transparency: decision and evaluation were based on clear rules and procedures that were published in the public guides for the evaluators and the applicants.

Confidentiality: the proposal, related data, and all other documents have been treated confidentially by experts and IMI personal involved in the process.

In the opinion of the IO:

- There were no violations against the rules of the published evaluation guidelines. The evaluators were of a very high quality and possessed the relevant expertise for the call topic.
- All participants approached their tasks professionally.
- The evaluation of the proposal, and the discussions in the panel, were exhaustive, frank and fair.
- The consortium hearing was organized in an effective manner and was welcomed by the evaluators.
- A consensus on scoring based on taking into account both the scientific quality of the proposal and its fit against the specifics of the Call topic text, was achieved by the IMI expert evaluators in the absence of the EFPIA representatives. The opinions of all experts on the panel were

¹ http://www.imi.europa.eu/sites/default/files/uploads/documents/8th_Call/5thCall_RulesForSubmission.pdf

² <http://www.esf.org/publications.html>

considered and discussed in equal terms while making the final decisions.

- The Consensus report was drafted with active participation of all evaluators and reviewed collectively, under the guidance of the IMI scientific officers to ensure the comments and recommendations were in line with the scores.

3. Role and approach of the independent observer

3.1 Role of the independent observer

As stated in the IMI's *Rules for submission, evaluation and selection of Expressions of Interest and Full Project Proposals, paragraph 3.4*, the role of the independent observers is as follows:

"The role of observers is to give independent advice to the IMI JU on the conduct and fairness of all phases of the evaluation sessions, on ways in which the experts apply the evaluation criteria, and on ways in which the procedures could be improved. As such, they shall verify that the procedures set out or referred to in these Rules are adhered to, and report their findings and recommendations to the IMI JU. They are also encouraged to enter into informal discussions with the IMI JU staff involved in the evaluation sessions and to suggest to the IMI JU any possible improvements that could be put into practice immediately. However, in the framework of their work, they should not express views on the expressions of interest and full project proposals under evaluation or the experts' opinions on the proposals."

3.2 Working methods of independent observer

In performing the task, the IO had access to all written information supporting the Stage 1 evaluation process. The IO attended both days of the evaluation taking place in Brussels 25-26 February 2014. During the evaluation sessions, the IO attended the briefing session, sat-in during the panel discussions, and spoke individually with many of the expert evaluators and EFPIA representatives present. The IO also had ample chance to speak with IMI employees, including the Scientific Officers acting as moderators and the IMI legal officer present

during the evaluation as well as with Michel Goldman, the Executive Director of the IMI.

4. Observations and recommendations

The following sections record the IO observations on the stage 1 evaluation process and collate comments that were received from participants during the two days of the meeting.

In general, the IO thinks that the evaluation process was well conducted and of excellent quality, implemented in fairness and conformed to international standards of peer-review.

4.1 The Call

The length of time between launch of the Call on 29 October 2013 and the deadline for accepting Expressions of Interest (EoIs) in response to the Call of 28 January 2014 at 17:00 hours was in line with that of previous calls.

IMI also held a webinar on the 10th Call topic on Thursday 24 October 2013. The webinar attracted 70 participants, and featured a presentation of the Call topic by the EFPIA topic coordinator, as well as time for questions and answers and provided an excellent opportunity for interested participants to learn more about the topic and interact directly with the topic coordinator.

Furthermore, the text of the Call was clearly written, well-structured and provided a great amount of detail. The role of the EFPIA consortium was well described in general and specifically for each foreseen Work-Package of the Call. This was helpful for participants to understand the public-private nature and philosophy of IMI projects and to further consider where EFPIA collaboration should be foreseen in the project plans.

4.2 Guidance to applicants

There was one eligible EoI submitted to this call, and applicants of this consortium had grasped the need to adhere to the overall demands and scope of the Call. Of note, however, was that in this very case, the priority order of the objectives of the Call might have been more fully understood had an Info Day been organised. For Call 10, there was no specific Info day, only a webinar.

The IO recommends that the IMI takes as a general rule the organization of an information day in relation to the call, as face to face interactions are often very beneficial to guide applicants.

The IEs felt that the text of the Call was however very clear in the first place, and that the consortium that submitted its EoI was nevertheless of excellent quality.

4.3 Expert evaluation panels

The experts in the evaluation panel were selected and invited by the Scientific Officers as described in “*Rules for submission, evaluation and selection of Expression of interest and Full Proposals, paragraph 3.2*”. All experts fulfilled the criteria stipulated there and the high quality of the individuals present pays tribute to the efforts of the IMI Scientific Officers in securing a good mix of people for the evaluation panel.

In addition, the evaluation panel also included the Coordinator and co-Coordinator of the EFPIA consortium.

This combination of independent and EFPIA-associated experts was beneficial for the evaluation as acknowledged by all IEs. The EFPIA Coordinator and co-Coordinator were provided with the opportunity at the beginning of the plenary session to detail the objectives of the topic and to describe how the EFPIA representatives had approached their own separate EoI evaluation, scoring and ranking process. While the scores provided by the EFPIA experts did not contribute to the final consensus evaluation scoring of the EoI, the EFPIA representatives made active contributions to the discussions. The information and context provided by EFPIA representatives was perceived to have a positive impact on the discussion held during the panel meetings.

The IEs noted that given the specific nature of the topic covered by this Call, close collaboration between Industry and Academia was of paramount importance. They felt that the discussions were neither dominated by the Industry nor the Academia, but rather reflected a true collaborative endeavor leading to a joint consensual evaluation.

Hearings:

The IO was pleased to note the organisation of a telecom hearing with the applicant consortium.

The hearing was a Q&A session. Questions were read aloud by the IMI Scientific Officer in order to maintain the anonymity of the panel. Answers were given by

the applicants. Participants were informed that they were not to receive any feedback on their answers from the panel and the phone was turned on mute when the moderator checked for possible additional questions and comments from the panel.

The hearing provided the IEs with a deeper understanding of the strengths and weaknesses of the submitted EoI and allowed an opportunity to evaluate the leadership and organizational capabilities of the Consortium coordinator.

The hearing was very helpful to further evaluate the EoI and related Consortium capabilities. This was of great help for the further preparation of the Evaluation consensus report from the panel and the final scoring of the EoI.

The IO recommends to continue with the good practice of holding telecom hearings with relevant applicants consortia.

4.4 Timelines

From discussions with the IEs during the evaluation meeting, the time allotted for remote evaluation of the EoI was fully adequate.

4.5 Guidance for evaluators

The IO can testify that the IEs possessed a good understanding of the process following a briefing teleconference organized by the Scientific Officers for all evaluators during the remote evaluation. During the teleconference, evaluators could discuss the process with IMI staff. IEs were pleased with the teleconference, and the *IO supports the continuation of this good preparatory practice.*

4.6 Role of the EFPIA coordinator and co-coordinator

It was noted that EFPIA coordinator and co-coordinator were fully engaged with the evaluation process and the panel discussions. The Coordinator and co-Coordinator were key stakeholders in the Call topic, and not simply 'representatives' of the EFPIA companies.

As an ongoing recommendation, the IO endorses the continued explicit clarification in both the briefing and the panel sessions on the respective roles of EFPIA representatives, as distinct from the independent evaluators.

Overall, the IO observed a good and constructive scientific exchange between the IEs and the EFPIA members.

4.7 Moderation of the expert evaluation panels

The expert evaluation panel was chaired and moderated by IMI Scientific Officers.

The moderators were also well supported by other members of the IMI Executive office. A dedicated IT officer and a legal officer were available throughout the sessions.

This challenging role was carried with tact, professionalism and impartiality.

When needed, advice was given on processes and regulations.

There was no issue with the moderation or the direction of the evaluation panel which testify of the outstanding skills of the individuals involved.

4.8 Choice of Rapporteur

The Rapporteur of the EoI was an IE chosen to present that EoI to the evaluation panel and then act as the primary scribe for the writing of the consensus Evaluation Report of the EoI. This is an important role with obvious direct impact on the discussions in the panel and the feedback given to applicant consortium then. The appointment of the Rapporteur before the consensus evaluation meeting helps to streamline the process so they could be prepared for this task. This was done in a timely manner in this case.

4.9 Remote evaluation

The expert evaluation panel had approximately 3 weeks to evaluate the EoI remotely. The process worked perfectly, with all IEs providing full reports prior to the face to face meeting on February 25 and 26. All IEs were able to be present in Brussels for the Evaluation meeting (Stage 1).

In general, no problems were reported in the viewing of the EoI, the supporting IMI guidance or the subsequent uploading of the IEs reports on the IMI secured area of the website (SOFIA).

4.10 The evaluation tool

The submission and evaluation system, SOFIA, functioned well during the evaluation and the writing/uploading of the Consensus Report.

4.11 Overall Conclusions and Comments

There were no apparent violations of the published Guidelines and the evaluations and discussions were fair and transparent. The IO attests that all procedures have been fully respected.

5. Acknowledgements

The IO was helped in her task by all participants in the Stage 1 consensus meeting.

The IO thanks all IEs and EFPIA consortium Coordinator and co-Coordinator for being amenable to being 'observed' and for the formal and informal conversations that helped formulate this report.

The IO further gratefully thank the IMI staff for their help, competence, hospitality and excellent professionalism both during and after the stay of the IO in Brussels in scientific, organizational, procedural and logistics matters.

Laure Sonnier,
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