

IMI-2 – 5th Call 2015

Evaluation of Stage 1
Nov 2015

Independent Observers' Report

Dr Erik Forsse

Karolinska Institutet, Sweden

&

Dr Frank Heemskerk

CEO Research & Innovation Management Services, Belgium

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 Expert evaluation panels
 - 4.2 Hearings
 - 4.3 Role of the EFPIA coordinators and deputy coordinators
 - 4.4 Moderation of the expert evaluation panels by IMI
 - 4.5 Interim Review
 - 4.6 Remote evaluation and ICT environment
5. Overall Conclusion and comments
6. Acknowledgements

Abbreviations:

EFPIA - European Federation of Pharmaceutical Industries and Associations; IMI Innovative Medicines Initiative_

2 JU; SP – Short Proposal; FP - Full Project Proposal

1. Background

This is the report of the independent observers for Stage 1 of the 5th Call for proposals by the Innovation Medicines Initiative-2 (IMI-2) under reference: H2020-JTI-IMI2-2015-05-01. The 5th Call was launched 9th July 2015 (<http://www.imi.europa.eu/content/imi-2-call-5-0>) and submission of proposals in response to 5 topics was invited: -1st Call theme: "opportunities to join new projects on Alzheimer's disease, diabetes, & patient engagement". The IMI IT submission tool accepted short proposals (SPs) in response to the Call up until a deadline for submission 13th October 2015.

Submitted SPs were then remotely evaluated over a three week period by independent experts. Additionally, those companies within the EFPIA consortium associated to a given topic also had access to the submitted proposals. The independent experts, along with the coordinators and deputy coordinators of the Call-generating EFPIA consortia associated to the topics, were then brought together for the evaluation meeting in Brussels from 16-20 November 2015 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 SPs for each Call topic. The results of these evaluations are communicated to applicants in Dec 2015, concluding stage 1 of the 5th Call for proposals.

2. Overall observations

The observers found that the Stage 1 evaluations were conducted professionally and fairly and according to the established procedures and regulations. Both observers were struck by the dedication of all participants to ensuring an impartial and thoughtful evaluation of all SPs. The IMI team once again performed an outstanding job in publishing and publicizing the Call, organizing the SP submission and evaluation process, contacting highly professional and well qualified professionals and in putting together the onsite evaluation meetings. The clarity of the onsite briefings for evaluators was especially appreciated as well as the excellent organization and coordination of the entire process, given that organizing the evaluations for 5 topics in one week with such a small team is a fairly complex task. The observers were very pleased to see that the 5 day process was set up according to the plan and the panels for the 5 topics ran 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 SPs, 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
- Good practice was to do a joint decision making whether it was necessary and appropriate to have such a 'hearing' (not for all topics), and it was fair to ask the same set of questions to the different consortia competing within the same topic.
- 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 independent experts in the case of all proposals, in the absence of the EFPIA representatives.
- The opinions of all experts on a panel were considered (also those participating remotely through Teleconference, which happened occasionally) and discussed in equal terms while making the final decision.

- 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 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 relevant IMI2 *Manual for submission, evaluation and grant award*, the role of the independent observers in the evaluation process is as follows:

- to observe the practical workings of the evaluation process;
- to give independent advice on:
 - the conduct and fairness of the evaluation sessions;
 - the application of the award criteria;
 - ways in which the procedures could be improved, but

Observers do not express views on the proposals or the other experts' opinions.

3.2 Working method of the independent observers

In performing their task the 2 independent observers had access to all written information supporting the Stage 1 evaluation process, and access to the SOFIA environment. They attended 5 days of evaluation sessions in Brussels. While there, they attended the briefing sessions, divided their attention across the parallel panel discussions, and spoke individually with many of the independent experts present and industry representatives. 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 the new IMI Executive Director, Dr Pierre Meulien.

4. Observations and recommendations

In the following sections we record our observations on the Stage 1 evaluation process and give some recommendations on issue to be aware of which we feel might benefit the process for 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 Independent expert evaluation panels

The experts in the evaluation panels were selected and invited by the Scientific Officers. All experts fulfilled the criteria stipulated 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 in none of the 5 panels, did one person monopolise the debate. The IMI staff encouraged the discussions of panels so that everyone contributed to all the discussions, apart from when they had to withdraw due to stated conflicts of interest.

There was some variation between panels in the number of experts present. Group dynamics is important for consensus and, in addition to covering necessary expertise, the overall aim should be to maintain a group size for good communication and efficiency. Although connecting a remote expert via phone is a possibility in exceptional cases, it is not optimal for interaction in the group.

Most of the evaluators were already aware of the nature and goal of the evaluation process, their responsibilities, the choices available to them and the consequences of their decisions. Rapporteurs had been appointed for each panel for each Topic prior to the meeting which worked well. Still, IMI Executive Director Dr Meulien and the IMI staff took sufficient time to explain the rules (eligibility, participation etc.), evaluation process and the decision making process, including impartiality and the various types of conflict of interest for which the evaluators should be alert.

Issues of potential conflict of interest were taken seriously and principles were explained by the IMI Executive Director and the other IMI staff in the Briefing sessions. These were reiterated by the IMI staff with the entire panel by arranging time for a round with open discussion in which each evaluator of the panel was invited to declare and explain any potential conflict of interest situations and how they would be dealt with.

A full information package on how the call was developed was submitted to the independent experts before they started their evaluation. We did observe, however, 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 the role of the EFPIA representatives as part of the evaluation discussion in the 1st stage and as applicants in the 2nd stage, is quite different from how H2020 calls are developed and these differences may not be understood immediately by every evaluator. We noticed that the IMI staff were aware about this and early in the discussions took the time to explain, which was essential for the quality of the further discussions.

In particular, in each evaluation panel there was the Coordinator and/or Deputy Coordinator (or appointed representative) of the EFPIA consortium present. This combination of independent experts and EFPIA representatives was beneficial for the evaluation. The EFPIA Coordinators and Deputy Coordinators were, as usual for IMI evaluations, provided with the opportunity at the beginning of each individual topic plenary session to present their views on the requirements of the topic and to describe how the EFPIA representatives had approached their own and separate SPs review process. The information and the context provided by EFPIA representatives was generally perceived as very helpful for evaluators and 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 SPs.

While the observers noticed and received feedback that there was generally a good balance and helpful contribution from the EFPIA representatives, in 2 of the 5 panels a number of the independent experts had the feeling that the EFPIA representatives were perhaps too present with their comments. Although the independent observers in each group did see very active EFPIA participation and strong opinions, the actual decision making and scoring was not influenced. It was noted that for the topics where these discussions took place, the separate EFPIA representatives review of the proposals (with scores and ranking) was significantly different (in scores and ranking) compared to the independent panel experts. The EFPIA representatives did express their concerns and reservations about the top selection of the independent experts in the open discussion after the ranking and scoring had been set. These concerns were discussed in both groups briefly, but it is recommended that also the sharing of the decision making process (the moment when the IMI officers tell the EFPIA representative of the outcome of the debates and decision on the final scoring by the independent experts) is done in the presence of the entire group, just to avoid discussion between EFPIA experts with IMI staff directly, in absence of the independent expert group to defend their decision. Final willingness to build/maintain trust between the EFPIA and the academic side of the consortia should always be the main objective and needs to be facilitated by IMI whenever possible, therefore it should be completely avoided that IMI staff at any moment can be drawn into the decision making process.

The basic process for the onsite panel discussions was as follows:

- 1) Each panel member was invited to briefly describe his/her main points of concern about the proposal and then the panel formulated a list of questions for the Hearing session with project coordinators,
- 2) The academic representatives/coordinators of the consortium received these questions as they were notified in advance of the hearing, then
- 3) each panel of independent experts worked separately on the preparation of their consensus evaluation report.

In all sessions, the independent experts brought specific knowledge, perspective and commitment to the discussions with the result that each proposal was critically examined. Considerable time was spent preparing a list of detailed and well-structured questions that were to be addressed during the hearing session. If each expert or the rapporteur had brought to the meeting a set of a few questions, the process might have been less time consuming.

Since recommendations were not to be made to the consortia at this stage, it fell to the responsible IMI scientific officer to repeatedly remind the panel members of this and steer away from such recommendations. Generally there was some frustration about this rule (imposed as to follow the general rules of H2020) as some recommendations would have been of critical importance for the success and impact of the later developed project proposal.

4.2 2 Hearings

The observers were pleased to note the continued use of a remote (by audio-conference) Hearing. IMI moderators repeatedly warned the panels to base their decisions and final scoring on the SP, the hearing was only to clarify minor issues.

The expert panel were told that the hearing questions were meant only to clarify certain key issues to help with consensus scoring and ranking, not to collect entirely new information. During the Hearing the questions were read out by the IMI staff member. These Hearings were quite 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.

The quality of the sound both during hearings and for remote experts was occasionally very bad indeed. Some thought should be spent on how to improve the quality of sound and reliability of connections. Another option to further develop the process would be that coordinators provide written answers just before the hearing. They sometimes seemed to be reading from such texts that they had prepared anyway.

4.3 Role of the EFPIA coordinators and deputy coordinators

In addition to the comments in section 4.1, 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.

4.4 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 one or 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 was not being missed, that comments made by independent evaluators who could not be physically present in the consensus discussions were well taken into account and that the overall wording reflected the scores and ranking.

4.5 Interim Review

N/A in first stage evaluations.

4.6 Remote evaluation and ICT environment

As noted above not all independent evaluators were able to be present at the evaluation sessions in Brussels, but their comments were readily available for everyone and the scientific officer made sure these were taken into account through the discussions. The online submission and evaluation system appeared to have functioned effectively without technical problems, albeit sometimes slow and generally it was recommended to use offline drafting/editing and then copy-paste into the online system. Here the lack of sufficient IT support was felt to preserve weaknesses and prevent continuous improvements in the entire system.

Once the remote evaluation was closed, all independent evaluators were able to see the other evaluators' (however anonymized) scores and comments to allow better preparation for the onsite evaluation meetings.

5. Overall conclusions and comments

Before re-iterating some of the points noted that could be incorporated or born in mind to further 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. The following recommendations were made:-

- 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 and independent observers, ensuring that they have timely notice and a clear brief so that they can prepare before coming to Brussels

- The balance of input from both independent experts and EFPIA representatives 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 rules and evaluations in other EU programs (i.e. H2020) and may be confused by the specific concept of co-funding under IMI.
- Similarly, independent experts from outside Europe (e.g. USA) may not have a good understanding of the EU funding and regulatory environment and also how the public health systems work and which key stakeholders are involved. Some extra education or background information will be required for these types of calls for evaluators coming from outside of Europe.
- In recent years the IMI-2 program has been forced into straightjacket of the unified H2020 program rules. Not all may be applicable to the IMI-2 program, with its very specific characteristics of co-funding with industry and a 2 stage process with only 1 selected consortium to build a full proposal.

Recommendation 1: allow recommendations to be provided by the expert panel, if positively constructive and adding value or contributing to the success, as under IMI-1 (argument to divert from general H2020 reviews rules: only 1 project is selected for stage 2). This could also mitigate the risk of failures in the 2nd stage, if decisions in the stage 1 evaluations - have to be made based on incomplete information- between 2 top proposals that seem to have different flaws.

Recommendation 2: continue with the optional hearings

Recommendation 3: the work load on the IMI staff to organize the logistics plus ensure the quality of these evaluations appears to be high (note: in H2020 many of the support tasks and logistics are taken care of by dedicated agencies, like REA). Although we would not recommend that these are all outsourced (given the specific nature and delicacies of the IMI program) we would suggest reinforcement of the IMI team with more personnel.

Recommendation 4: include more IT support to the IMI staff / team, to maintain the online system and redesign where necessary

Recommendation 5: allow longer and/or a broader content for stage 1 proposals (with longer page limits?): e.g. allow some information on governance to be judged (like a mini proposal with summarized info on all 3 aspects that will be part of the 2nd stage proposal). Much frustration was vented during the evaluations about the complete lack of insight in essential governance approaches, work plan and budget, although this could make or break a good decision on selection of the top consortium. Again: only 1 consortium is invited for stage 2, which is fundamentally different from the H2020 2-stage process.

Recommendation 6: perhaps, and if possible, re-negotiate the position and participation of the other stakeholders (EMA and ECDC for instance) in IMI consortia: how they are engaged, at which stage and above all, whether they can receive funding, as their active participation in the consortia sometimes can be essential to the success and impact given the broad and inclusive nature of some calls. 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.

Recommendation 7: There is a need to address the training needs for IMI staff: currently no budget nor time and capacity are foreseen for this.

Recommendation 8: perhaps one needs to consider how the key stakeholders like EMA, ECDC, JRC can be consulted actively in the preparation of the calls. It may be necessary to ensure that they have contributed to the

development of the priorities and the call text.

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 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 these consensus evaluation meetings.