

IMI – 5th Call 2012

Evaluation of Stage 2
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Independent Observers' Report

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Abbreviations:

EFPIA - European Federation of Pharmaceutical Industries and Associations, EoI - Expression of Interest, FPP - Full Project Proposal, IMI - Innovative Medicines Initiative

1. Background

This is the report of the Independent Observers for Stage 2 of the 5th Call for proposals by the Innovation Medicines Initiative (IMI). The 5th Call was launched 6th March 2012 and submission of proposals in response to 1 Call theme: the European Lead Factory was invited, covering two topics (i. European Screening Centre, and ii. Joint European Compound Collection).

The resulting Expressions of Interest (EoIs) submitted by applicant consortia were evaluated in June 2012, leading to the selection of one highest-ranked EoI for each topic. This marked the end of 'Stage 1' of the 5th Call. In Stage 2, the consortium responsible for generating the highest-ranked EoI for both Call topics were then invited to join together with the matched consortium of EFPIA member companies, forming a larger project consortium which together would submit a single Full Project Proposal (FPP).

The FPP was then evaluated by Independent Experts, first through remote evaluation and then in a panel discussion in Brussels 27th Sept 2012. The Stage 2 evaluation process ended with the generation of a consensus evaluation report for the FPP, which was then communicated to the applicants.

2. Overall observations

The Observers found that, as with Stage 1, the Stage 2 Evaluation was conducted professionally, fairly and according to the established procedures and regulations. Both Observers noted the dedication of all participants to ensuring an impartial and thoughtful evaluation of the FPP. The IMI team once again performed an outstanding job in organizing the FPP submission and evaluation process, contacting highly professional and well qualified professionals to perform the remote and face to face evaluations and in putting together the onsite evaluation meetings.

In particular, and as highlighted in more detail below, significant improvements in the procedures from the previous Call were obvious to both Observers. The clarity of the briefings for Evaluators was especially appreciated as well as the excellent organization and coordination of the process in particular as it relates to the organization of the complex steps in the process such as the face to face session with applicant consortia.

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.
- The evaluation of the proposal was fair and transparent.
- The consensus evaluation report generated incorporated the opinions of all Experts and truly represented the consensus opinions of the panel.

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 were briefed on their role and had access to all written information supporting the Stage 2 evaluation process. They attended all panel discussions at the Crown Plaza Hotel in Brussels on 27th Sept 2012 and spoke individually with many of the Expert Evaluators and the IMI staff that were present. The Observers and Evaluators were briefed carefully by IMI on the evaluation process and the principles to follow. In doing this, the Observers were greatly encouraged by Michel Goldman who, during his briefing session, had expressed his desire that the participating Evaluators should speak freely with the Independent Observers. The Observers also had ample chance to speak with other IMI employees that were present, including the Scientific Officers and IMI lawyer, with the IT and other support staff (who quickly resolved any small technical and administrative issues).

4. Observations and recommendations

In the following sections we record our observations on the Stage 2 evaluation process, collect comments from the participants (with particular emphasis on those from the Evaluators), and give some recommendations for modifications that we feel could help further improve the process for future calls. In this instance and a credit to the response of the IMI JU team to the reports and recommendations of the Independent Observers from previous Calls, we have no 'specific' recommendations, rather 'on-going' recommendations to maintain the good quality and standard of the process. 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 follow international peer review standards.

4.1 Preparation of the Full Project Proposals

The preparation of the FPPs following the choice of the top-ranked EoIs during Stage 1 evaluation is a demanding task. Within the space of around 3 months, the coordinators (in most cases coming from EFPIA member companies) are required to bring together the full consortium and then lead it to generate the FPP. The time allocated for this process is rather short, however on this occasion as previously it was generally considered to be adequate.

The Independent Observers report from Call 4 Stage 2 made specific recommendations to:

i. further review the template and guidelines for the Stage 2 FPP submission and evaluation forms, in order to give more focus to providing Evaluators with clear information on the consortium Integration, Implementation and Input (especially from newly added EFPIA members), and ii. for the Guidelines to Applicants (and Evaluators) that Integration, Implementation and Input are new criteria for assessment in Stage 2 and that irrespective of the Stage 1 evaluation projects will only be recommended for funding if these Stage 2 criteria are satisfied.

We are pleased to note that the IMI JU team has fully reviewed the corresponding text of the Guidelines and modified this to put a greater emphasis of the ‘marriage’ between the consortium and EFPIA partners in writing the FPP and that the experts are considering this when assessing the proposal (under criterion 2 Excellence for the project implementation plan).. On this Call 5 Stage 2 the FPP certainly reflected these changes to the Guidelines, and it will be interesting to see how this develops in Call 6 and beyond.

4.2 Remote Evaluation Stage

Following the generation of the FPPs, the Expert Evaluators had around 10 days in which to evaluate them remotely. This process worked very well for the scientific Evaluators and was facilitated by a webinar briefing session.

As recommended in the Call 3 Independent Observers Report, and implemented from Call 4, the ethical reviewers now have timely notice, a clear brief and read/write access to the SOFIA tool to enable them to evaluate the FPP and ahead of the Stage 2 panel meetings. It is understood that for future Calls the ethical reviewers will have a dedicated form within the SOFIA, and it will be interesting to see how this develops in Call 6 and beyond.

4.3 Expert Evaluation panels

The Experts in the evaluation panels were selected and invited by IMI JU officials 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. As mentioned in par. 3.2, the Evaluators were briefed by the Scientific Officer, in addition to the more general process, about any specific issues related to the project under evaluation they needed to be aware of (e.g. approval of changes in project budget that would require an IMI Board decision, the role of IMI in general communications about projects). The Scientific Officer instructed the Evaluators upfront to stick, during the hearing (see below), to a formal process: e.g. not to engage in open debate with the Coordinators or to disclose any judgment, but to focus the hearing on obtaining further explanations on specific issues that were raised by the panel.

The Observers were impressed to see that the composition of the panel was essentially the same as that in the Stage 1 evaluation, with only one replacement due to a conflict of interest identified in Stage 1. Most of the Evaluators were thus already familiar with the project to be evaluated, the considerations of the panel in Stage 1 and with the views and Expertise of each other. Panel members were also aware of the nature and goal of the evaluation process, their responsibilities, the choices available to them and the consequences of their decisions and recommendations. This obviously contributed to consistency in the evaluation decisions and very constructive and open discussions in panels, as observed.

The basic structure for the onsite panel discussions is as follows: 1) each panel member is invited to briefly describe his/her main points of concern about the proposal and then the panel formulate a list of questions for the project coordinators, 2) The EFPIA and academic coordinators of the consortium are then invited into the panel to give a short presentation and to answer questions and comments posed by panel members, then 3) the panel of Expert Evaluators work on the preparation of their recommendations and the consensus evaluation report.

In all sessions, the Expert reviewers brought specific knowledge, perspective and commitment to the discussions with the result that each FPP was critically examined and clear recommendations made. A considerable time was spent preparing a list of very detailed and well structured questions that were to be addressed during the hearing session. Much effort was made to improve the proposals and adjustments were suggested that would not have been possible without meeting face to face. Preparing the questions, discussing those with the applicants as well as defining adjustments and recommendations was a very beneficial result of the onsite evaluation. Since the implementation of recommended adjustments to the FPP falls to the responsible IMI scientific officer, the active involvement of the scientific officers in the evaluation discussions is of critical importance. As noted in our report on Stage 1, we were again pleased to observe that this involvement was aided by the provision of administrative support for the Scientific Officers.

The Independent Observers report from Call 4 Stage 2 made specific recommendations that IMI Scientific officers leading the onsite evaluation panels take 5-10 minutes to go through a standard check list that will describe what is expected from the Evaluators at Stage 2, what is the criteria, the flow of the process and answering questions if necessary. We were pleased to see that this was implemented in this Call 5 Stage 2 and look forward to seeing the wider benefit for future Calls addressing multiple Topics with different Moderators.

4.4 Consensus Evaluation Reports

A Rapporteur was chosen from the Evaluation panel to lead the development of the list of questions for the hearing and the writing of the consensus report. During the hearing, the panel adhered to the timing set and to the scope of the questions prepared jointly. The panel took a considerable amount of time to work on the final recommendation and the consensus Evaluation Report. Because the report was made during the panel sessions it reflects well the view of the entire panel of Evaluators and in general the panel members quickly reached agreement on the main points.

4.5 Budgeting

No budget issues were raised by the Evaluators for this panel.

4.6 Ethical Review

As noted, two ethical Experts, who perform the ethical screening at the end of Stage 1 for the highest ranked EoIs, had access to the SOFIA to contribute to the FPP evaluation. On this occasion the IMI JU team took the pragmatic decision not to invite the ethical reviewers to the panel meeting, since significant ethical issues had not been raised for this particular Call. We understand that ethical reviewers will again be invited to the panel for Call 6 Stage 2, and

that the ethical review is under on-going improvement to continue to recognise its importance and we look forward to seeing how this develops.

4.7 Moderation of the Expert Evaluation Panels

An IMI Scientific Officer provided moderation of the Expert evaluation panel and was well prepared and well acquainted with the FPP and the consortium. The Officer fulfilled the essential and often difficult role of moderating the evaluation panels with intelligence and fairness, answering Evaluators questions rapidly and supplied information where needed, helping the panel to reach an impartial consensus. The Scientific Officer took this role as moderator seriously, actively facilitating the discussions by assisting to organize the questions and suggestions on exact wording of recommendations to improve the project monitoring (e.g. on key performance indicators), without influencing the content of the Consensus Evaluation Report at any point. The Observers consider it as good practise that the Scientific Officer was present throughout Stage 1, during the discussions with the EFPIA coordinators and at Stage 2 evaluations. This ensures that any critical issues, with a potential to block negotiation (e.g. because they could not be accepted by some consortium parties or would raise concerns from IMI) or which could impede implementation of a particular project, were identified early enough to be addressed in time. The Observers were pleased with this aspect of the Evaluation process.

4.8 Interim Review

The Independent Observers report from Call 4 Stage 2, made specific recommendations that during the generation of the FPPs, the coordinators should be required to generate a series of (4-5) 'High Level' Deliverables, relating to the objectives in the Call Topic, against which project progress will be reviewed at the interim review level. We were pleased to see that this was partially included in this Call 5 Stage 2 FPP and make the recommendation to explore how this could be generalised for future Calls, acknowledging that at the interim stage the projects will be assessed based upon all of their objectives, the degree of achievement of the project work plan for the relevant period and the related deliverable as laid out in their respective description of work.

5. Acknowledgements

The Independent Observers were helped in their task by all participants in the Stage 2 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.

The Independent Observers would also like to recognize IMI efforts in setting up a new evaluation venue that appears to be more cost effective and that promotes interactions between the different Evaluators, the IMI officers and the Independent Observers.