

IMI – 2nd Call 2009-2010

Evaluation of Stage 1
February 2010

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 2nd 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 IMI website began accepting Expressions of Interest (EoIs) in response to the Call on 8 January 2010, with a deadline for submission of 8 February 2010.

Submitted EoIs were then evaluated remotely and individually by both independent experts and representatives of the EFPIA consortia that generated each Call topic. The independent experts, along with the coordinators and deputy coordinators of each Call-generating EFPIA consortium, were then brought together in the IMI offices in Brussels from 23-26 February 2010 to finish the Stage 1 evaluation process with a series of panel discussions, resulting in a consensus ranking of the submitted EoIs for each Call topic. The results of these evaluations will be communicated to applicants in mid-March 2010, concluding Stage 1 of the 2nd Call for proposals.

2. Overall observations

In general, the observers found that the Stage 1 evaluations were conducted with the utmost professionalism and attention to fairness. The dedication of all participants to discharge their important responsibilities in as effective way as possible and to ensure an impartial and thoughtful evaluation of proposals, was striking. The IMI team has performed an outstanding job in organizing the evaluation meetings and in gathering and distributing the vast amounts of information involved. Excellent onsite briefings were also especially appreciated.

In our opinion:

- There were no violations against the rules of the published evaluation guidelines.
- The evaluators possessed sufficient and relevant expertise and displayed a professional approach to their task.
- Evaluation of the proposals, and discussions in the panels, was fair and transparent.
- A consensus on scoring and ranking, based on taking into account both the scientific excellence of the proposals and their fit against the specifics of the Call topic text, was achieved by the expert evaluators in the case of all proposals. The opinions of all experts on a panel were considered and discussed in equal terms while making the final decisions.

Alongside these general observations we do have some recommendations for slight modifications that might improve the Stage 1 process for future Calls. These are reported in detail in Section 4 of this report, and most of the following suggestions fall under the broad banner of attempting to increase the transparency of the Stage 1 submission and evaluation process.

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 sit in

on some panel discussions, but they should not participate in any discussion on particular EoIs. They may on the other hand discuss the evaluation methodology and documentation with the Moderators of the Panel and with the individual experts discuss the evaluation.

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 1 evaluation process. They attended the entire 3.5 day evaluation sessions at the IMI offices in Brussels between 23-26 February 2010. While there they sat in on the majority of panel discussions (with just 3 observers covering 4 concurrent panels on some days, complete coverage was not possible), 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 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 with the observers 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 1 evaluation process and give some numbered 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 carefully and fairly implemented throughout.

4.1 The Call

We noted that although the 2nd call was made public on 14 September 2009 it appeared that many of the applicants had only had about two months to prepare their proposals, i.e. from the time of the official press release announcing the call on 27 November 2009.

Recommendation 1 - IMI could investigate ways to advertise the Calls more efficiently to ensure that all the time available for the preparation of proposals is indeed used.

Several evaluators expressed the view that the call was often too broad and the number of key deliverables requested too numerous. The result of this were proposals that tried to cover everything, resulting in unfocused, thin proposals. The requirement to meet all key deliverables within the Call also resulted in rejection of some very good but focused proposals proposed by consortia of excellence. In some cases, the evaluators pointed out that the Call produced by the EFPIA consortium covered an unrealistically broad field (e.g. in terms of number of deliverables to be addressed).

Recommendation 2 – It might have been desirable to focus Calls on fewer goals or alternatively to produce ranked lists of deliverables in the call topics, so that rather than requiring an all or nothing approach to the deliverables by the applicant consortia, success in most areas, but not all, might be acceptable if the EoI proposed a truly transformational or innovative approach.

The role of the EFPIA participants in the call is described in very general terms, with the result that applicants cannot match their work plan with the possible contribution of EFPIA consortium. For this reason the work plans of some otherwise excellent proposals seemed weak and in other cases the evaluation panel was unsure whether the EFPIA consortium could provide the contribution anticipated by the applicant consortium.

Recommendation 3 – Call topic descriptions would benefit from a more detailed description of the level and type of resources to be committed by the EFPIA consortium

4.2 Guidance to applicants

During the evaluation sessions views were expressed that not all applicant consortia had fully grasped the intended nature, responsibilities and scope of the research work described in the Call, particularly in terms of the cooperation with the EFPIA consortium. This lack of familiarity with the special nature of the IMI Calls might have resulted in some poor proposals. Doubts were also expressed as to whether all applicants had been aware that under the rules of the IMI only one EoI for each Call topic can be invited to go forward to form a full consortium with the EFPIA members. This was in spite of the fact that the procedure was described precisely in the Call documents.

Recommendation 4 - More thorough guidance on the particular nature of the IMI Calls could be provided for applicants. The IMI Open Day in November was an excellent occasion for providing information to applicants, but more should be done for those unable to attend an Open Day in Brussels. Webinars with the EFPIA coordinators for each Call topic and the generation of Call-specific FAQs for potential applicants might be very useful additions.

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. In addition there was in each evaluation panel the Coordinator and Deputy Coordinator of the appropriate EFPIA consortium. This combination of independent and EFPIA-associated experts was beneficial for the evaluation. The EFPIA Coordinators and Deputy Coordinators had a double role. Firstly they were experts with special knowledge on aspects of the industrial feasibility and applicability of the proposals of applicant Consortia and they thus complemented the knowledge of academic experts in an important way; especially in those panels with few or no independent experts with industrial backgrounds. Secondly, they could inform and guide, when necessary, other experts of the panel on the required complementarity of a proposal with that of the EFPIA consortium.

Certain EFPIA moderators did call into question whether the combination of experts on their particular evaluation panels possessed exactly the right mix of expertise and suggested that EFPIA coordinators might be well-placed to suggest broad areas of expertise that ought to be represented on the panel.

4.4 Timeline for evaluation of Expressions of Interest

Many participants, both independent experts and EFPIA consortia members, observed that the time allocated for a thorough evaluation of the EoIs (just over a week) was too little. This comment was heard in all panels, but especially in those with the largest number of EoIs, particularly the oncology topics where 53 proposals had to be evaluated across two panels.

Recommendation 5 – Ensure that a longer period is available for evaluation. Three weeks seems to be viewed by most as an acceptable timeframe.

4.5 Guidance for evaluators

It was clear from the Q&A during the daily briefing sessions in Brussels and subsequent questions that many of the evaluators were unaware of some of the key limitations/provisions of the IMI Call process. For instance, prior to the briefings some evaluators were unaware that only one EoI was allowed to move forward to Stage 2, or that applicant consortia were ‘fixed’ and could not be changed at this stage. The instructions that were sent out to evaluators did contain all the details needed (process, decision making etc.) if the evaluators had the time to read them all. However, requests were made for an information-rich summary of the guidelines to be sent out because evaluators are just too busy to read every detail of the full guidelines.

Recommendation 6 – Help evaluators understand the details of the IMI process better via the generation of FAQs, summaries and perhaps the scheduling of teleconferences prior to their evaluation of the EoIs.

4.6 Role of the EFPIA coordinators and deputy coordinators

The EFPIA Coordinators and Deputy coordinators had variously exploited the option provided by the Rules to consult (confidentially) the member companies of their consortium. In most cases meetings had been held by teleconference, but in at least one case the EFPIA consortium companies had held face-to-face meetings to discuss the EoIs. By these processes, the consortia had evaluated and ranked the proposals according to the evaluation criteria 1.2 and 2.2 and these consensus evaluations were provided to the panel by the coordinator and deputy coordinator. However, not all EFPIA coordinators took the chance to explain how their particular EFPIA consortium members had arrived at their consensus scores. That was a pity since a better understanding of this process by the panels would, in our opinion, improve the robustness of the final evaluation and the eventual fusion of the applicant and EFPIA consortia.

Recommendation 7 - The proposals were obviously not “evaluated” similarly and using similar criteria in all EFPIA consortia. EFPIA should be encouraged to generate a harmonized procedure for dealing with proposals and thus make sure that proposals of all topics are evaluated on similar terms in each panel, and this process should be communicated to all evaluators.

Further to this point it was suggested that although details of the Call were available, the logic and stance of the EFPIA consortia members (including their long term objectives and the resources that they were prepared to bring to assist the selected consortia) were not fully appreciated. One idea was that the EFPIA coordinator could orient their team of experts to the background, nature and objective of the Call before they undertake the evaluation and ranking of the EoIs, possibly via a webinar.

4.7 Moderation of the expert evaluation panels

The evaluation sessions were moderated by members of the IMI office and IMI has produced a truly excellent guidance document for moderators which carefully addresses both legal and practical tips for ensuring impartial and effective discussions. Although all the moderators met the main objectives, such as reaching an impartial consensus, we would have liked to see them play a more active role in the discussions. For example, moderators should be encouraged to:

- More actively direct the discussion to highlight diverse opinions and arguments of experts. To use the average scoring as a starting point is not always the most effective and fastest way to reach a robust consensus and is actually not encouraged by the guidance document.
- Provide more supplementary information. All were happy to provide this on request, but not spontaneously when it might have helped facilitate the discussion or keep it on the right track.
- More actively ensure the quality of the consensus reports. To ensure consensus and quality we recommend the method used in some panels: the draft report is beamed onto the screen and then edited to ensure that there is consensus agreed by all panel members.
- Push the team to explore clearly outlying scores to make sure that a key point is not being missed. We did not observe a moderator doing this.

Recommendation 8 – We noted that the moderators had to spend a good deal of their time filling out forms and dealing with administrative tasks. It might be optimal if some of these tasks could be moved outside of the sessions so that the moderators are freer to concentrate on ensuring that the evaluation panels explore all avenues in their discussions and that all arguments are fully explored before consensus is reached.

4.8 Remote evaluation

Remote evaluation by experts not able to be present at the evaluation sessions was observed to play a marginal role. Their comments could not be easily related to the in-depth discussion in the panel. However, remote evaluation could nevertheless serve a significant function in the evaluation process if special expertise is required and an expert is not able to attend the consensus meeting.

Recommendation 9 – Where a remote evaluator's scores differ significantly from those of the other panel members, the moderator could request additional comments from the remote evaluator to use during the roundtable evaluation discussion.

4.9 The evaluation tool

The online submission and evaluation system appeared to have functioned effectively. One possibility for future Calls would be to allow evaluators to see all other evaluators' scores and comments on the EoIs as soon as they have submitted their own individual scores. This is fairly standard practice for many online peer review systems and would allow better preparation for the onsite evaluation meetings.

4.10 Intermediate selection process

Our final observation suggests a more radical change to procedures than any of the preceding ones, and we recognize that this one may be hard to implement. Perhaps because they were struggling with so many EoIs, the strong recommendation from certain panels was to create an intermediate

step in the evaluation process in which the top 3-5 EoIs would be selected for further elaboration by the applicant consortia, with comments and suggestions from the experts being included in the feedback given to each consortium. The selected applicant consortia would be invited to craft a more extensive proposal (of perhaps around 20 pages) that contains a fuller description of how the consortia envisage working with the EFPIA consortia to meet the criteria of the call. This would of course slow down the process and require a further evaluation meeting by experts. The EFPIA coordinators strongly agreed with this proposal, and the observers feel that such a two staged procedure would result in a robust evaluation and selection procedure in cases where very many high quality EoIs were in competition for the same Call topic funding.

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.