

IMI – 2<sup>nd</sup> Call 2009-2010

Evaluation of Stage 2  
September 2010

**Independent Observers' Report**

Graham Johnson

Senior-Vice President Preclinical Development and Research, AVI Biopharma, USA

&

Matti Sarvas

Professor Emeritus, National Institute for Health and Welfare, Helsinki; and Chairman of The  
Board for Gene Technology, Ministry of Social Affairs and Health, Finland

&

Adam Smith

Editor-in-Chief, Nobel Web AB, Stockholm, Sweden and London, England

## **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
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 2<sup>nd</sup> Call for proposals by the Innovation Medicines Initiative (IMI). The second Call was published on 14 September 2009 and submission of proposals in response to 9 Call topics was invited. The Expressions of Interest (EoIs) in response to the Call were evaluated in February 2010 and the consortium responsible for generating the highest-ranked EoI was then invited to join with the relevant EFPIA consortium to generate a Full Project Proposal (FPP). All consortia invited to do so filed FPPs.

The FPPs were then evaluated by independent experts, first through remote evaluation and then in a series of panels in the IMI offices in Brussels from 13-16 July 2010. 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 the utmost professionalism and attention to fairness. 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 all 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 slight modifications that might improve the Stage 2 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 *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 between 13-16 July 2010. While there they sat in on all 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 and give some recommendations for modifications that we feel might benefit 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 EFPIA coordinators are required to bring together the full consortium (a job made all the more difficult in some cases by changes in the composition of the EFPIA part of the consortium) and then lead it to generate the FPP. Some consortia found the time allocated for this process to be rather short and it was generally thought that more time might have resulted in more precisely written and robust proposals. It might also have afforded the EFPIA members the chance to more precisely specify their scientific and financial contributions, which were sometimes unclear to the evaluators. One result of allocating extra time to FPP generation might have been fewer problems for evaluators (more clarity and precision on some key issues) and fewer subsequent requests for adjustments to the FPPs.

Evaluators also remarked upon the fact that the way that the FPPs are required to be structured, being divided into multiple work packages, necessarily leads to considerable overlap and redundancy in the writing, and to extremely long documents. The exceptional length of some of the FPPs did not make the evaluation process any easier.

Project coordinators also stressed the value of having the IMI scientific officers involved in helping to guide the formation of the FPP and indeed thought that increased levels of guidance in this respect would have been helpful.

**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.

## 4.2 Remote Evaluation Stage

Following the generation of the FPPs, the expert evaluators had about one week in which to evaluate them remotely. It was suggested that even a few days of extra time would have been welcome. One further common request from evaluators was 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.

**Recommendation B:** Provide more time for remote evaluation of the (very long) FPPs and investigate the possibility of providing experts with remote access to all the evaluators' reports in their topic once they have submitted their own report.

## 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 well 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 our opinion, the onsite meeting of the reviewing experts was critical to the process and the quality of the subsequent work product. In all sessions, each expert reviewer brought specific knowledge, perspective and commitment to the discussion and the process that ensured that each FPP was critically examined and discussed and clear recommendations made. Much effort was made to improve the proposals and adjustments were made that would not have been possible without meeting face to face. Defining such adjustments was one very beneficial result of the evaluation. This was not a rubber stamp exercise.

The agenda for each day's panel discussions was broadly as follows:

- 1) Each panel member briefly described his/her main points of the concern about the proposal and the panel formulated questions for the project coordinators.
- 2) Coordinators, and sometimes other members of the consortium, were invited into the panel to give a short presentation and to answer questions and comments posed by panel members.
- 3) After lunch, the afternoon was then devoted to the preparation of the consensus evaluation reports.

The first part of the day's schedule was very useful. The main points were immediately raised for further consideration and deviating opinions were immediately highlighted. This helped to structure and focus the discussion.

It became clear that the day's agenda generally afforded insufficient time for the experts to convene, review and collate their remotely generated input into specific questions prior to meeting the project coordinators. After observing this process over the course of 4 days, it was evident that through careful preparation, the moderators could play an important role in expediting and orchestrating this process. Insufficient time was also set-aside for the subsequent question and answer session with the program coordinators, which the expert evaluators found to be extremely valuable. In contrast, the experts commented that, with efficient moderation, the time set aside for the generating the consensus report could be somewhat reduced without detriment to the quality of the work product.

**Recommendation C:** Devote more of each day's available time to the initial discussion focused on generating questions for the coordinators and particularly to the question and answer session with the coordinators. Reduce the time devoted to the writing of the consensus evaluation reports.

#### **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**

More clarity and guidance on budgetary matters should be given to each review panel. Considerable time was dedicated by some panels in attempts to balance the financial contribution of EFPIA and IMI to a project. Clear, concise and consistent guidance from the IMI office on the proper role of expert evaluators regarding budgetary considerations would have helped avoid many hours of needless discussions and would have allowed each team to concentrate more of their time and effort on the scientific evaluations. That being said, in many of the proposals the underlying budgetary concern was exacerbated by the frequent lack of clarity and detail in both the nature and magnitude of the in-kind contribution to a project from the EFPIA partners (as previously mentioned in section 4.1). Among reasons given by several of the EFPIA coordinators for this deficiency were the limited time available for meeting with the selected academic consortia and uncertain staffing availability from the industrial partners.

**Recommendation D:** Give clearer guidance to evaluators as to their expected level of engagement in assessing the budgetary aspects of the FPPs.

#### **4.6 Ethical Review**

Ethicists were invited to review the ethical aspects of the FPPs. The task of the panel 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). Two procedures were used. For topics 1-6 the

ethicists met at the end of the week as a separate team. One advantage of this separate ethical panel was that its broad composition ensured comprehensive review of proposals due to the wide range of expertise present. However, although clearly thorough in their analysis, this arrangement tended to disconnect the ethical experts from the scientists involved in the main panels, an undesirable consequence given the importance of ethics and legal issues to all of these projects. In some respects, this was also a missed opportunity to increase the scientist's awareness of ethical issues. For topics 7-9, the ethical experts were invited to be a part of the main scientific evaluation panels.

The expertise of the ethical experts covered a range of different aspects and all also had practical experience and knowledge of the biomedical substance of the proposals. The ethical experts were therefore in a good position to provide a robust evaluation based on thorough analysis of proposals and a detailed report with requests for adjustments where necessary. Reporting was facilitated by a report format itemized in detail.

**Recommendation E:** The procedure for ethical review of FPPs should be standardized across call topics. It would be beneficial if a practical way could be found for the ethical experts to discuss any concerns directly with the coordinators of the projects, as is the case for the scientific evaluators.

#### **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. They provided information (spontaneously or by request) on consortia and the process of preparing the FPP and were careful to ensure that they had fully understood the wishes of the panel on any adjustments and recommendations. However, it is worth noting that the technical, leadership and management skill sets of the coordinators remains rather uneven, as was the effectiveness and depth of the preparation for these reviews. These are very large and complex proposals involving cutting edge scientific technologies and the moderators have a critical role to play in guiding and assisting the experts to identify weaknesses, reach clear conclusions and frame concise comments. Leading such teams of experts requires clear abilities in leadership, delegation and negotiation. Additional training of IMI scientific officers in these skills would, in our opinion, be a worthwhile investment.

#### **4.8 Interim Review**

Mention was made during the morning briefings that all projects would be subject to interim program reviews. However, it was not evident that this concept had yet been completely formed and it was unclear to the evaluators whether clear deliverables and milestones would be set for such reviews and whether the panel of experts who had originally recommended funding would have any more involvement in the process.

Given that we were, as previously mentioned, impressed by the dedication of the expert evaluators to the evaluation process and by their willingness to serve, we suggest that it might be desirable to involve a subset of them in the mid-term review procedure. Maintaining independent scrutiny of ongoing projects would surely help to build confidence in the IMI, and with this in mind we make two recommendations.

**Recommendation F:** 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.

**Recommendation G:** The expert panel (or a subset of them) should be involved in interim reviews of project progress (in the 18-24 month period). If necessary, this could be accomplished by the use of webinar technology.

## 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.