IMI – 11th Call 2013

Evaluation of Stage 2

7 – 10 October 2014

Independent Observers' Report

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Table of Contents

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 11th Call for proposals by the Innovation Medicines Initiative (IMI).

Further to the evaluation of eligible EoIs submitted in Stage 1 of the IMI 11th Call for proposals which took place from May 13th to 16th 2014, 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 September 9th 2014.

The Call topics are:

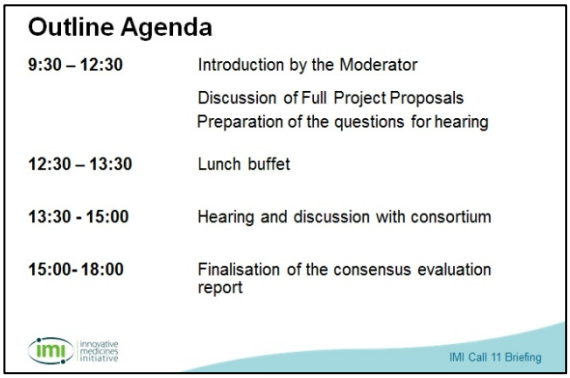
- Topic 1 – Applied Public-Private Research enabling OsteoArthritis Clinical Headway
- Topic 2 – European Platform to Facilitate Proof of Concept for Prevention in Alzheimer's Disease
- Topic 3 – Blood-Based Biomarker Assays For Personalized Tumour Therapy: Value Of Latest Circulating Biomarkers
- Topic 4 – Zoonoses Anticipation and Preparedness Initiative
- Topic 5 – Generation of research tools to enable the translation of genomic discoveries into drug discovery projects
- Topic 6 – ND4BB Topic 6: Epidemiology research and development of novel systemic antibacterial molecules against healthcare-associated infections due to clinically challenging Gram-negative pathogens
- Topic 7 – ND4BB Topic 7: Development of novel inhaled antibiotic regimens in patients with cystic fibrosis (CF) and patients with non-CF Bronchiectasis (BE)
- Topic 8 – EcoRiskPrediction

The submitted FPPs were then remotely evaluated until October1st 2014 by Independent Experts (IEs). Independent Observers (IOs) had also remote access to all submitted FPPs.

The IEs, Coordinators and Consortia, were then brought together in Brussels from October 7th to 10th 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.

Typical agenda:



The Governing Board decision made by written procedure is expected to take place end of October 2014 and the result will be immediately communicated to the Applicant Consortia. Grant agreement negotiation will take then place and final approval and contract signature are to happen by November / December 2014, concluding Stage 2 of the 11th Call.

2. Overall observations

The 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.

An on-site briefing for IEs took place on the morning of four 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. Hugh Laverty, IMI Scientific Officer.

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. Precision the main differences with the Stage 1 : No competition and EFPIA companies are now part of the consortium

With a strong focus on:

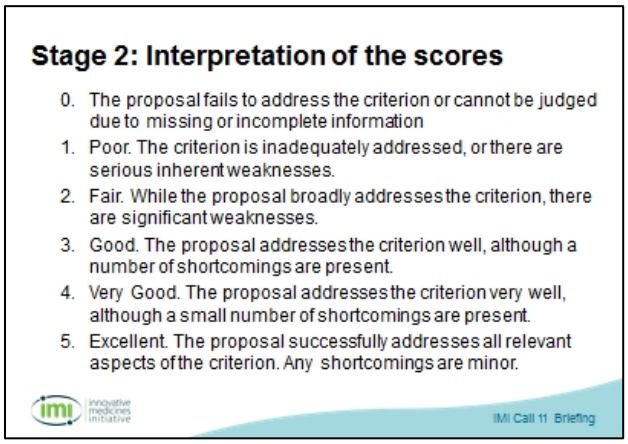
- Consistency between the EoI and the FPP
- Experts' recommendations expressed in the EoI Consensus Evaluation Report have been addressed
- EFPIA contribution and role in the project well documented and integrated
- Project management and ethical issues properly addressed
- Budget/use of resources aligned with the tasks and deliverables for each Work Package.

And according to the following evaluation criteria:

- Scientific and/or technological excellence
- Excellence of the project implementation plan
- Consistency with Call Topic at stage 1
- Potential impact of project results
    - Likelihood of IMI key benefits to be achieved following dissemination / publication of research results.
- Overall evaluation
    - Of assistance to the consortium if it is selected for entering into negotiations

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 reviews were carried out by specific experts. Panels were running in parallel, offering the possibility for interaction if needed (including potential clarification with the Consortium). Experts of the Ethical Panel took part to the Hearings for which they also supplied questions. Their expected output 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 as for stage 1 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 2011 :

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

Fairness and 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 distinguish 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 each proposal.
- 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. 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 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, four days of the briefing and evaluation sessions, Panel discussions and Hearings held in Brussels. We spoke individually with many of the IEs, Ethics experts, 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 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 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. Questions were provided to the representative of the Consortia one hour before the Hearing.
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.

Physical separation between the IEs and the Consortium until the hearing was really well managed with a dedicated employee of IMI "filtering" and regrouping the arrival of the Consortium. Confidentiality is well preserved. Globally the flux between the IEs and the Consortium members is perfectly managed.

Signature of the Consensus report were well managed with no problems as the panel of IEs was more than the minimum of 3 legally needed. See our recommendation B for the IEs who would like to leave the session before the end of the day for a plane.

In the organization of IMI the panel of IEs is managed by IMI Scientific Officer and not by another IE which to our view is really positive. Indeed it allows all the IE to express themselves with liberty and no constraints (could occur for some expert in front of a peer scientific reviewer).

A specific highlight was done on new potential Conflict of Interest to be specifically assessed in this Stage 2 which is really a good approach;

All our interviews done among IEs or Ethical Committee were positive. The Experts found the IMI evaluation process professional, well organized and fair.

<u>RECOMMENDATION A</u>: Even if the topics 1 to 8 are in different domains and the experts without interrelation, some exchanges could occur and confidentiality broken by discussion between the IEs of different projects evaluated in parallel. It could be interesting to remind in the briefing that interaction between the two IEs group is not allowed (in the particular day were 2 evaluation processes are organized in parallel)

RECOMMENDATION B: Signature of the final consensus report. Remind in the briefing that at least 3 experts of the IE panel must sign.

RECOMMENDATION C: Remind more strongly in the briefing of the IEs that the hearing is not to document more the project but at this stage 2 to help them in the scoring of the project. The answers are not written in reports. The project is evaluated "to the state"

RECOMMENDATION D: it appeared that the discussions between the IEs and the Ethical Committee were long, especially when projects included clinical trial. Perhaps it would be more appropriate in the organization to manage a specific timing for discussion between the Ethical Committee and the IEs after the hearing to prevent extended time.

RECOMMENDATION E: some members of the Consortium brought their USB key with the latest presentation and answers to the questions just before the hearing. In one case the PC of the IMI Scientific Officers "crashed" due to the reading of such a key. It does not seem appropriate to introduce any external device in the computer regrouping all the ongoing evaluation of the project.

4.4 Timelines

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

4.5 Moderation of the Expert Evaluation Panels

The expert evaluation panels were chaired and moderated by one IMI's Scientific Officer with another IMI scientific Officer as a "backup", present but not directly interacting. This organization is really "safe" and major.

The moderating Scientific Officers were given considerable support by other Members of the IMI Executive office. A dedicated IT officer and one lawyer 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 independent Expert 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 Evaluator 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. 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.

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.

The Independent Observers wish to emphasize that the conduct of the assessment of IMI Calls is consistent with its rules that guaranty the quality of the evaluation but also that the role of the IMI Moderating Scientific Officers during the expert meeting was central to ensure fairness and impartiality. To our knowledge, this is quite unique and usually it is one of the Experts who is acting as Chairman of the panel session. The high quality of the IMI Scientific Officers moderating the discussion and helping to ensure a high quality of the reports should be awarded.

5. Acknowledgements

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

Our thanks to the Independent Experts, Consortia members and the Ethical Committee 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.

Dr. Nicole Haeffner-Cavaillon and Dr. Olivier Arnaud.