

IMI – 3rd Call 2010-2011

Evaluation of Stage 2
July 2011

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 3rd Call for proposals by the Innovation Medicines Initiative (IMI). The 3rd Call was published in October 2010 and submission of proposals in response to 7 Call topics was invited. The resulting Expressions of Interest (EoIs) submitted by applicant consortia were evaluated in February 2011, leading to the selection of one highest-ranked EoI for each topic. This marked the end of ‘Stage 1’ of the 3rd Call. In Stage 2, the consortium responsible for generating the highest-ranked EoI for each Call topic was then invited to join with the matched consortium of EFPIA member companies, forming a larger project consortium which together would submit a Full Project Proposal (FPP). All consortia invited to do so submitted FPPs.

The FPPs were then evaluated by independent experts, first through remote evaluation and then in a series of panel discussions in Brussels from 5-8 July 2011. The Stage 2 evaluation process ended with the generation of consensus evaluation reports for each FPP, which were then communicated to the applicants.

2. Overall observations

In general, the observers found that, as with Stage 1, the Stage 2 evaluations were conducted with great professionalism and according to the established procedures and regulations. As mentioned in our report on the Stage 1 evaluation process in February, the efforts made by all participants to ensure an impartial and thoughtful evaluation of proposals were striking. The IMI team has once again managed the process of organizing the evaluation meetings very efficiently.

In our opinion:

- There were no violations against the rules of the published evaluation guidelines.
- The evaluators generally possessed sufficient and relevant expertise and displayed the utmost professionalism.
- The evaluation of the proposals was fair and transparent.
- The consensus evaluation reports generated by all panels incorporated the opinions of all experts and truly represented the consensus opinions of the panels.

Alongside these general observations we do, as with Stage 1, have some recommendations for modifications that might improve the Stage 2 process for future Calls, particularly concerning the ethical review procedure. 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 *Moderating consensus meetings* document, pages 6-7, the role of the independent observers is as follows:

“Independent Observers will observe the Call. The role of the Observers is to verify that the evaluation is done according to published evaluation guidelines and rules.”

“The Observers will produce a report after the evaluation including their ‘observations’ and they may point out unclear aspects of the evaluation and they can also propose improvements for future evaluations.”

3.2 Working method of the independent observers

In performing their task the independent observers had access to all written information supporting the Stage 2 evaluation process. They also attended all the evaluation sessions held at the IMI offices in Brussels from 5-8 July 2011. While there they sat in on the majority of the panel discussions, attended the daily 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 those acting as moderators, and with Michel Goldman, the Executive Director of the IMI.

As well as soliciting opinions from participants the observers found that some moderators and several of the participants requested interviews in order to give us the benefit of their thoughts on the process. In doing this, they were greatly encouraged by Michel Goldman who, during his daily briefing sessions, had expressed his desire that participants should speak with the independent observers.

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 improve the process for future calls. The most important of these recommendations are designated by “Recommendation A, B, C...etc”. 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 carefully and fairly implemented throughout.

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 and it was generally thought that more time might have resulted in more precisely written proposals.

Several evaluators commented that the FPPs were extremely long and sometimes rather poorly structured, with considerable overlap and redundancy in the writing, which did not make the evaluation process any easier. Some evaluators suggested that the proposers should be requested to focus their FPPs more heavily on the work packages and that they might also be asked to concentrate on detailing work to be carried out during the early stages of the project, for instance during the first 18 months.

Changes in composition of the consortia between Stage 1 and Stage 2 were again the focus of some discussion. In both the daily briefings and in several individual cases the IMI office clarified the issue by stating that changes in the composition of the applicant consortium between stages 1 and 2 were only permissible following specific recommendations in the Stage 1 evaluation reports that specific expertise should be added to, or removed from, the consortium.

A comment repeated from the Stage 1 evaluation was the issue of one PI taking part in more than one proposal, with, for example, the consequence that research infrastructure (such as experimental animal facilities) could receive funding via several funded projects. It was also questioned whether participants appearing in more than one proposal would have the capacity to take on all the assigned tasks.

Project coordinators again stressed the very great value of having the IMI scientific officers involved in helping to guide the formation of the FPP, and praised the helpfulness of the IMI JU staff during the writing of the FPPs.

Recommendation A: If possible, allow more time for the generation of the FPPs in future calls. Consider changing the guidance on FPP generation with the goal of reducing redundancy in their formulation.

Recommendation B: Written guidelines detailing the circumstances under which changes in the composition of consortia between Stages 1 and 2 are permissible should be made available to evaluators.

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 well for the scientific evaluators, although some again mentioned that it would have been useful to their preparation for the panel discussions if they could have been provided with access to the other evaluators' remote reports after submitting their own, rather than having to wait until their arrival in Brussels to see these.

Due to technical short-comings, the ethics reviewers were, however, not able to fill out and submit the individual ethics review forms on-line. They were instead requested to submit their comments within the scientific evaluation form, which was inappropriate for the task and lead to confusion and a variable outcome. These technical problems should be corrected for the next call evaluation.

Recommendation C: Ensure that ethical reviewers are able to have remote access to the individual ethics review forms for submission of their comments.

4.3 Expert valuation 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.

The composition of panels was essentially the same as those in the Stage 1 evaluations, with only a few replacements. 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 the very constructive and open discussions in panels, as observed.

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. Much effort was made to improve the proposals and adjustments were suggested that would not have been possible without meeting face to face. Defining such adjustments was a very beneficial result of the 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 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 formulates 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.
- 3) Following this Q&A session, the panel of expert evaluators work on the preparation of their consensus evaluation report.

The first part of this process, during which the panellists define their concerns, was very useful, with key points and deviating opinions immediately highlighted. We were pleased to see that extra space has been devoted to this important element as compared to the process for last year's 2nd Call.

We noted some variability in the procedure for the second part of the process, the evaluators' Q&A with coordinators, between the different projects. In some panels the consensus evaluation score was discussed before the Q&A hearing, and in others afterwards. The time used for the coordinators' presentation of the project varied considerably, and hence also the time available for Q&A. In some panels the IMI JU scientific officer took the lead in managing the Q&A, in others the appointed expert rapporteur. We would therefore suggest that the IMI JU scientific officers develop and agree on a common structure for the Q&A process.

The time set aside for the third part of the process, the generation of the consensus report, was sufficient in all cases.

Recommendation D: Develop a more standardized template for the evaluators' face-to-face meeting with the project coordinators.

4.4 Consensus Evaluation Reports

We noted that in some panels not much emphasis was given to the numerical scores awarded, the general feeling being that if the FPP score was above threshold, that was enough. Given the fine-grained nature of the FPP scoring system, we suggest that more guidance be provided to evaluators about how to use the scoring system in the generation of consensus evaluation reports.

4.5 Budgeting

Some evaluators mentioned the lack of detail regarding both the nature and magnitude of the in-kind contribution of the EFPIA partners as described within the FPPs. EFPIA coordinators attributed this deficiency to the limited time available for meeting with the selected academic consortia, together with uncertain staffing availability from the industrial partners. For several FPPs the evaluators also noted an imbalance in the funding contributions expected from IMI and EFPIA

sources. Michel Goldman explained in his briefing sessions for all evaluators that the aim of achieving 1:1 matching in IMI-EFPIA funding for the initiative needs to be considered at the overall initiative level, rather than at the individual project level, but nevertheless some evaluators expressed concern at the comparatively low level of the contribution from the EFPIA part of the consortium for certain Call topics in particular.

4.6 Ethical Review

Ethical reviewers were invited to review the ethical aspects of the FPPs. For each topic, two ethical experts were invited to be a part of the main scientific evaluation panels and the task of these reviewers was to identify any ethical issues either addressed insufficiently or neglected in the proposals, and suggest or request clarifications or amendments. There was also the ultimate possibility of rejecting a proposal on ethical grounds (not found necessary in any case).

The procedure for ethical review has been amended since the 2nd Call, allowing ethics reviewers to meet the project coordinators in all cases. While this change is to be welcomed, it was apparent both from observation and from reviewers' comments that the current procedure has potential for further improvement.

Apart from the already-mentioned problem with online access to the individual ethical review forms (see Section 4.2), the ethics review's advisory function came into operation too late in the process, leading to the possibility of the need for extensive changes late in the consortium negotiation phase. Several of the ethics reviewers also complained that there was insufficient information in the FPPs for an adequate assessment. Both of these problems could be avoided by adding a remote ethics 'screening' stage to the selected EoI from Stage 1 of each Call. As detailed in Recommendation E below, this screening should be carried out immediately after the stage 1 evaluation in order to advise the proposers in their preparation of the FPP.

Apart from a general reference to FP7 ethics rules, the reviewers were not provided with any selected reading (instruction) material to prepare for the ethics review and there was no special briefing provided on site for the ethics reviewers. The ethics reviewers should be given at least a minimum of briefing on the role of the ethics reviewer (at EC level).

Ethics review is normally and ideally carried out by a multi-disciplinary panel of experts with competencies covering fields such as law, psychology, various relevant life and medical sciences. The panels often include clinicians and animal health experts. Selecting one or two "ethical experts" to review an FPP at Stage 2 cannot provide the coverage of review by an ethics panel covering the full range of competencies.

As detailed in Recommendation G below, we therefore suggest that the ethics reviewers meet, before or after the initial discussion in the evaluation panels but before the face-to-face hearings with the FPP coordinators, to discuss the proposals among themselves (with an IMI JU moderator present). The group as a whole could then cover more competencies (and possibly level out certain individual inconsistencies), before the ethics reviewers return to their assigned topics for the meetings with the FPP coordinators.

Recommendation E: A remote ethics 'screening' stage should be added after the completion of Stage 1 of each Call. This screening should be carried out immediately after the stage 1 evaluation in order to advise the proposers of any ethical issues that they should take into account in their preparation of the FPP.

Recommendation F: The ethics reviewers should be given more information on their expected role.

Recommendation G: In order to ensure full coverage of competencies for all topics, all the ethics reviewers assigned to each topic should have the chance to meet together onsite before the hearings with the FPP coordinators, to discuss the proposals among themselves (with an IMI JU moderator present).

4.7 Moderation of the expert evaluation panels

The IMI Scientific Officers provided moderation of the expert evaluation panels and were, in general, well prepared and well acquainted with the FPP and the consortium. All Scientific Officers fulfilled the essential and often difficult role of moderating the evaluation panels with intelligence and fairness. 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, working well together, and that the writing of the consensus reports proceeded smoothly.

One minor point is that, where remote evaluators are used who cannot be present at the onsite hearings, moderators might encourage the onsite evaluators to take more careful note of the remote evaluators' comments to make sure that key points are not being missed.

4.8 Interim Review

Mention was again made during the evaluator briefings that all projects would be subject to interim program reviews. However, it was not completely clear to the evaluators how this interim review would be conducted and whether definite deliverables and milestones would be set for such reviews. Given the number of references to the importance of the interim review made during the panel discussions, clearer guidance on the details of the interim review stage would have been useful.

Several evaluators specifically raised the question of what deliverables the projects they were evaluating would be judged against, at the interim review and final project report stage.

Recommendation H: During the generation of the FPPs, the coordinators should be required to generate a series of high level deliverables against which project progress will be judged. This list could then be validated or challenged by the panel of experts at the Stage 2 evaluations.

4.9 Gender Ratio

We observed that the representation of women on the evaluation panels was generally rather low and would encourage the IMI office to aim for a more closely matched male:female evaluator ratio for future calls.

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.