

IMI - JU – 2011_04

Evaluation of Stage 1
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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 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 IMI website accepted Expressions of Interest (EoIs) in response to the Call up until a deadline for submission of 18 October 2011.

Submitted EoIs were then remotely evaluated over a three week period spanning the 24 October and 14 November 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 21-25 November 2011 to finish the Stage 1 evaluation process with a series of plenary, panel discussions and telecom hearings, resulting in a consensus ranking of the submitted EoIs for each Call topic. The results of these evaluations will be communicated to applicants in early/mid-December 2011, concluding Stage 1 of the 4th Call for proposals.

2. Overall observations

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, contacting highly professional and well qualified professionals and in putting together the onsite evaluation meetings. In particular, and as highlighted in detail below, very significant improvements in the procedures from the first three Calls were obvious to both observers, from personal experience (IH; Call 2), from a comparison with previous published reports and procedures (CLC) as well as comparison with evaluation processes at other international funding agencies. The clarity of the onsite 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 new and complex steps in the process such as the hearing sessions. The observers were very pleased to see that the entire 5 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.
- All participants approached their tasks professionally.
- The evaluation of the proposals, and the discussions in the panels, were exhaustive, frank and fair.
- The new use of ‘Hearings’ were organized in a very effective manner and appeared universally welcomed, as highlighted below.
- 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 3rd Call.

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 1 evaluation process. They attended all 5 days of evaluation sessions at the IMI offices in Brussels between 21-25 November 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, 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 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 well, carefully and fairly implemented throughout and that the overall process is of excellent quality and follow international peer review standards.

4.1 The Call

The observers were pleased to note that the Open Information Day for the 4th Call was held on 17 June 2011, one month before the official launch of the Call, thus giving almost four 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.

The observers were especially pleased to see, following recommendations from previous Calls, a greatly expanded level of detail with each of the individual calls. Each of the 7 topics was explained not only on the relevant documents but also during the webinars. Concrete examples, detailed information and key expected deliverables were provided to guide applicants on the submission of the EoI. Combined with clear communication this led to noticeably closer agreement between the independent remote scoring and ranking performed by both expert evaluators and EFPIA which also facilitated the panel discussion in Brussels. Call requirements were detailed even to the level of specifying individual Work Packages for each of the topics. In this later respect, EFPIA and IMI might consider the balance between 'prescription' and allowing a certain degree of 'interpretation' in the EoI. Too much dependence on prescribed Work Packages might disincentivise Applicants from looking 'outside of the box' and 'innovating' to find new ways forward, which is surely part of the IMI objective. Recommendations from previous Calls had suggested that individual calls might list ranked deliverables, and these with an 'outline' framework of Work Packages (rather than being too prescriptive) might afford a balance.

The observers were further pleased to see, following recommendations from previous Calls, a more comprehensive description of the role of the EFPIA participants in the Call, with the result that EoIs were better able to match their work plans accurately with the possible contribution of EFPIA consortium members.

Finally, in alignment with the 'social medial' revolution that is impacting society in general and the scientific community in particular, the observers recommend that IMI make full use of social media, in particular LinkedIn and Twitter, to publicise the Calls, provide information about the critical steps and reach out to a larger scientific. The use of social medial could be also important to inform the scientific community and the general public of the success stories related to projects already funded by IMI.

4.2 Guidance to applicants

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 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.

However, even with the efforts made on information sessions and webinars, a significant number of EoI did not appear to have appreciated the maximum budget required by individual topics on Call 4th; where this was referred to in the Call as e.g. 50%, rather than a specific Euro figure. In addition, where the maximum budget was understood (and/or following clarification by IMI) for some individual topics (especially Topic 1) the EoI consortia expressed a difficulty in matching the wide-reaching requirement of the topic with the budget allocated. We recommend placing further emphasis on the need for a clear maximum budget in the standard application and also paying specific attention to a realistic alignment between the expectations of the call and particular topics and the budget allocated to each of them

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 and were not subject to any kind of conflict of interest). In some instances it was clear that the IMI team had benefited from a suggestion of experts from the EFPIA partners. In addition there was in each evaluation panel the Coordinator and/or 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 were, for this Call 4, provided with the opportunity at the beginning of each individual topic plenary session to detail the requirements of the topic and to describe how the EFPIA representatives had approached their own separate EoI evaluation, scoring and ranking process. While generally 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. The information and the context provided by EFPIA representatives was generally perceived as very helpful for evaluators had a positive impact on the discussion held during the panel meetings

While the observers noticed and received feedback that there was generally a good balance and helpful contribution from the EFPIA representatives, on occasion the IMI moderator was required to clarify that the independent experts alone are responsible for the consensus evaluation scoring of the EoIs and on occasion it was found beneficial for the EFPIA representatives to leave the panel room while this process took place. We recommend the continuation of this practice, the more explicit clarification in both the briefing and the panel sessions on the respective roles of EFPIA representatives, and for the IMI team to consider standardising the practice of the EFPIA representatives leaving the room only for this final consensus scoring and ranking part of the process.

4.3.1 Hearings

The observers were pleased to note the new introduction of telecom Hearings, into the evaluation panels. Here, the top 4 ranked proposals from the remote evaluation (and in one case top 5, where scores were very close between 4 and 5) are joined into the process to answer specific questions (maximum 5-7 specific questions per EoI) composed by the independent experts. The observers saw firsthand and received widespread feedback endorsing the value of this contribution to the process, which on several occasions resulted in a changed consensus score and ranking of a given EoI. We strongly recommend the continuation and further evolution of this practice. Given that all EoI consortia are primed to keep the respective day clear for a possible Hearing, it may be possible (subject to logistics) to inform the choice and number of EoI consortia brought into this Hearing during the first day of the evaluation and thus benefiting from initial panel discussion, rather than a decision made solely based on the remote ranking. A minor comment in order to improve the Hearing process, we recommend to have a 5 minutes panel discussion (outside the teleconference, or with the phone on mute) to ensure that all questions were answered to the satisfaction of the entire panel and that there are not other questions remaining.

4.4 Timelines

4.4.1 Timelines for evaluation of Expressions of Interest

The further increased time allotted for remote evaluation of the EoIs (three weeks on this occasion as opposed to two weeks for the 3rd Call) was noted, and appeared to be adequate. No complaints about the timeframe were received from the evaluators, save with regard to the notice for Rapporteurs as discussed below.

4.4.2 Timelines for Preparation of FPP

The time allotted for preparation of FPP (between the results of these evaluations being communicated to applicants in early/mid-December 2011 and the deadline for FPP 13 March 2012) was commented on by a number of the EFPIA representatives in respect of Topic 1, by comparison with the other topics. Here, for the first time, Topics 1 addresses the “Big Themes” proposed by the EFPIA companies under the Annual Scientific priorities for 2011 and requires integrating 3 separate sub-topics. The time for preparation appears to be sufficient for most of the topics on Call 4. However, for Topic 1, due to its complexity, the time might not be enough to ensure preparation of high quality proposals. A full evaluation of the timelines and eventual recommendations regarding those will only be possible at Stage 2.

4.5 Guidance for evaluators

As noted following Call 3, there was a relative absence of questions following the evaluator briefing sessions at the onsite evaluation meeting in Brussels. This implied that the evaluators possessed a much greater understanding of the process than in earlier years. A contributory factor was again 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.

An FAQ document for evaluators was one recommendation from Call 3, however a number of expert evaluators felt that there was now enough ‘paperwork’ and so perhaps the availability of webinar coverage of the teleconferences already organized by the Scientific Officers would address this.

4.6 Role of the EFPIA coordinators and deputy coordinators

The EFPIA Coordinators and Deputy coordinators had clearly 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.

It was noted especially in this case that EFPIA had fully engaged with the evaluation process and the panel discussions, with the coordinator and deputy coordinator themselves often being a strong stakeholder in the

respective call topic, and not simply a ‘representative’ of the consortia. As already noted, we recommend more explicit clarification in both the briefing and the panel sessions on the respective roles of EFPIA representatives, as distinct from the expert evaluators

4.7 Moderation of the expert evaluation panels

As with the 3rd Call, the evaluation sessions were moderated by Scientific Officers from the IMI office. Once again each Scientific Officer was given considerable support by another member of the IMI office staff, with a dedicated IT officer and with two lawyers available throughout the week relieving them of some of the administrative burden and allowing them to concentrate more fully on their role as moderators and to answer directly any questions regarding potential conflict of interest from the evaluators. 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. Once again, the IMI Lawyers were on hand to read all consensus reports and ensure that the language used was well aligned with the scores. The observers were pleased to note that moderators encouraged the team of evaluators to explore clearly outlying scores in greater detail to make sure that a key point is not being missed, as recommended from Call 3, although, as noted here there were many fewer examples of outlying scores at Call 4

The observers noticed and received feedback that there was perhaps longer than necessary discussion around the very low scoring proposals. Whilst it is a crucial part of the process to provide fair and reasonable feedback to all EoI consortia, who have all put effort into their submission, it is recommended that a pragmatic approach be taken to ensure that the best use is made of the evaluators time. Perhaps time could be weighted accordingly, with more discussion on the top 1-5 EoIs, and less with 6-10. For further proposals or ones very low score or below threshold values should warrant considerably less time and somewhat more generic feedback.

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. The assignment of a Rapporteur should also help to streamline the process.

The observers were pleased to see that, as recommended from Call 3 and as previously used for Call 2 Rapporteurs were once again pre-assigned before they arrive in Brussels, thus in principle giving them time to prepare for this role.

We recommend that the pre-assignment of Rapporteurs continue as a valued part of the process, and that additional care is given to ensuring that all prospective Rapporteurs are given at least 2 working days notice ahead of their first day in Brussels and that they be fully briefed on the role expected of them. In particular, their role on preparing a first consensus rapport and presenting it to the panel in Brussels in order to provide the necessary context to open the panel discussion. The other evaluators should only, if needed, build upon or challenge the Rapporteur comments.

4.9 Remote evaluation

It was noted that across the 7 call topics very few remote evaluators were not able to be present at the evaluation sessions in Brussels. When evaluators were not able to be present, and where their input was required in order to have the legal minimum of 5 evaluators required by IMI, such evaluators were brought into the consensus ranking via telecom and were also asked to approve by email the consensus rapport. Invariably their comments could not be easily related to the in-depth discussion in the panel, and they were unable to benefit from the information that the other panellists discovered onsite during the course of their earlier discussions. We would recommend where possible, avoiding the use of remote-only evaluators in future and making best effort to make use of telecom, as was used, or ask remote evaluators 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.

From observation and feedback, we would recommend IMI consider the use of Median scoring rather than Average scoring for the provisional ranking, or eventually presenting both, Median and Average scores. This recommendation is based upon the observation that the use of Median puts less weight on the occasional outlier score. Topic 3: Delivery of Biopharmaceuticals, being a case in point. By average the top 5 remote scored projects return 38.6, 37.1, 36.9, 36.7 and 35.5 respectively, with the top 4 being called for a telecom Hearing. With the use of Median scoring the No. 1 project became 42 (a near 3 point correction, which reflects a single low scoring outlier IER), No. 2 became 39, while the No. 3, 4 and 5 are now tied on 36. Were Median to be used the No. 5 would likely also have been called for a telecom Hearing. Whilst not contributing to the consensus scoring/ranking, it was interesting to note that the EFPIA representatives scored the No. 5 rather highly (37), and the 2, 3, and 4 less so (22/18, 26, 22/23 respectively).

As previously mentioned, and recommended from previous Calls, 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 finalised 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

Before re-iterating some of the points noted that could be incorporated or born in mind to ever enhance the Stage 1 selection process for future Calls, it is worth complimenting the IMI team on having achieved a really professional and smooth-running evaluation process. While a major role of the Independent Observers is to ensure fairness and transparency, it has also proven through the incremental improvements that have been seen through Call 1 to Call 4 that this report itself and suggestions for improvements by listening to the team, evaluators and EFPIA have played a significant part in that improvement.

Five points are highlighted from this report, as follows:

- The balance of input from both Evaluators and EFPIA is considered appropriate, and this balance should be carefully maintained.

- We strongly endorse the continued use and development of the Hearings as an integral part of the Stage 1 process.
- While ensuring fair feedback to all Applicants, the evaluation panel and Moderators might actively take less time discussing in detail the low ranking projects where there are many applicants in a topic.
- Continue the use of Rapporteurs, ensuring that they have timely notice and a clear brief so can prepare before coming to Brussels
- We recommend, as did previous observers, that all evaluators have access to all IERs comments and scores once they have finalised their own IER and before arriving at the panel meeting in Brussels

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.