

IMI – 7th Call 2012

Evaluation of Stage 1

November 2012

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 7th Call for proposals by the Innovation Medicines Initiative (IMI). The 7th Call was launched 17th July 2012 and submission of proposals in response to the 2 topics was invited: -1st Call topic: “Developing a framework for rapid assessment of vaccination benefit/risk in Europe” and -2nd Call topic: “Incorporating real-life clinical data into drug development”. The IMI website accepted Expressions of Interest (EoIs) in response to the Call up until a deadline for submission of 9th October 2012.

Submitted EoIs were then remotely evaluated over a three week period, both by independent experts and by representatives of the companies within the planned EFPIA consortium for the Call topic. The independent experts, along with the coordinators and deputy coordinators of the Call-generating EFPIA consortium, were then brought together in the Crowne Plaza meeting rooms in Brussels from 8-9 November 2012 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 Dec 2012, concluding Stage 1 of the 7th 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. As highlighted below, improvements in the procedures from the previous Calls were implemented and conserved. The clarity of the onsite briefings for evaluators was especially appreciated as well as the excellent organization and coordination of the process. The observers were very pleased to see that the 1,5 day process was set up according to the plan and all panels for the 2 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 carried 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 continued use of ‘Hearings’ were organized in a very effective manner and appeared universally welcomed.
- 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 IMI expert evaluators in the case of all proposals, in the absence of the EFPIA representatives. The opinions of all experts on a panel were considered and discussed in equal terms while making the final decisions.
- The Consensus reports were drafted with active participation of all evaluators and reviewed collectively, under the guidance of the IMI project officers to ensure the comments and recommendations were in line with the scores.

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 both days of evaluation sessions at the Crowne Plaza meeting rooms in Brussels 8-9 Nov 2012. While there, they attended the briefing sessions, sat in on the panel discussions, 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.

4. Observations and recommendations

In the following sections we record our observations on the Stage 1 evaluation process, we 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 noted that the Open Information Day for Applicants on the 7th Call was held on 30 May 2012, about 6-7 weeks before the official launch of the Call on 17 July 2012. This, combined with the provision of webinars for potential applicants (see 4.2 below) and other forms of communication, 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 2 topics was explained not only in 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.

The observers were further pleased to see a 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.

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.

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). The mix of the panel ensured a balance such that no one person monopolised the debate and everyone contributed to all the discussions, apart from when they had to withdraw due to stated conflicts of interest.

A full information package on how the call was developed was submitted to the evaluators before they started their evaluation, we did observe that there was still a slight confusion on exactly how the text of the Call was developed and the Vision behind it. The concept of joint development of a vision with industry for instance and role of the EFPIA representatives as evaluators in the 1st stage and applications in the 2nd stage, are quite different from how FP7 calls are developed and these differences may not be understood immediately by every evaluator. We would suggest that although this was well explained at the beginning of the stage 1 evaluation sessions and the background was available as link in the information package, it might be helpful to include a copy of the presentation and a link to the webinar in the main message to the evaluators.

In addition, in each evaluation panel there was the Coordinator and/or Deputy Coordinator (or appointed representative) of the appropriate EFPIA consortium present. This combination of independent and EFPIA-associated experts was beneficial for the evaluation. The EFPIA Coordinators and Deputy Coordinators were once again, for this Call 7, 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. 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. On the other hand, to ensure independency in evaluation, the EFPIA representatives left the room during the consensus evaluation and scoring of the EoIs.

While the observers noticed and received feedback that there was generally a good balance and helpful contribution from the EFPIA representatives, in one group a few independent experts had the feeling that the EFPIA representatives were perhaps too present with their comments. This concern was discussed in this group, but it was not shared with all other experts. Also the independent observer in that group did see very active EFPIA participation, but not any influencing on the decision making.

It was noted that for the topic where this discussion took place, EFPIA had scored and ranked the proposals with very much the same scores and ranking as the independent panel experts. In the second panel the EFPIA representatives were highly engaged, but not seen as exerting under influence on the panel.

4.3.1 Hearings

The observers were pleased to note the continued use of telecom Hearings. Here, during the initial consensus discussions a few of the top ranked proposals from the remote evaluation were invited (through teleconference) into the process to answer specific and suitably detailed questions (maximum 5 specific questions per EoI) composed by the independent experts and EFPIA representatives jointly. The consortia representative had been warned in advance that in principle there was a chance they could be called. Questions were sent 1- 2 hours before the call to allow them to reflect briefly. The expert panel received the recommendation that the hearing questions were meant only to clarify certain key issues to help with consensus scoring and ranking, not to collect new information. During the call the questions were read out by one of the IMI staff, while the phone was on mute so anonymity of the expert evaluators was guaranteed (following a previous recommendation from independent observers). These hearings were extremely useful in providing the panels with a deeper understanding of the strengths and weaknesses of the proposals. We strongly recommend the continuation of this practice.

4.4 Timelines

4.4.1 Timelines for evaluation of Expressions of Interest

The time allotted for remote evaluation of the EoIs (three and a half weeks on this occasion) appeared to be adequate. There was a last minute drop-out of one expert on one panel and therefore –in order to have the min of 5 experts required - one expert had to be appointed last-minute (on 6 November) and agreed to carry out the remote evaluation until 7 November, late afternoon. However no complaints about the timeframe were received from the evaluators.

4.4.2 Timelines for Preparation of FPP

The time allotted for preparation of FPP (indicative 21/11/2012 to 01/02/2013) was not commented on by the independent observers on this occasion.

4.5 Guidance for evaluators

As noted in previous Observer reports, the evaluators possessed a greater understanding of the process than in earlier years of the IMI program. As noted above under paragraph 4.1 the information package was needed. A contributory factor was also 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 for the EFPIA consortium coordinators. These calls took place on 25 October 2012, 26 October 2012, 29 October 2012 and the 6 November according the availability of the evaluators.

Also, the IMI director, Michel Goldman, and the IMI staff took sufficient time on the first day of the panel discussions to explain the rules (eligibility, participation), evaluation process and the decision making process, including impartiality and the various types of conflict of interest for which the evaluators should be alert. Also, to avoid any interference between the two panels dealing with the 2 topics, the evaluation panel discussions took place on two different floors of the building.

4.6 Role of the EFPIA coordinators and deputy coordinators

In addition to comments in section 4.3, it was again noted 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 an ongoing recommendation, we endorse the continued explicit clarification in both the briefing and the panel sessions on the respective roles of EFPIA representatives, as distinct from the independent evaluators. It is also important that the EFPIA representatives are of sufficient seniority and experience to be able to clearly articulate the rationale behind the call (i.e. the question to be answered) as well as command the respect of the expert panel.

4.7 Moderation of the expert evaluation panels

As with previous Calls, the evaluation sessions were moderated by Scientific Officers from the IMI office. Once again the 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 sessions 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, that comments made by independent evaluators who could not be physically present in the consensus discussions were taken into account as well and that the overall wording reflected the scores and ranking.

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 before the consensus meetings helps to streamline the process so they could be prepared for this task and this should be done in a timely manner.

4.9 Remote evaluation

It was noted that not all independent evaluators were able to be present at the evaluation sessions in Brussels, but as stated in 4.7, their comments were readily available for everyone and the scientific officer made sure these were taken into account through the discussions. In the case of one panel, two members participated from the USA remotely. However the use of a camera to relay the proceedings in the room worked extremely well and these remote panellists were very engaged in the review at all times. The use of a camera really added to this and is certainly warranted where there is more than one remote evaluator.

4.10 The evaluation tool

The online submission and evaluation system appeared to have functioned effectively, for the most part.

All independent evaluators were able to see the other evaluators' (anonymized) scores and comments to allow better preparation for the onsite evaluation meetings.

It was further noted that, following recommendations from earlier Calls, a remote ethics screening stage has been added after the completion of Stage 1.

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 6 that this report itself and suggestions for improvements by listening to the team, evaluators and EFPIA have played a significant part in that improvement.

Four 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 ensuring clear communication of the respective roles. New independent evaluators may be more familiar with the FP7 program rules and evaluations and may be confused by the specific concept of co-funding under IMI.
- As these calls have illustrated, ex-Europe evaluators do not have a good understanding of the EU regulatory environment and also how the public health systems work and the key stakeholders involved. Some education or background will be required for these types of calls for evaluators outside of Europe.
- We strongly endorse the continued use and development of the Hearings as an integral part of the Stage 1 process.
- Continue the use of Rapporteurs, ensuring that they have timely notice and a clear brief so can prepare before coming to Brussels

5 Other recommendations

As the broader aim of IMI is to make strategic changes in the entire sector, it is clear that other stakeholders than the usual projects partners (academics, SMEs, EFPIA members) should be involved more deeply in the projects where appropriate. For example, dissemination of new methodology will not ensure adoption and implementation of those methodologies in practice. Also, they need to be recognized by the regulators as valuable and eligible in the regulatory process. Moreover, these innovations need to be to the actual benefit of the patients, HTA schemes need to recognize the added value for Healthcare Outcome and national reimbursement schemes need to be ready and willing to pay back. This goes towards recognition that Innovation is needed beyond the product or service level with clinical value, but involves also a focus on socio and economic parameters that affect uptake and market.

The 2 topics under Call 7 already move in that direction in which CROs, patient organizations, regulators (EMA, ECDC) and HTA organizations were specifically mentioned in the call text and invited to participate in the consortia. Practical problems could arise if one specific key organization (e.g. EMA) then has to be present/be invited into competing consortia in order to be eligible for receiving funding. An alternative option could be to set aside a special budget line (of a few %?) from the IMI budget, not from its overheads and separate from the call funds and at the discretion of the IMI Board, to be allocated to support the active involvement of such key stakeholders to the consortia that go through the first stage evaluation (top up their project budget). Flexibility to include non-traditional participants if required might also be necessary e.g. if diagnostics or medical devices become important for a particular proposal.

In one panel there were some discussions about the two highest ranked proposals both of which had some deficiencies. There was some discussion of merging them. Clarity about the process and whether projects can be joined or not ahead of time was given by the IMI office. However this highlighted an issue which may be more important if more of these types of call are progressed in future. This is where there are key public bodies (either data holders, historical hubs etc) that would need to engage with a highly ranked proposal but don't do so in practise. This could be because they have decided to set up their own proposal or for some other reason, such as perceived loss of control/influence. This could lead to a real issue in terms of a lack of incentives to really make an impact and to do things differently i.e. it will lead to maintenance of the status quo and panels making 'safe bets' rather than fund proposals that could create real step changes.

Looking at one of the proposals, there was a very regional perspective and this may occur more where significant regional differences exist in regulations, care systems, record keeping etc. Perhaps there is a need to have more exemplars when launching this type of call to show the preference for pan-European solutions rather than regional specificity of calls.

Independence of regulators and government bodies involved in setting guidelines for administration and approval may be challenged by their involvement in this type of call.

6 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. In particular they would also like to thank the IMI staff for their help before, during and after our stay in Brussels for the consensus evaluation meetings.