

IMI – 9th Call 2013

Evaluation of Stage 1
November 2013

Independent Observers' Report

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Abbreviations

CoI	Conflict of Interest
EFPIA	European Federation of Pharmaceutical Industries and Associations
EoI	Expression of Interest
FPP	Full Project Proposal
IMI	Innovative Medicines Initiative
IE	Independent Experts
IO	Independent Observers
ND4BB	New Drugs For Bad Bugs
WP	Work Package

1. Background

This is the report of the Independent Observers for Stage 1 of the 9th Call for proposals by the Innovation Medicines Initiative (IMI). The 9th Call publication date was 9 July 2013. Submission of proposals was invited in response to four Call themes:

1. WEBAE – Leveraging emerging technologies for pharmacovigilance.
2. Developing innovative therapeutic interventions against physical frailty and sarcopenia (ITI-PF&S) as a prototype geriatric indication
3. Driving re-investment in R&D and responsible use of antibiotics (ND4BB topic 4)
4. Clinical development of antibacterial agents for Gram-negative antibiotic resistant pathogens (ND4BB topic 5)

Both “3” and “4” are part of a wider programme to fight antimicrobial resistance initiated by the IMI JU in May 2012 under the IMI’s 6th Call.

The IMI JU through its electronic submission tool accepted Expressions of Interest (EoI) in response to the Call up until a deadline for submission of 9 October 2013.

Submitted EoIs were then remotely evaluated over a two week period prior to the 12 November 2013, both by Independent Experts (IE) and representatives of the companies within the planned EFPIA Consortium for the Call topic. As happened in some previous Calls, one IE disclosed a conflict of interest after the EoI submission deadline. Independent Observers (IO) had also remote access to all submitted EoIs.

The IE, Coordinators and Deputy Coordinators of the Call-generating EFPIA consortium, were then brought together in the Steigenberger Hotel meeting rooms in Brussels from 12-15 November 2013 to finalise the Stage 1 evaluation process with a series of plenary, panel discussions and telecom hearings.

The evaluations for each Call were spaced throughout the week with each taking between one and two days. General discussion on the merits of each application, initial rankings and cogent questions to ask each set of applicants, if and when applicable, took place on the first of these days, with the collated questions being asked and the evaluations being finalised on, the first or second day. This resulted in a consensus ranking of the submitted EoIs for each Call topic. The Governing Board decision of the ranking will take place by end November 2013 and the result will be communicated to the Applicant Consortia in December 2013, concluding Stage 1 of the 9th Call.

The first ranked consortium for each topic will be invited to join the respective EFPIA consortium to develop a full project proposal (FPP) which will be discussed in Stage 2 in April 2014.

2. Overall observations

Stage 1 evaluations were, in the view of both IOs, conducted professionally, fairly and with commitment from all participants, ensuring an impartial and thoughtful evaluation of all EoIs.

This assessment is based on personal observation and interactions with IE and EFPIA coordinators as well as IMI staff.

We used the following methodology:

- personal observation during the panel evaluations with repartition of panels between the two IOs to ensure presence and some form of continuity
- informal discussions mainly during the breaks and at lunch time with all present
- more formal interviews with IE and EFPIA coordinators (we used the questionnaire at the end of this section as a guide for the interviews)

To be noted, there were 18 and 11 EoIs for two out of the four topics but only two EoIs for the other two topics evaluated in this Call.

As in previous Calls, the IMI Team organised the EoI submission and evaluation process skilfully. Well qualified professionals were contacted to conduct the evaluations, and take part in the onsite evaluation meetings as IE.

On site briefing for IE took place on the first day of each of the four groups of evaluators convening, 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 either Professor Michel Goldman, Executive Director of IMI or Colm Carroll, Scientific project Manager and Call Coordinator of IMI.

The key objectives of the Stage 1 review were clearly outlined:

1. To select and rank the best EoIs submitted by applicant Consortia for each topic
2. To provide each applicant with fair and clear feedback in the Consensus Evaluation Report

With a strong focus on:

- science of the proposals
- partnership
- budget alignment with the tasks and deliverables
- identification of any potential ethical issue

And according to the following principles:

- Excellence (science, management)
- Transparency
- Fairness and Impartiality (beware of conflicts of interest)
- Confidentiality

These on-site briefings were also the opportunity for the IOs to get introduced to the Evaluators.

The on-site evaluation and review process was conducted in accordance with the plan set out at the start of the week, and all Panels for the four topics ran smoothly in line with the pre-defined Agenda. Meetings were moderated by IMI Scientific Officers.

We observed that 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 2011¹ :

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 5, but the proposals of the 4 calls were assessed by 8 to 10 experts of which 2 were from the EFPIA.

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 ranking 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.

The non-disclosure of the identity of the experts was respected during the first step of evaluation and the anonymity was ensured even during the hearings of the applicants by the experts during the panel session.

Ethical and integrity considerations were taken into account as part of the assessment.

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 are potential conflicts where the IMI legal team is involved.

In our 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 proposal of the four calls to benefit of an outstanding quality assessment.
- There were no violations against the rules of the published evaluation guidelines.
- IE were of a high quality and possessed all the relevant expertise for the evaluation of each topic.
- All participants approached their tasks with commitment and professionally.
- Evaluation of the proposals, panel discussions and questioning of the applicants, were fair and transparent. Hearings were organized in a very effective manner and appeared universally welcomed.
- A consensus was reached by the IE on the scoring and ranking of all proposals, in the absence of the EFPIA representatives.

¹ European Peer Review Guide – Integrating Policies and Practices into Coherent Procedures :
<http://www.esf.org/publications.html>

- The Final Consensus Evaluation Reports were drafted with active participation of all Panel members and reviewed collectively, under the guidance of the IMI scientific officers to ensure the comments and recommendations were aligned with the scores. They faithfully represent the consensus opinion of the Panels.

As with previous Calls, included in this report are some observations and general recommendations we hope may improve the Stage 1 process for future Calls. These are described in detail later in this document.

Questionnaire

Evaluation tool: During the remote evaluation did SOPHIA work effectively?

Remote evaluation:

- Was the time allotted for the evaluation sufficient?
- Where the guidance for evaluation and scoring helpful?

Scientific Officers: How did you appreciate their role?

Expert evaluation panel: Did you find all the expertise required to assess all the aspects of each proposal?

Hearings:

- Was it useful and did the answers change your mind in your final scoring?
- Was the time allotted to questions sufficient?

Do you have any *recommendation or suggestion* to improve the evaluation process?

3. Role and approach of the independent observers

3.1 Role of the independent observers

As stated in the IMI's "*Rules for submission, evaluation and selection of Expressions of Interest and Full Project Proposals 3.4*", the role of the IOs 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 method of the independent observers

Both IOs had access to all written and on-line information supporting the Stage 1 evaluation process and attended singly and jointly, all four days of the briefing and evaluation sessions, Panel discussions and tele-conferences held at the Steigenberger Hotel meeting rooms in Brussels 12-15 November 2013.

We spoke individually with many of the IE, EFPIA representatives and IMI employees. These included the Scientific Officers who acted as moderators, the supporting Secretariat, IMI legal team, the IT support specialist and Professor Michel Goldman, the Executive Director of the IMI.

4. Observations

The following sections record our observations on the Stage 1 evaluation process and collate comments we received from participants over the four days of the meeting.

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

4.1 The Call

The length of time between launch, the 9 July 2013 and the deadline for the submission of Expressions of Interest (EoI) on the 9 October 2013 was in line with that of previous Calls. As stated above, the arrangements and execution of the evaluations were expertly undertaken.

4.2 Guidance to applicants

Like in previous Calls and as already reported in previous IOs' reports, most applicant Consortia had grasped the need to adhere closely to the demands of the Call, though, as in previous Calls, a small number of Consortia submitted proposals that were only partially in scope and a couple were out-of-scope as reflected by their scoring.

Some IE felt EoIs were lacking important details while fully in-scope. Instructions in the Guide for Applicants regarding this point are not very detailed but for the request to keep the project plan, including all WPs description, to three pages, which, according to some IE, is not enough. *This probably deserves attention in order to further enhance the quality of the information provided to IE for their remote and on-site appraisals.*

4.3 Expert evaluation panels

IE in the evaluation panels were selected and invited by the IMI JU as described in "Rules for submission, evaluation and selection of Expression of Interest and Full Proposals, 3.2". All IE fulfilled the criteria stipulated there. 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 each panel, an especially hard task given the difficulty of finding suitably-qualified expert evaluators who are not involved in any applicant Consortia and were not subject to any kind of conflict of interest.

Despite the fact that a full information package on how the Call was developed was available to the IE before they started their evaluation, we did observe that there was still a slight confusion for a couple of IE on the full process (Stage 1 EoIs and Stage 2 FPP and the decision-making process in between and after Stage 2) as well as how exactly the text of the Call was developed. *This probably deserves attention in order to further enhance the understanding of the process by IE prior to attend the Panel discussion.*

Nevertheless, Panel members appeared aware of the nature and goals of the evaluation process, their responsibilities, the choices available to them and the consequences of their decisions and recommendations. These were reiterated by the IMI's Executive Director or one of his substitutes prior to the start of each of the Topic meetings and a short Q&A session following the presentation helped clarify the remaining questions.

The four scientific Expert Panel discussions consisted of:

1. Each panel member including the EFPIA representatives for each Topic being invited by the IMI Chairperson, to introduce themselves.
2. The EFPIA Coordinators and/or the Deputy Coordinators were provided with an opportunity at the beginning of each individual topic plenary session, to detail the requirements of the Topic and to describe how the EFPIA representatives had approached their own separate EoI evaluation, scoring and ranking process. The scores provided by the EFPIA Members did not contribute to the final consensus evaluation scoring which helped rank the EoIs.
3. The Rapporteur responsible for the writing of the Consensus evaluation report and appointed prior to the meeting, was invited to briefly describe the key points of the EoI and any concerns and observations he / she had as to the proposal.
4. Other Panel members were then invited in turn to give their views on the EoI and if any issues might benefit from additional information from the Consortia members. The EFPIA representatives made active contributions to the discussions.
5. A series of questions were collated and ranked separately for each Topic in order of importance. In some instances the set of questions were specifically prepared for each EoI, though in others the expert evaluators decided on a basic set of common questions for all EoIs with additional questions for individual EoIs.
6. Top ranked EoI applicants were invited after they were sent the collated questions, to answer the questions in a pre-arranged telecom with the Panel.
7. The independent experts then finalised their recommendations and the consensus evaluation report, based on the earlier discussion and answers provided by the applicant.

All IE brought considerable knowledge and understanding of the issues to the Panel evaluations. All reviewers took an active role in the preliminary discussions and the drafting of the collated questions prior to the hearings. The IMI moderator and wider on site Secretariat, gave considerable support to all involved parties.

The combination of IE and EFPIA-associated experts was beneficial for the evaluation. The information and the context provided by EFPIA representatives was perceived as helpful by IE and had a positive impact on the discussion held during the Panel meetings.

While the IOs noticed and received feedback that there was generally a good balance and helpful contribution from the EFPIA representatives, in one group a few IE had the feeling that the EFPIA representatives were too present with their comments. In particular, the discussion revolved about the need for innovation, even in clinical development and the fact that public money should go hand in hand with more risk taking in terms of innovation. It provided for a moment of tension, polite and respectful but not very friendly, which took time to be resolved.

This underlines the need to have both IMI Scientific Officers at all times in the room, so that, if need be, one can moderate, while the other continues to take care of the process and the scientific content of the Panel discussion.

A small logistic point was brought to the attention of the IOs: the potential usefulness to have access to the EoIs in electronic format during the Panel evaluation, either on-line or off-line. This was raised in particular by IEs who had not saved the EoIs on the hard-drive of their laptops. *This probably deserves attention in order to further help IE during the Panel discussion.*

Hearings

The IMI JU rules state that a maximum of four of the top ranked proposals from the remote evaluation may be asked to take part in Hearings. Applicants were asked to answer specific and suitably detailed questions formulated by consensus from both the IE and EFPIA representative in each Panel.

We observed that special care was taken in giving the same time allocation (30') to each EoI for the hearing. The applicants received the questions the evening of the day before the Hearing, together with information on when they must be available for the Hearing itself. Some IE thought that 30' was not always sufficient to gather the appropriate discriminating information. *This probably deserves attention in order to further help IE during the Panel discussion: when less than 4 EoIs are selected for a hearing, could IMI JU envision increasing the allotted time for Hearings for each EoI? Fairness here would mean an identical allotment of time for each EoI going through the hearing in a specific topic.*

The Hearing is a Q&A session: questions being read aloud by the IMI moderator (in order to maintain the anonymity of the Panel) with answers being given by the proponent(s). In several cases more than one person answered, depending on the question. Participants were informed they will not receive any feedback from the Panel on their answers and the phone was turned on mute when the moderator checked for possible additional questions or comments.

Hearings provided with a deeper understanding of the strengths and weaknesses of the selected EoIs and allowed an opportunity to judge the leadership and organisational capabilities of Consortia coordinators.

Viewing figures and graphics from each EoI, during the specific Hearing, on the screen, as selected by the IMI moderator provided additional support to aid discussion. This was praised by Panel members.

4.4 Timelines

According to IE answers to the questionnaire, the time allotted for remote evaluation of the EoIs appeared adequate.

4.5 Role of the EFPIA coordinators and deputy coordinators

The EFPIA Coordinators and/or the Deputy Coordinators detailed at the beginning of each individual topic plenary session the requirements of the Topic and described how the EFPIA representatives had approached their own separate EoI evaluation, scoring and ranking process.

Overall, we observed a good and constructive scientific exchange between IE and EFPIA members. Some IE felt it could be useful to understand the relative importance of specific WP to EFPIA members at an early stage.

It was noted that EFPIA had fully engaged with the evaluation process and Panel discussions, with the Coordinator and Deputy Coordinators attending the meetings often being substantive stakeholders in the respective Call topic. It is important that the EFPIA representatives are of sufficient seniority and experience to be able to clearly articulate the rationale behind the Call (i.e. the question to be answered) as well as command the respect of the Expert Panel.

4.6 Moderation of the Expert Evaluation Panels

The expert evaluation panels were chaired and moderated by the IMI's Scientific Officers.

The moderating Scientific Officers were given considerable support by other Members of the IMI Executive office. A dedicated IT officer and two lawyers were available throughout the sessions.

This difficult role was done with tact, professionalism and impartiality. Where needed, advice was given on process and compliance with regulations. No issues arose concerning the moderation or direction of the Evaluation Teams, which given the complexity and number of Topics, was a huge compliment to the skill of the individuals.

4.7 Choice of Rapporteur

The Rapporteur for each EoI was an IE chosen to present the EoI to the Evaluation Panel and then act as the primary scribe for the writing of the consensus evaluation Report for that EoI. This is an important role, with a direct impact on the discussions in the Panels and the feedback given to the applicant Consortia. The assignment of a Rapporteur also helps to streamline the process and brings focus to the Evaluator group.

Rapporteurs were pre-assigned prior to arriving in Brussels, giving them time to prepare for this role which they played very well.

4.8 Remote Evaluation

The panels had approximately three weeks to evaluate the EoIs remotely. This process worked well with the IE providing full reports prior to the Brussels' meeting.

When some of the IE were not able to be present at the evaluation sessions in Brussels, their comments were readily available to everyone and the Scientific Officer made ensured they were taken into account through the discussions. In the case of one Panel, a couple of IE, including one from the USA, participated remotely. The communication through a phone call was not optimal.

In general, no problems were reported in the viewing of the EoIs, the supporting IMI Guidance or the subsequent uploading of the independent reviewer's reports.

4.9 The Evaluation Tool

The online submission and evaluation system, SOFIA functioned well during both during the remote evaluation and the writing / uploading of the Consensus Reports.

The user-friendliness and usefulness of SOFIA were pointed by several IE. One IE mentioned a small malfunctioning; another one contacted the help desk which was able to solve the issue. Both were browser-related and *could be avoided in the future by providing guidance on browser compatibility.*

We noted Scientific Officers had to juggle between software tools on top of SOFIA (Word and Excel). *Having some of the simple capabilities of these software tools built in SOFIA could simplify the process and avoid possible mistakes related to copy-and-paste or retyping activities, especially when topics have been popular with applicants and provided for 10+ EoIs.*

4.10 Overall Conclusions and Comments

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

Both IOs attest that all procedures have been fully respected.

5. Recommendations to enhance Stage 1 selection process

While the key assignment of the IOs is to ensure fairness and transparency, suggestions and recommendations for improvement by listening to the team, evaluators and EFPIA can play a role in further improving the evaluation process.

Five points, in two categories, are highlighted from this report.

5.1 Applicants and EoIs

Attracting applicants

Having 18 and 11 EoIs for two out of the four topics but only two EoIs for the other two topics evaluated in this Call attracted our attention.

One of the topics with only two EoIs was “Driving re-investment in R&D and responsible use of antibiotics (ND4BB topic 4)” and the other “Clinical development of antibacterial agents for Gram-negative antibiotic resistant pathogens (ND4BB topic 5)”.

While the clinical development topic was very prescriptive and difficult to match but for a very small number of potential applicants, we felt the more “economic” topic could have attracted more applicants.

In cases where science in healthcare is only part of the topic, could the publishing and publicising of the call by the IMI team towards new and less well-known targets be improved to reach a sufficient number of EoIs?

Nature of projects

Some topics are more conducive to quantum innovation than others and even incremental innovation can lead to improvement in healthcare.

While we understand that innovation is probably more difficult to implement in late clinical development, Panels should still strive to include meaningful, even if riskier, attempts to innovate, like new biomarkers.

Including other stakeholders

As already discussed in the IOs’ report from Call 7 – Stage 1, the broader aim of IMI is to make strategic changes in the entire sector. Other stakeholders than the usual projects partners (academics, SMEs, EFPIA members) should be involved more deeply in the projects where appropriate and mechanisms to do so should be explored and implemented.

In particular, for the WEBAE theme (Leveraging emerging technologies for pharmacovigilance), one specific key organization (e.g. EMA) has to be present/be invited into all competing Consortia. The same situation arose with ND4BB’s topic 4 and ECDC.

5.2 Independent Experts

IE pool and proactivity

We observed that, for several topics, IE were invited, only to discover at a late stage that there was a CoI. Additionally, one IE agreed to be a panelist but did not connect at all.

Having a larger pool of IE, as well as selecting more IE per call and topic, as well as being even more proactive using appropriate means could probably help in this matter.

Potential conflicts of interest

Expert panels are crucial to the success of IMI JU, both in quantity and quality.

Healthcare is a small world and even smaller in the EU, meaning that finding IE without any CoI is becoming increasingly difficult. This is especially true with very successful Calls attracting numerous EoIs, tying up a large proportion of the expert population.

We questioned the IMI legal team who confirmed the rules are not IMI-specific but the Commission's rules.

One may wonder whether general rules are fully applicable to IMI or whether full disclosure, like in peer-reviewed healthcare publications, would not be sufficient, as long as no IE benefits directly or indirectly financially of a decision.

Additionally, having Panel consensus provide an additional safety belt as it is unlikely just one individual will tip the whole group towards an Applicant for which the IE would have disclosed a (potential) CoI.

If possible at all, we recommend addressing the question with the appropriate stakeholders and decision-makers at the Commission level.

6. Acknowledgements

We were helped in our task by all participants in the Stage 1 consensus meetings.

Our thanks to the IE and Consortia members for being amenable to being “observed” and for the formal and informal conversations that helped formulate this report.

We particularly thank the IMI staff for their help, competence and hospitality before, during and after our stay in Brussels in scientific, organisational, procedural and logistic matters.

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Brussels, 19 NOV 2013