

IMI – 9th Call 2013

Evaluation of Stage 2

April 2014

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 2 of the 9th Call for proposals by the Innovation Medicines Initiative (IMI).

A two-stage submission and evaluation process is followed:

- Stage 1: Expressions of Interest (EoIs)
- Stage 2: Full Project Proposals (FPPs)

Further to the evaluation of eligible EoIs submitted in Stage 1 of the IMI 9th Call for proposals which took place from November 12 to 15, IMI launched Stage 2 of the Call process.

Accordingly, the first-ranked Applicant Consortia from Stage 1 have been invited to form Full Consortia with the corresponding EFPIA participants and to prepare and submit Full Project Proposals (FPPs) to IMI JU by 4 March 2014.

The four Call topics are:

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 topics 3 and 4 (ND4BB topics 4 and 5) are part of a wider programme to combat antimicrobial resistance initiated by the IMI JU in May 2012 under the IMI's 6th Call.

Submitted FPPs were then remotely evaluated over a period from March 7 to 27, 2014 by Independent Experts (IEs). The review period was extended by 24 hours. Independent Observers (IOs) had also remote access to all submitted FPPs.

The IEs, Coordinators and Consortia, were then brought together in Brussels from 1-2 April 2014 to finalise the Stage 2 evaluation process with a series of plenary, panel discussions and hearings.

The FPPs were evaluated with each taking one day, two of them running in parallel on each day. The morning agenda was devoted to a general briefing and an introduction by the

Moderator, then discussion of the FPP and preparation of the questions for the hearing. The afternoon was devoted to the hearing and discussion between the Panel and the Consortium followed by the finalisation of the Consensus Evaluation Report.

The Governing Board decision, made by written procedure, is expected to take place mid-April 2014 and the result will be immediately communicated to the Applicant Consortia. Grant agreement negotiation will then take place and final approval and contract signature are to happen by end June 2014, concluding Stage 2 of the 9th Call.

2. Overall observations

Stage 2 process was, in the view of both IOs, like Stage 1, conducted professionally, fairly and with commitment from all participants, ensuring an impartial and thoughtful evaluation.

As in the previous stage, the IMI Team organised the evaluation process skilfully. The same well qualified experts contacted to conduct the review of EoIs at Stage 1 were invited to do the remote evaluation of the FPPs and take part in the onsite process for Stage 2 as IEs.

On site briefings for IEs took place on the morning of both days, with an overview of the process and the obligations of both the IEs and the IMI Team as a whole, being set out clearly by either Professor Michel Goldman, Executive Director of IMI or Dr. Elisabetta Vaudano, IMI Principal Scientific Manager.

The key objectives of the Stage 2 review were clearly outlined:

1. Provide the IMI Governing Board with an overall recommendation on the FPP as follows:
Funding recommended: - Yes
 - Yes with recommendations
 - No
2. Provide the applicants with fair/clear feedback in the Consensus Evaluation Report & Ethics Review Report
3. Provide an opinion on the potential impact of the project

With a strong focus on:

- Consistency between the EoI and the FPP
- Experts' recommendations expressed in the EoI Consensus Evaluation Report have been addressed

- EFPIA contribution and role in the project well documented and integrated
- Project management and ethical issues properly addressed
- Budget/use of resources aligned with the tasks and deliverables for each Work Package.

And according to the following principles:

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

The expected output was a Consensus Evaluation Report for each FPP which:

- Provides consensus views and scores on the proposal's strengths and weaknesses
- Includes comments and scores for all criteria with careful consideration to the proper alignment of the two.
- Based on the comments, scores of between 0 and 5 are assigned to each criterion (scores must match comments), half-marks may be given and the whole range of scores should be used
- Also includes any other remarks which may be of assistance to the consortium if selected to progress to the negotiation phase

Ethics review was carried out in parallel of scientific evaluation. Panels were running in parallel, offering the possibility for interaction if needed (including potential clarification with the Consortium) and members of the Ethical Panel took part to the Hearings for which they also supplied questions. The expected output here, as well, was an Ethics Review Report for each FPP.

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

We observed, like during Stage 1 of this Call, 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 :

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

Excellence: for each proposal, the excellence of the proposals was based on the assessment performed by high quality 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 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.

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 distinguishes conditions that would automatically disqualify an expert, and those that are potential conflicts thus requiring further assessment with the IMI legal team.

In our opinion:

- There were no violations against the rules of the published evaluation guidelines.
- IEs were of a high quality and possessed the relevant expertise for the evaluation of each topic.
- Evaluation of the proposals, panel discussions and questioning of the applicants, were fair and transparent.
- A consensus was reached by the IEs on the scoring of all proposals.
- The Final Consensus Evaluation Reports 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 2 process for future Calls. These are described in detail later in this document.

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 IO 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 2 evaluation process and attended singly and jointly, both days of the briefing and evaluation sessions, Panel discussions and Hearings held in Brussels 1-2 April 2014. We spoke individually with many of the IEs, Ethics Experts, Consortia representatives (post-Hearing) and IMI employees. These included the Scientific Officers who acted as moderators, the supporting Secretariat, IMI lawyer, the IT support specialist and Professor Michel Goldman, the Executive Director of the IMI.

4. Observations and recommendations

The following sections record our observations on the Stage 2 evaluation process, collate comments we received from participants over both days of the meeting (a comment box for anonymous written comments was available at the reception desk and was empty at the end of both days) and give some recommendations and suggestions for modifications we feel could further improve the process for future Calls. Designated as “Recommendations A, B, C...etc...” these observations and recommendations should be read against the background of the general comments given above under Section 2. 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 and deadline for the submission of FPPs 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, applicant Consortia had, in the opinion of the evaluation panels, attempted to adhere closely to the demands of the Call.

4.3 Expert evaluation panels

IEs 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 IEs fulfilled the required criteria.

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 prior to the start of each of the Topic meetings.

The four scientific Expert Panel discussions consisted of:

1. Each panel member for each Topic being invited by the IMI Chairperson, to introduce themselves.
2. 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 FPP and any concerns and observations he / she had as to the proposal.

3. The other panel members were then invited in turn to give their views on the FPP and if any issues might benefit from additional information from the Consortia members.
4. A series of questions were collated for each FPP.
5. The Consortia were invited to make a presentation of the FPP and answer the questions in a pre-arranged Hearing with the Panel, IMI moderator and Members of the IMI Executive Office.
6. The IEs then finalised their recommendations and the Consensus Evaluation Report, based on the earlier discussion and answers provided by the Consortia.

All IEs 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.

Hearings

As described in “Rules for submission, evaluation and selection of Expression of Interest and Full Proposals, 3.8 (c)”, the IMI JU may organize hearings during the consensus panel meetings. Consortia were invited to make a presentation of the FPP and asked to answer specific and suitably detailed questions formulated by consensus in each Panel.

The Consortia received the questions one hour before the Hearing.

Consortia did not always respect the time limit of 30’, however the consortium usually provided answers to a number of questions from the IE panel during their presentation. Some IEs felt the time taken by the presentation in that case was too long and did not leave enough time for exchanges. This is especially true when many questions have to be addressed (one Panel had 19 questions for the Consortium, including the ethical ones).

RECOMMENDATION A: As Consortia members answer some questions during their time allocated to the presentation of the project (30’), would it be possible to have time flexibility in the second part of the Hearing in order to have more exchanges between experts and candidates? Alternatively would it be possible to limit the overview to 10-15’ with a strong focus on the riskiest

parts of the plan (budget estimates, coordination, human potential ...) without responding to questions send by IE panel. More time could then be given to the specific questions from experts.

One IE seemed not to fully understand the concept of IMI. He was surprised to realize that the same EFPIA contributor was present with them during stage 1 and during the Hearing with the Applicants.

The same IE felt that the evaluation and the questions during the Hearing were mainly oriented on the scientific aspects of academic teams and not enough on the involvement of the industrial partners. He wondered about the possibility of providing an opportunity to focus on each aspect, for instance by establishing two separate Hearings.

RECOMMENDATION B: A preventative measure for such confusion would be to further clarify, during stage 1, the involvement of industry in the two stages with their specific role during the hearing of stage 2.

During stage 2, have the IMI Executive Director presenting the briefing remind that EFPIA representatives will be present during the Hearing, as well as have the IMI Moderator remind the Panel that the presence of industry at the Hearing is to further evaluate their participation in the project and to develop specific questions about their involvement.

4.4 Timelines

The time allotted for remote evaluation of the FPPs appeared adequate.

4.5 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 a member of the legal team 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.

4.6 Choice of Rapporteur

The Rapporteur for each FPP was an IE chosen to present it to the Evaluation Panel and then contribute to the writing of the Consensus Evaluation Report for that FPP. This is an important role, with a direct impact on the discussions in the Panels. The assignment of a Rapporteur also helps to streamline the process and brings focus to the IE group.

Rapporteurs were pre-assigned prior to arriving in Brussels, giving them time to prepare for this role.

4.7 Remote Evaluation

The panels had approximately three weeks to evaluate the FPPs remotely. This process worked well with the IEs providing full reports prior to the Brussels' meeting. When some of the IEs were not able to be present at the evaluation sessions in Brussels, their comments were readily available to everyone and the Scientific Officer made sure they were taken into account through the discussions. In the case of two Panels, one IE participated remotely. The communication through a phone call was not optimal. Remote participation should only be used as a last resort and only to make sure enough IEs and expertise is represented appropriately around the table. In general, no problems were reported in the viewing of the FPPs, the supporting IMI Guidance or the subsequent uploading of the IEs' reports.

RECOMMENDATION C: Ensure physical presence of IEs and avoid remote presence by phone. Quality of communication is variable, level of attention is variable, actual presence is variable. A possible substitute could be video-conferencing with a request for presence during the whole day of meeting.

4.8 The Evaluation Tool

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

4.9 Overall Conclusions and Comments

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

5. Other recommendations and proposals

The following recommendations are offered:

RECOMMENDATION D: one of the Consortia presented a FPP that will not be fully funded via IMI/EFPIA which came as a surprise to the Panel who flagged it when reviewing the FPP in the morning. Additionally, the supplemental funding was not secured yet and no credible alternative/risk mitigation/risk management approaches were offered during the Hearing by the Consortium. We recommend finding out ways to discuss this type of funding issue before the Panel meeting.

RECOMMENDATION E: One IE shared with us that, in his view, and for the FPP he worked on, the project management chapter of this FPP was on the weak side as he was expecting both more in terms of quantity and quality of information. This is already addressed in the Guidance document on the FPP (section 5.1), although we recommend strengthening the FPP requirements with project management specifications to harmonise the minimum available information on such an important topic at FPP stage.

6. Acknowledgements

We were helped in our task by all participants in the Stage 2 consensus meetings.

Our thanks to the Independent Experts and Consortia members for being amenable to being “observed” and for the conversations that helped formulate this report. We would like to particularly thank the IMI staff for their help and hospitality before, during and after our stay in Brussels for the consensus evaluation meetings.

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