

IMI – 6th Call 2012

Evaluation of Stage 1

July 2012

Independent Observers' Report

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Abbreviations:

EFPIA - European Federation of Pharmaceutical Industries and Associations

EoI - Expression of Interest IMI Innovative Medicines Initiative

1. **Background**

This is the report of the independent observers for Stage 1 of the 6th Call for proposals by the Innovation Medicines Initiative (IMI). The 6th Call was launched 24th May 2012 and submission of proposals in response to one Call theme: Combating Antibiotic Resistance: NewDrugs4BadBugs (ND4BB), which falls under one of the new key research priorities: ‘infectious diseases’, which is correlated to the Disease Drug Efficacy Area of Interest, was invited. The Call covers two topics (Topic 1. Innovative Trial Design & Clinical drug development, and Topic 2. Learning from success and failure & Getting Drugs into Bad Bugs), with Topic 1 further divided into two subtopics (Subtopic 1A, Workpackage 1-4 and Subtopic 1B, Workpackage 5). NB. A further Subtopic 1C (Workpackage 6 & 7) will be launched later in 2012 under a new Call. The IMI website accepted Expressions of Interest (EoIs) in response to the Call up until a deadline for submission of 9 July 2012.

Submitted EoIs were then remotely evaluated over a two week period spanning 10 July to 23 July 2012, both by independent experts and by representatives of the companies within the planned EFPIA consortium for the Call topic. The independent experts, along with the coordinators and deputy coordinators of the Call-generating EFPIA consortium, were then brought together in the Crowne Plaza meeting rooms in Brussels from 25-27 July 2012 to finish the Stage 1 evaluation process with a series of plenary, panel discussions and telecom hearings, resulting in a consensus ranking of the submitted EoIs for each Call topic. The results of these evaluations will be communicated to applicants in early August 2012, concluding Stage 1 of the 6th Call for proposals.

2. **Overall observations**

The observers found that the Stage 1 evaluations were conducted professionally, fairly and with commitment from all participants to ensure an impartial and thoughtful evaluation of all EoIs. The IMI team again performed an outstanding job in publishing and publicising the Call, organizing the EoI submission and evaluation process, contacting highly professional and well qualified professionals and in putting together the onsite evaluation meetings. The clarity of the onsite briefings for evaluators was especially appreciated as well as the excellent organization and coordination of the process. The 2 ½ day process was held according to the plan and all panels for the 2 topics run smoothly according to the pre-defined agenda.

In our opinion:

- There were no violations against the rules of the published evaluation guidelines. The evaluators were of a very high quality and in possession of the relevant expertise for each of the topics.
- All participants approached their tasks professionally.
- The evaluation of the proposals, and the discussions in the panels, were exhaustive, frank and fair.
- Hearings, where required, were organized in a very effective manner and appeared universally welcomed.
- A consensus on scoring and ranking was achieved by the expert evaluators in the case of all proposals, with the opinions of all experts on a panel being considered and discussed in equal terms.

As with the observers’ reports from the previous Calls, we do have some ongoing recommendations for slight modifications that may improve the Stage 1 process for future Calls. These are reported in detail in Section 4 of this report.

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 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 method of the independent observers

In performing their task the independent observers had access to all written information supporting the Stage 1 evaluation process. They attended all 2 ½ days of evaluation sessions at the Crowne Plaza meeting rooms in Brussels 25-27 July 2012. While there, they sat in on the panel discussions, attended the briefing sessions, and spoke individually with many of the expert evaluators and EFPIA representatives present. They also had ample chance to speak with IMI employees, including the Scientific Officers acting as moderators, with IMI lawyers, the IT support specialist and with Michel Goldman, the Executive Director of the IMI.

4. Observations and recommendations

In the following sections we record our observations on the Stage 1 evaluation process, note improvements in the process compared to that for previous Calls, and give some recommendations for modifications which we feel might benefit future Calls. These observations and recommendations should be read against the background of our general comments in section 2 above, where we express our overall opinion that the evaluation process has been well, carefully and fairly implemented throughout and that the overall process is of excellent quality and follows international peer review standards.

4.1 The Call

The observers noted that with this Call 6, there was only 6 ½ weeks between launch (24 May) and the deadline for EoI submission (9 July), compared to the 10 weeks allowed for Call 5 and 13 weeks for Call 4. While the unique circumstances necessitating this short timeframe for Call 6 were clarified, it was a concern raised by many evaluators and may have limited the number of EoIs submitted fully addressing the Call. In spite of this, two webinars (24 May 2012 and 12 June 2012; see 4.2 below) and a workshop organised during the IMI Stakeholder Forum (30 May 2012), helped publicize the Call effectively.

The observers were again pleased to see, following recommendations from previous Calls, a greatly expanded level of detail with each of the individual calls. Each of the 2 topics was explained not only on the relevant documents but also during the webinars. Concrete examples, detailed information and key expected deliverables were provided to guide applicants on the submission of the EoI. Combined with clear communication this led to close agreement between the independent remote scoring and ranking performed by both expert evaluators and EFPIA which also facilitated the panel discussion in Brussels. Call requirements were detailed to the level of specifying individual Work Packages for each of the topics. As an ongoing recommendation in this later respect, EFPIA and IMI should continue to keep in mind the balance between 'prescription' and allowing a certain degree of 'interpretation' in the EoI.

4.2 Guidance to applicants

It was clear from the evaluation panels that most applicant consortia had grasped the need to attempt to adhere closely to the demands of the Call. This was presumably due, at least in part, to the provision of webinars for each Call topic in which potential applicants who had been unable to attend the Open Information Day in Brussels had a chance to learn about the individual Call topics and details of the application procedure. We recommend the continuation of this practice.

A small number of applicant consortia submitted proposals that were only partially in scope. This prompted discussion on the scoring and recommendation process for preparation of the Consensus Reports. The Call documentation is clear on the requirement to fully address all of the criteria of the Call Topic, yet the scoring can seem a little inflexible in dealing with and providing recommendation/feedback for a proposal that only partially addresses the Call Topic, yet which is of high quality for the parts that are addressed. While this is dealt with in the Rules we recommend that the IMI JU further consider how such proposals are scored and how feedback is best given to the applicants.

RECOMMENDATION A: It is recommended that the IMI JU further consider how proposals that are only partially in scope are scored and how feedback is best given to the applicants.

4.3 Expert evaluation panels

The experts in the evaluation panels were selected and invited by the Scientific Officers as described in “Rules for submission, evaluation and selection of Expression of interest and Full Proposals, 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 each panel.

In addition there was in each evaluation panel the Coordinator and/or Deputy Coordinator (or appointed representative) of the appropriate EFPIA consortium. This combination of independent and EFPIA-associated experts was beneficial for the evaluation. The EFPIA Coordinators and Deputy Coordinators were provided with the 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. While the scores provided by the EFPIA experts did not contribute to the final consensus evaluation scoring which helped to rank the EoIs, 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.

4.3.1 Hearings

The observers were pleased to note the continued use of telecom Hearings. A maximum of 4 of the top ranked proposals from the remote evaluation were asked to take part in these hearings. Proposers were asked to answer specific and suitably detailed questions (maximum 5-7 specific questions per EoI) formulated by the independent experts and EFPIA representatives. We strongly recommend this practice be continued.

There was some discussion amongst the evaluators and the IMI Team, as to whether Hearings should be obligatory if it is felt that the applicant proposals contain sufficient information to make a clear decision without further questions/clarification. We recommend that the use of Hearing is further clarified in the Guidelines and communicated by moderators as appropriate.

RECOMMENDATION B: It is recommended that the Guidelines be updated to reflect that, with the help of the moderator, the evaluators should first decide whether or not they require Hearings to assist their decision process. Then, if there is a requirement for hearings, between a minimum of 2 and up to a maximum of the top 4 ranked proposals from the remote evaluation be requested to join the Hearing.

4.4 Timelines

4.4.1 Timelines for evaluation of Expressions of Interest

The time allotted for remote evaluation of the EoIs, albeit shorter than previously (two weeks on this occasion) appeared to be adequate. No complaints about the timeframe were received from the evaluators.

4.4.2 Timelines for Preparation of FPP

Due to time constraints for this Call 6 the IMI JU had worked on streamlining the process for preparation of FPP. The time allotted for preparation of FPP (6 weeks only) was not commented on by the EFPIA representatives on this occasion, but should be monitored further at Stage 2.

4.5 Guidance for evaluators

As with previous calls, the evaluators possessed a good understanding of the process following teleconferences organized by the Scientific Officers for all evaluators during the remote evaluation. During these teleconferences, evaluators could discuss the process with IMI staff and the EFPIA consortium coordinators.

4.6 Role of the EFPIA coordinators and deputy coordinators

In addition to comments in section 4.3, it was again noted that EFPIA had fully engaged with the evaluation process and the panel discussions, with the Coordinator and Deputy Coordinator themselves often being strong stakeholders in the respective call topic, and not simply a ‘representative’ of the consortia. As an ongoing recommendation, we endorse 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.

4.7 Moderation of the expert evaluation panels

As with previous calls, the evaluation sessions were moderated by Scientific Officers from the IMI office. Once again the Scientific Officer was given considerable support by another member of the IMI office staff. A dedicated IT officer and two lawyers were available throughout the sessions, relieving the Scientific Officer of some of the administrative burden and allowing them to concentrate more fully on their role as moderators. The presence of the lawyers allowed the Secretariat to answer directly any questions regarding potential conflicts of interest from the evaluators. All Scientific Officers fulfilled the essential and often difficult role of moderating the evaluation panels with intelligence and fairness, and the standard of moderation across panels was seen to be relatively homogeneous. Moderators answered evaluators questions rapidly and supplied information where needed, helping the panels to reach an impartial consensus. Signs of the effectiveness of the moderators’ handling of the panels were the observations that the experts functioned as teams, worked well together and the writing of the consensus reports proceeded smoothly.

As highlighted in 4.2, a small number of applicant consortia submitted proposals that were only partially in scope, and failed to fully address all Call criteria. This prompted some discussion on the scoring and recommendation process for preparation of the Consensus Reports. As recommended under 4.2, it is suggested

that the IMI JU further consider how proposals that are only partially in scope are scored and how feedback is best given to the applicants..

4.8 Choice of Rapporteur

The Rapporteur for each EoI is an expert evaluator chosen to present that EoI to the evaluation panel and then to be the primary scribe for the writing of the consensus evaluation report for that EoI. This is an important role, with an obvious, 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.

The observers were pleased to see that Rapporteurs were once again pre-assigned before they arrived in Brussels, thus in principle giving them time to prepare for this role.

4.9 Remote evaluation

It was noted that with one exception, all independent evaluators were able to be present at the evaluation sessions in Brussels. The independent evaluator who was not present was for most of the session linked to the panel via teleconference.

4.10 The evaluation tool

The online submission and evaluation system appeared to have functioned effectively.

All independent evaluators were able to see the other evaluators' (anatomised) scores and comments to allow better preparation for the onsite evaluation meetings.

As with Call 5, a remote ethics screening stage has been added after the completion of Stage 1. It will be interesting to see the impact of this new process on Stage 2.

4.11 Enhancement of the Stage 1 selection process.

Before re-iterating some of the points noted that could be incorporated or born in mind to enhance the Stage 1 selection process for future Calls, the Observers wish to compliment the IMI team on having achieved a really professional and smooth-running evaluation process. While the primary role of the Independent Observers is to ensure fairness and transparency, the incremental improvements seen through Calls 1 to 6 as a result of incremental improvements based on suggestions in these reports and listening to the IMI Team, evaluators and EFPIA attendees, have played a significant part in that improvement.

Three points are highlighted from this report:

- The balance of input from both Evaluators and EFPIA is considered appropriate, and this balance should be carefully maintained, ensuring clear communication of the respective roles.
- It is suggested that a baseline check of all proposals be made by the IMI Scientific Officers prior to their remote evaluation. This may prevent proposals which either lie out of scope or fail to address all call criteria, from being reviewed. This would hopefully speed the review making decision.
- We strongly endorse the continued use and development of Hearings as an integral part of the Stage 1 process.

- The use of pre-informed Rapporteurs, ensuring that they have timely notice of their role and a clear brief before coming to Brussels, should continue.

5 Acknowledgements

The independent observers were helped in their task by all participants in the Stage 1 consensus meetings, and they would like to thank the independent experts and the EFPIA coordinators for being so amenable to being 'observed', and for all the conversations that helped so greatly in the formulation of this report. They would also particularly like to thank the IMI staff for their help before, during and after our stay in Brussels for the consensus evaluation meetings.