

IMI – 3rd Call 2010-2011

Evaluation of Stage 1
February 2011

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 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 IMI website accepted Expressions of Interest (EoIs) in response to the Call up until a deadline for submission of 18 January 2011.

Submitted EoIs were then remotely evaluated over a two week period spanning the end of January and the beginning of February 2011, both by independent experts and by representatives of the companies within the planned EFPIA consortium for 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 14-17 February 2011 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 2011, concluding Stage 1 of the 3rd Call for proposals.

2. Overall observations

As with the previous two Calls, the observers found that the Stage 1 evaluations were conducted professionally and fairly. Both observers were struck by the dedication of all participants to ensuring an impartial and thoughtful evaluation of all EoIs. The IMI team once again performed an outstanding job in publishing and publicizing the Call, organizing the EoI submission and evaluation process, and in putting together the onsite evaluation meetings. In particular, and as highlighted in detail below, improvements in the procedures from the first two Calls were obvious to both observers, both from personal experience (AS) and from a comparison with previous published reports and procedures (EF). The clarity of the onsite briefings for evaluators was again especially appreciated.

In our opinion:

- There were no violations against the rules of the published evaluation guidelines.
- The evaluators were generally of a very high quality and in possession of the relevant expertise.
- All participants approached their tasks professionally.
- The evaluation of the proposals, and the discussions in the panels, were frank and fair.
- 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.

As with the observers' reports from the previous Calls, we do have some recommendations for slight modifications that might improve the Stage 1 process still further for future Calls. These are reported in detail in Section 4 of this report, which also catalogues certain improvements to the process that have been incorporated since the 2nd Call.

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 days of evaluation sessions at the IMI offices in Brussels between 14-17 February 2011. While there they sat in on the panel discussions (with just 2 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 the Scientific Officers 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 spontaneously gave us the benefit of their thoughts on the Stage 1 process. In doing this, they were greatly encouraged by Michel Goldman 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 1 evaluation process, note improvements in the process compared to that for previous Calls, and give some 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

The observers were pleased to note that the Open Information Day for the 3rd Call was held very shortly after the launch of the Call, on 22 October 2010, thus giving almost three full months between the Open Information Day and the deadline for EoI submission. This, combined with the provision of webinars for potential applicants (see 4.2 below), helped publicize the Call effectively.

Once again, evaluators commented on the broad nature of the individual calls and particularly on the number of key deliverables requested, making them, in some cases, unrealistically broad in their coverage. As previously suggested, it might be 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.

Evaluators again noted that the role of the EFPIA participants in the Call is described in very general terms, with the result that it is hard for applicants to match their work plans accurately with the possible contribution of EFPIA consortium members. Although the observers recognize that it is difficult to specify precisely what contribution will be made by the EFPIA consortium before it is decided which applicant consortium will be selected to move forward to the full project proposal stage, we suggest that, as mentioned in the observers' report for the 2nd Call, Call topic descriptions would benefit from a more detailed description of the level and type of resources that might potentially be committed by the EFPIA consortium

4.2 Guidance to applicants

The observers were pleased to note that the recommendation of the 2nd Call observers that "More thorough guidance on the particular nature of the IMI Calls could be provided for applicants" appeared to have been followed. It was clear from the evaluation panels that most applicant consortia had grasped the need to attempt to adhere closely to the demands of the Call. This was presumably due, at least in part, to the provision of webinars for each Call topic during late October and November 2010 in which potential applicants who had been unable to attend the Open Information Day in Brussels had a chance to learn about the individual Call topics and details of the application procedure. We recommend the continuation of this practice.

A number of the evaluators commented on the variation among proposals in their degree of adherence to the EoI template. Although we recognize that it is hard to control for this variability, we recommend placing further emphasis on the need for standard application procedures.

4.3 Expert evaluation panels

The experts in the evaluation panels were selected and invited by the Scientific Officers 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 and the high quality of the individuals present pays tribute to the efforts of the IMI Scientific Officers in securing a good mix of people for each panel (an especially hard task given the difficulty of finding suitably-qualified expert evaluators who are not involved in any applicant consortia). In addition there was in each evaluation panel the Coordinator and Deputy Coordinator (or appointed representative) of the appropriate EFPIA consortium. This combination of independent and EFPIA-associated experts was beneficial for the evaluation. The EFPIA Coordinators and Deputy Coordinators, while not taking part in the consensus evaluation scoring of the EoIs, could inform and guide, when necessary, other experts of the panel on the required complementarity of a proposal with that of the EFPIA consortium.

4.4 Timeline for evaluation of Expressions of Interest

The increased time allotted for remote evaluation of the EoIs (two weeks on this occasion as opposed to just over a week for the 2nd Call) was noted, and appeared to be sufficient. Unlike the 2nd Call, no complaints about the timeframe were received from the evaluators.

4.5 Guidance for evaluators

A striking difference between this 3rd Call and last year's 2nd Call was the relative absence of questions on this occasion following the evaluator briefing sessions at the onsite evaluation meetings in Brussels. This implied that the evaluators possessed a much greater understanding of the process than in previous years. A contributory factor was no doubt the teleconferences organized by the Scientific Officers for all evaluators during the remote evaluation, in which they could discuss the process with IMI staff and the EFPIA consortium coordinators.

There were still cases of individual evaluators not fully grasping some of the special features of the IMI evaluation process (such as the fact that only the top-ranked EoI can move forward to the next stage), and thus we recommend that still further steps are taken to make the process fully transparent to evaluators before they submit their online evaluations of the EoIs prior to coming to Brussels. An FAQ document for evaluators might be one helpful addition, especially since several evaluators commented that they had little time to read all the documentation provided, and receiving the essential information in *summary* form would be most helpful.

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 by face-to-face meetings, teleconferences and e-mail. By these processes, the consortia had evaluated and ranked the proposals according to the evaluation criteria and these consensus evaluations were provided to the panel by the coordinator and deputy coordinator. In most, but not all cases, the scores of the coordinator and deputy coordinator were the same, thus representing the consensus view of the EFPIA consortium. Having access not just to the scores of the EFPIA consortium members but also to the coordinator and deputy coordinator themselves, who could explain the logic and stance of the EFPIA consortium members in reaching these scores, was highly useful to the expert evaluators. Furthermore, the coordinator and deputy coordinator played an important role in orienting the team of experts as to the background, nature and objective of the Call, both during the teleconference held during the remote evaluation phase and during the onsite meetings in Brussels.

4.7 Moderation of the expert evaluation panels

As with the 2nd Call, the evaluation sessions were moderated by Scientific Officers from the IMI office. This time, however, a positive development was that each Scientific Officer was given full-time support by another member of the IMI office staff, relieving them of some of the administrative burden and allowing them to concentrate more fully on their role as moderators. All Scientific Officers fulfilled the essential and often difficult role of moderating the evaluation panels with intelligence and fairness, and the standard of moderation across panels was seen to be relatively homogeneous. 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 moderators might in future more actively push the team of evaluators to explore clearly outlying scores in greater detail to make sure that a key point is not being missed.

4.8 Choice of Rapporteur

The Rapporteur for each EoI is an expert evaluator chosen to present that EoI to the evaluation panel and then to be the primary scribe for the writing of the consensus evaluation report for that EoI. This is an important role, with an obvious, direct impact on the discussions in the panels and the feedback given to the applicant consortia. We observed that the standard procedure used for choosing the Rapporteurs was to invite the panellists to volunteer for the role at the start of the panel discussions, and then, if no volunteer was forthcoming, for the moderator to assign a Rapporteur to each EoI. Although all panellists should be familiar with all proposals, particularly where there are only a few EoIs, we recommend that it might result in better proposal 'presentations' if moderators followed the procedure used for the 2nd Call of pre-assigning Rapporteurs before they arrive in Brussels, thus giving them time to prepare for this role.

4.9 Remote evaluation

Remote evaluation by experts not able to be present at the evaluation sessions was again observed to play a marginal role. Their comments could not be easily related to the in-depth discussion in the panel, and they were of course unable to benefit from the information that the other panellists discovered onsite during the course of their discussions. We would recommend, where possible, avoiding the use of such remote-only evaluators in future. But if they are to be used, in order for evaluation from experts who cannot be present in Brussels to be useful, it is recommended that they are asked to write more detailed reports (which perhaps focus on specific points of interest/concern) for consideration by the onsite experts. This would be particularly important if a remote evaluator's scores differ significantly from those of the other panel members, in which case the moderator should request additional comments from the remote evaluator to use during the roundtable evaluation discussion.

4.10 The evaluation tool

The online submission and evaluation system appeared to have functioned effectively. As previously mentioned, a useful 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.

4.11 Enhancement of the Stage 1 selection process

As with the observers' report for the 2nd Call, our final observation leads us to suggest a more radical change to procedures than any of the preceding ones. Many of the evaluators commented (both individually and collectively) that they found it difficult to make decisions on which proposal to rank top based on the information contained within the EoI. This was especially commented upon by panels dealing with the task of choosing between two closely-ranked EoIs. There was a general perception that the brevity of the EoIs made the task difficult and that any change in the evaluation

procedure that would allow the experts to understand more clearly what the applicants were intending would be helpful.

Given that the great majority of the discussion within each panel focused on the top-ranked proposals, it was suggested by many evaluators that it might be better to focus the onsite meetings on the top-ranked proposals alone. This could be achieved by using the remote, online evaluation stage to whittle down the list of EoIs to be considered (for instance by removing those that fall well below the threshold for scientific innovation), and thus concentrate the onsite meetings on only the 3 or 4 top-ranked proposals.

Two main suggestions were put forward for how to increase the information available to the evaluators at the onsite panel meetings. The first (in line with a suggestion made in the observers' report from Stage 1 of the 2nd Call) was the creation of an intermediate step in the evaluation process in which the top-ranked EoIs would be selected for further elaboration by the applicant consortia. The selected applicant consortia would then be invited to craft more extensive proposals (of perhaps around 20 pages and possibly including preliminary results to back-up their applications) for consideration at the onsite meetings. This would of course slow down the process.

The other suggestion (and the two are not necessarily mutually exclusive) was to allow the expert evaluators to question the applicants during their onsite evaluation meetings to get clarifications on particular aspects of the EoIs. This idea was popular among the experts and EFPIA coordinators alike, and various suggestions for how it might work in practice were put forward. While the majority of experts favoured being able to question the applicants directly (preferably in person, but by teleconference if face-to-face meeting wasn't possible), a few raised the issue of evaluator confidentiality and suggested that it would be better to put their questions to the applicants via teleconferences at which the moderator would question the applicants on behalf of the expert panel.

Although we recognize the difficulties of introducing additional elements into the already smooth-running evaluation process, based on the many comments we received during the meetings in Brussels we would recommend exploring scenarios that enhance the expert evaluators' access to information about applicant consortia's plans.

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.