



Innovative Medicines Initiative

11th Call 2013

Evaluation of Stage 1 May 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

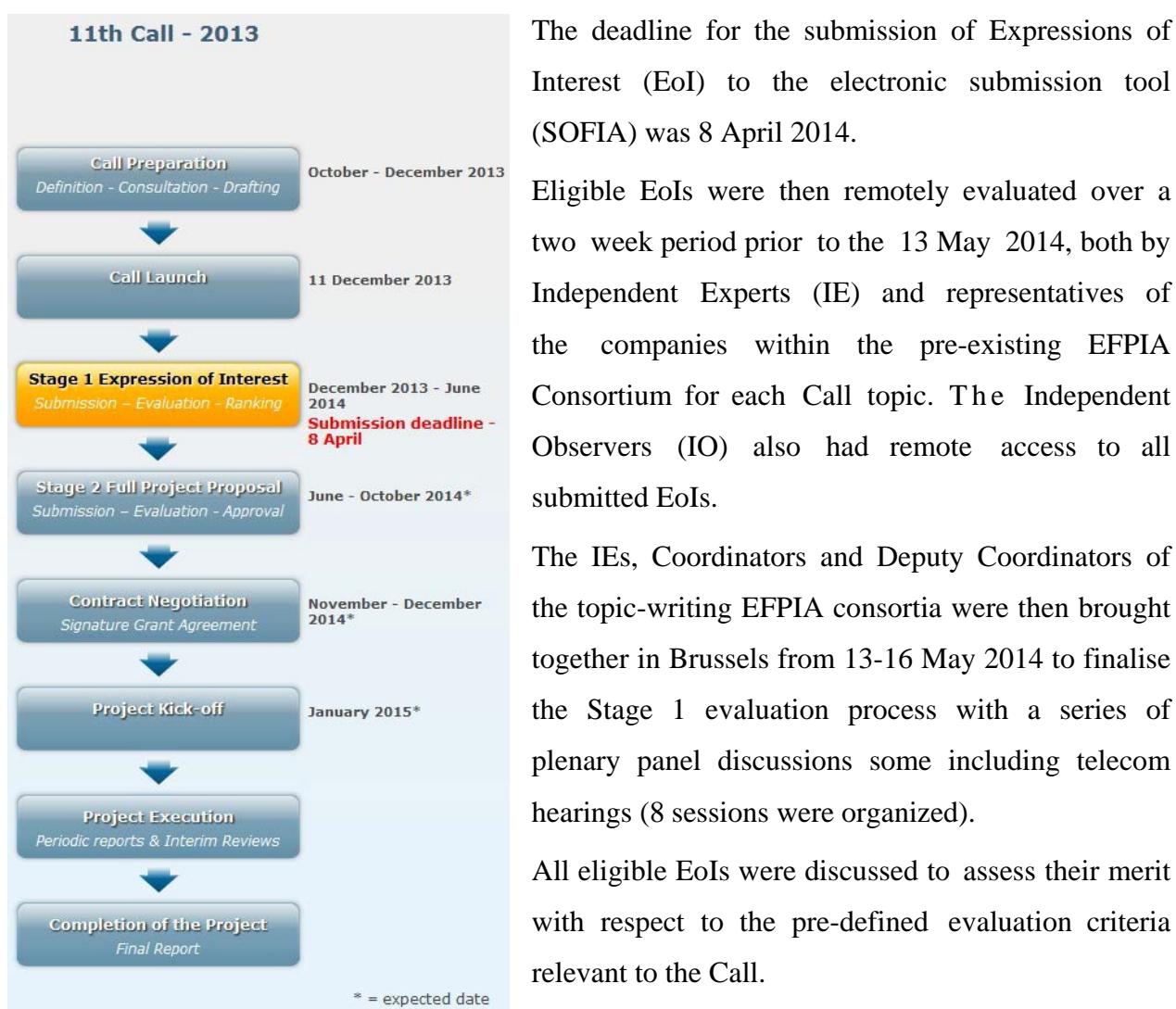
1. Background

This is the report of the Independent Observers for Stage 1 of the 11th Call for proposals by the Innovation Medicines Initiative (IMI). The 11th Call publication date was 11 December 2013. Submission of proposals was invited in response to 8 Call topics:

- *Applied public-private research enabling osteoarthritis clinical headway*
- *European platform for proof of concept for prevention in Alzheimer's Disease*
- *Blood-based biomarker assays for personalised tumour therapy: value of latest circulating biomarkers*
- *Zoonoses anticipation and preparedness initiative*
- *Generation of research tools to translate genomic discoveries into drug discovery projects*
- *EcoRisk Prediction*

Topics under the New Drugs for Bad Bugs (ND4BB) program on antimicrobial resistance:

- *Epidemiology research and development of novel systemic antibacterial molecules against healthcare-associated infections due to Gram-negative pathogens*
- *Development of novel inhaled antibiotic regimens in patients with cystic fibrosis (CF) and patients with non-CF bronchiectasis (BE)*



The evaluations for each topic were spaced throughout the four days with each taking two days. General discussion on the merits of each application, hearings with some applicants, consensus rankings and drafting of the final

Consensus Evaluations were conducted. Each panel was moderated by an IMI scientific officer. Following the decision by the IMI JU Governing Board on the outcome of the evaluation, 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 during Stage 2 evaluations in October 2014. All the rules for submission, evaluation and selection are fully described in the publicly available document IMI-GB-DEC-2012 Annex 3.¹

The detailed evaluation criteria (scoring, thresholds and weighting) are fully described in the publicly available document IMI-GB-DEC-2012-12.²

To fulfil the IMI JU evaluation rules based on transparency, two independent observers were invited to follow all the evaluation process (from the remote evaluation up to the end of stage one).

2. Overall observations

The assessments are based on IOs personal observations and interactions with IEs and EFPIA coordinators as well as IMI staff.

It is noteworthy that both IOs have a strong experience in national and European evaluation procedures.

Nicole Haeffner-Cavaillon belongs to the Inserm Evaluation Department since 2000 and was the principal promoter in 2002 of the EVA tool used for remote evaluation as well as management system. The Inserm evaluation department received in 2012 the certification ISO 9001 by the AFNOR Group. She also was involved in the first year of the evaluation management for the junior and senior ERC grants. She was a scientific independent expert for several national institutions as well as for FP7 calls.

Olivier Arnaud belongs to the Research Patient Foundation JDRF, specialized in Type 1 Diabetes and investing in research projects through a long tradition of organizing calls (*Request for Applicants, Innovative Grants , Postdoctoral Fellowship, Advanced Postdoctoral Fellowship, Career Development Awards, Early Career Patient-Oriented Diabetes Research Awards*).

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

² http://www.imi.europa.eu/sites/default/files/uploads/documents/10th_Call/IMI_Call10_EvaluationForm_Stage1.pdf

He has also participated to specific evaluation of EFSD projects in Dusseldorf in 2013.

2.1. Remote evaluation

The IOs received access to view the Expressions of Interest (EoI) submitted for IMI Call "IMI-JU-11-2013" from 11 April 2014 until the remote evaluation deadline of 8 May 2014. The SOFIA tool was always accessible throughout the evaluation period and did not show any malfunction. For IEs, the tool was of easy use and worked perfectly well. The time allocated for the remote evaluation was sufficient even for the IEs with more than 10 proposals.

2.2. Stage 1 panel evaluation meeting

In the view of both IOs, the evaluation was conducted very professionally, fairly and with commitment from all participants, ensuring an impartial and thoughtful evaluation of all EoIs.

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 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 of the 8 topics
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 8 topics ran smoothly in line with the pre-defined agenda. The meetings were moderated by IMI Scientific Officers.

The IOs 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 2011:³

Excellence: for each proposal, the excellence of the proposals was based on the assessment performed by high quality experts (the minimal number of independent experts considered by IMI is 5. Most of the proposals were assessed by a panel of 7 to 10 experts of which 2 were from the pre-existing EFPIA consortium.

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. Particular attention was taken not to leave documents (proposals or evaluation reports) unattended in an empty office.

The non-disclosure of the identity of the experts was respected during the hearings of the applicants: only the IMI moderator interacted with the applicants (phones were muted during panel discussions).

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

Conflicts 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 from the entire evaluation, and those that would prevent an IE evaluating a single proposal. The IMI legal team was involved in assessing the conflicts in both situations.

In the IOs 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 for all 8 topics to benefit of an outstanding quality assessment.
- There were no violations against the rules of the published evaluation guidelines.

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

- 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, and hearings with the applicants were fair and transparent. Hearings were organized in a very effective manner and appeared universally welcomed.
- A consensus was reached by the IEs on the scoring and ranking of all proposals in the absence of the EFPIA representatives.
- 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.

3. Role and approach of the independent observers

3.1. Role of the independent observers

As stated in section 3.4 of the “*IMI Rules for submission, evaluation and selection of Expressions of Interest and Full Project Proposals*”, 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 hearings. Their liberty of access to any room review and at any time for the IOs was fully understood and respected.

IOs spoke individually with many of the IEs, 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.

More than fifty IEs were selected and invited by the IMI JU as described in section 3.2 of the “IMI Rules for submission, evaluation and selection of Expression of Interest and Full Proposals.” All IEs fulfilled the criteria stipulated therein. 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.

4.1. Remote Evaluation

The IEs had approximately three weeks to evaluate the EoIs remotely. This process worked well with the IE providing full reports prior to the on-site Brussels’ review 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 ensured they were taken into account through the discussions.

4.2. The Evaluation Tool

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

The user-friendliness and usefulness of SOFIA were pointed by several IEs.

4.3. Timelines

According to IEs, the time allocated for remote evaluation of the EoIs appeared adequate.

4.4. Role of the EFPIA coordinators and deputy coordinators

At the beginning of each individual topic plenary session , the EFPIA Coordinators and/or the Deputy Coordinators detailed the requirements of the topic and described how the EFPIA representatives had approached their own remote evaluations.

4.5. 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.

4.6. Moderation of the Expert Evaluation Panels

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

The IOs have noted that 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 which allow a perfect transparency and efficiency in the evaluation process.

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.

The 8 scientific Expert Panel discussions proceeded as follow:

1. Each panel member including the EFPIA representatives for each Topic were 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 during the remote evaluation did not contribute to the final consensus evaluation scoring.
3. The Rapporteur responsible for the writing of the Consensus evaluation report was appointed prior to the meeting, was invited to briefly describe the key points of the EoIs 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 EoIs. Special care was taken by the IMI moderators to ensure that all IEs expressed their opinion. The discussion between EFPIA representatives and IEs were constructive, open and cordial. In order to answer certain remaining questions about some of the EoIs, the panel members prepared a list of questions for the applicants. It is important to underline the very helpful role of the IMI moderator during this phase.

5. When considered necessary by the expert panel, the top ranked EoI applicants were invited to take part in hearing on the second day of the evaluation. The questions for the hearing were sent by email on the evening of the first day of the evaluation. During the hearing the IMI moderators read the questions and the consortia responded. Up to 45 minutes where allowed for all answers. All hearings unfolded as planned and contributed to a better understanding of the EoIs.
6. The EFPIA experts left the room while the IEs finalised the scores and ranking based on the earlier discussions and answers provided by the applicants. The consensus evaluation reports were then prepared. During this stage, the involvement of IMI moderators was very important to secure a broad consensus and that the final scores were in accordance with the comments or recommendations of the final consensus report.
7. As a minimum, the Rapporteur for each EoI signed the Consensus Evaluation Report to indicate that the report reflects the views of the entire panel.

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 and IMI lawyers, 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.

4.7. Hearings

The IMI JU rules state that up to four of the top ranked proposals may be invited 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 to each EoI for the hearings in a single topic. The applicants received the questions the evening before the hearing, together with information on when they must be available for the hearing itself. The hearing is a Q&A session: the 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.

During each hearing, the text of the applicants EoI was displayed on the screen to allow the viewing of figures and graphics. This provided additional support to aid discussion and was praised by panel members.

5. 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.

Both IOs agreed that the evaluation was conducted by the IMI staff in a very professional way. This stage 1 evaluation involved more than fifty experts and an important logistics preparation of the meetings (travels, hotel booking, printing evaluation reports, call documents, applicant proposals, IT system etc.). None of the experts expressed any complaints, they rather emphasized the quality of the information they received, the professionalism of the staff and were very positive on the meeting organisation.

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.

6. Acknowledgements

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

Our thanks to the IEs 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.

Dr. Nicole Haeffner-Cavaillon and Olivier Arnaud. Brussels, 22/05/2014