

IMI – 4th Call 2011–2012

Evaluation of Stage 2
April 2012

Independent Observers' Report

Ian Hayes

Managing Director, Science 2 Business Ltd, Cork, Ireland

&

Catalina Lopez-Correa

Vice-President Scientific Affairs, Genome Quebec, Montreal, Canada

Table of Contents

1. Background
2. Overall Observations
3. Role and approach of the independent observers
 - 3.1 Role of the independent observers
 - 3.2 Working methods of independent observers
4. Observations and recommendations
 - 4.1 Preparation of the Full Project Proposals
 - 4.2 Remote Evaluation Stage
 - 4.3 Expert Evaluation Panels
 - 4.4 Consensus Evaluation Reports
 - 4.5 Budgeting
 - 4.6 Ethical Review
 - 4.7 Moderation of the Expert Evaluation Panels
 - 4.8 Interim Review
 - 4.9 Evaluation of Topics 1 “Big Theme”
5. Acknowledgements

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 4th Call for proposals by the Innovation Medicines Initiative (IMI). The 4th Call was published in July 2011 and submission of proposals in response to 7 Call topics was invited, covering three clusters within Knowledge Management and Predictivity of Safety Evaluation (i. EU medical information system, ii. Chemistry, manufacturing and control, and iii. Technology and molecular disease understanding). For the first time, one of these Topics (Topic 1: A European Medical Information Framework (EMIF) of Patient-level Data to Support a Wide Range of Medical Research) addresses the “Big Themes” proposed by the EFPIA companies under the Annual Scientific priorities for 2011; metabolic complications of obesity and protective and precipitating markers for the development of Alzheimer’s disease and other dementias.

The resulting Expressions of Interest (EoIs) submitted by applicant consortia were evaluated in November 2011, leading to the selection of one highest-ranked EoI for each topic (Topic 1 required integrating 3 separate sub-topics). This marked the end of ‘Stage 1’ of the 4th 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 17-20th April 2012. 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 professionally, fairly and according to the established procedures and regulations. Both observers were struck by the dedication of all participants to ensuring an impartial and thoughtful evaluation of all FPPs. 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 sessions with applicant consortia. The observers were very pleased to see that the entire 4 days process was set up according to the plan and all panels for the 7 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.

- 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 format of the FPP submission and evaluation forms and 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 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 2 evaluation process. They attended all 4 days of evaluation sessions at the Crown Plaza Hotel in Brussels between 17-20 April 2012. While there they attended all panel discussions and spoke individually with many of the expert evaluators 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.

As well as soliciting opinions from participants the observers found that some moderators and several of the evaluators spontaneously gave us the benefit of their thoughts on the Stage 2 process. In doing this, they were greatly encouraged by Michel Goldman and the moderators who, during his briefing sessions, had expressed his desire that participants should speak freely 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 help further 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 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 it was generally considered to be adequate.

The observers again noted that 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. Whilst good attention was given to the science and technology (S/T), as well as the work packages and consortium partners, detail surrounding the ‘marriage’ and synergies between the EFPIA partners and the applicant academic/SME partners could be further highlighted. Indeed, the S/T was central to the Stage 1 evaluation and therefore ensures that only projects with a solid S/T proposal are selected at the Stage 1 level of the evaluation process. Once the S/T standard has been confirmed in the Stage 2 evaluation, and consensus report recommendations taken into account, the primary objective of Stage 2 is to evaluate and ensure that the new and enlarged consortium is balanced, well managed and that the contribution from all partners (in particular EFPIA) is clear and appropriate to ensure the success of the project. It was clear from the hearing sessions, where the consortium partners presented to and took questions from the evaluators that the EFPIA partners were indeed fully engaged and providing significant contribution – somehow this hadn’t been communicated fully in the written FPPs.

The Call 3 Independent Observers Report noted that changes in composition of the consortia between Stage 1 and Stage 2 had been the focus of some discussion. Guidelines covering this are found in the rules for submission of FPPs, and in Call 4 Stage 2 while some changes were noted this was not considered to be a significant issue requiring further recommendation.

Recommendation A: It is recommended to 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).

Recommendation B: It is further recommended 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.

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.

The Call 3 Independent Observers Report recommended ensuring that ethical reviewers are able to have remote access to the individual ethics review forms for submission of their comments. This was indeed implemented for Call 4 with reviewers having timely notice and a clear brief as well as read/write access to the Rivet Tool to enable them to begin summarising comments ahead of the panel meetings.

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.

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.

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.

We noted some variability in the procedure for the onsite evaluation process, between the different projects. Even with the extra efforts put on the Webex briefing sessions ahead of the on-site, we would suggest that the IMI JU scientific officers repeat this briefing or develop and agree on a short format that could be presented to each panel at the start of the day, to explain the process, roles and objectives, as well as allowing time for Q&A.

Recommendation C: It is recommended 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.

4.4 Consensus Evaluation Reports

All panels took a considerable amount of time to work on the final recommendation and the consensus Evaluation Reports. Because the reports were made during the panel sessions they all reflect well the view of the entire panel of evaluators. The observers were pleased with this part of the process.

4.5 Budgeting

A comment repeated from previous Calls was the issue of one PI taking part in more than one proposal (in the Call 4 this related principally to a Management Services provider), with, for example, the consequence that infrastructure could receive funding via several funded projects.

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).

A number of recommendations had been made from Call 3, for further improvement to the ethics review process. As a consequence of these recommendations, for Call 4 ethical reviewers were able to have remote access to the individual ethics review forms for submission of their comments. In addition, IMI staff had a telecom with ethical reviewers ahead of Stage 2 to explain their role in the evaluation and the process in general.

In spite of the clear improvements made to the ethics review, there was still a strong sense from the ethical reviewers that their advisory function came into operation too late in the process, leading to the need for extensive changes late in the consortium negotiation phase for many of the projects. A common complaint was of insufficient information in the FPPs for an adequate assessment of possible ethical issues. It was felt that both of these problems could be avoided by adding a remote ethics 'screening' stage to the selected EoI from Stage 1 of each Call and the addition of an ethics section to remote briefings.

Recommendation D: 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.

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 was done collectively and proceeded smoothly.

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 E: 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

4.9 Evaluation of Topics 1 "Big Theme"

For the first time, Topic 1: A European Medical Information Framework (EMIF) of Patient-level Data to Support a Wide Range of Medical Research) addresses the "Big Themes" proposed by the EFPIA companies under the Annual Scientific priorities for 2011; metabolic complications of obesity and protective and precipitating markers for the development of Alzheimer's disease and other dementias. The project selected to address those issues had then three components, a Patient-level Data platform and two therapeutic applications (Metabolic complications of Obesity and Alzheimer markers).

The integration of these three projects in a single and well managed project was an extensive topic of discussion at the Stage 2 level of the evaluation process and is viewed by experts as an important challenge of Call 4 selected projects. The evaluators and IMI Scientific officer in charge of this panel worked together to ensure that a series of recommendations were put in place to ensure integration of the three themes. However, concrete results of this integration will only be measurable at the interim and final review process of the project.

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.