IMI – 5th Call 2012

Evaluation of Stage 1
June 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 5th Call for proposals by the Innovation Medicines Initiative (IMI). The 5th Call was launched 6th March 2012 and submission of proposals in response to 1 Call theme: the European Lead Factory was invited, covering two topics (i. European Screening Centre, and ii. Joint European Compound Collection). The IMI website accepted Expressions of Interest (EoIs) in response to the Call up until a deadline for submission of 16 May 2012.

Submitted EoIs were then remotely evaluated over a three week period spanning the 23 May and 13 June 2012, 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 18-20 June 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 early July 2012, 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. 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. Once again, and as highlighted below, improvements in the procedures from the previous Calls were obvious to both observers. 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 2½ 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 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 continued use of ‘Hearings’ (newly introduced in Call 4) 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 ongoing 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 improvements to the process that have been incorporated since the 4th 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 2½ days of evaluation sessions at the Crowne Plaza meeting rooms in Brussels 18-20 June 2012. While there, they sat in on the panel discussions, 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.

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 noted that the Open Information Day for the 5th Call was held on 27 February 2012, only one week before the official launch of the Call. There was however, a draft of the Call available from 3 February 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 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. As an ongoing recommendation in this later respect, EFPIA and IMI should continue to keep in mind 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.
The observers were further pleased to see, as noted also from Call 4, 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.

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).

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 once again, for this Call 5, 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, there were some comments raised concerning the EFPIA scoring of the proposals and how these were presented to the independent experts. It was noted that EFPIA had scored and ranked the top 3-4 proposals for each topic, but then scored remaining proposals as Zero. In presenting the EFPIA scoring the EFPIA representatives clearly indicated that if selected by the independent experts, the consortia scored as Zero would not be supported by EFPIA.

RECOMENDATION A: Ensure that EFPIA objectively score all proposals according to the same criteria as the independent experts, and present balanced reasoning for pros, cons and ranking.

4.3.1 Hearings

The observers were pleased to note the continued use of telecom Hearings. Here, between 2 and up to a maximum of the top 4 ranked proposals from the remote evaluation were joined into the process to answer specific and suitably detailed questions (maximum 5-7 specific questions per EoI) composed by the independent experts and EFPIA representatives. We strongly recommend the continuation of this practice.
While there was a noticeable improvement in the telecommunications system used, compared to Call 4, there was still some room for improvement in the audio quality for all to be able to hear the conversation. The availability of a mute button, which was absent, is also recommended.

**RECOMMENDATION B:** Given the strong value placed on the Hearing, it is recommended to further look to improve the audio quality and functionality of the telecommunications system used.

### 4.4 Timelines

#### 4.4.1 Timelines for evaluation of Expressions of Interest

The time allotted for remote evaluation of the EoIs (three weeks on this occasion) appeared to be adequate. 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 (3 months) was not commented on by the EFPIA representatives on this occasion.

### 4.5 Guidance for evaluators

As noted following Call 4, 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.

### 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.

### 4.7 Moderation of the expert evaluation panels

As with the 4th Call, 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.

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 Rapporteurs were once again pre-assigned before they arrive in Brussels, thus in principle giving them time to prepare for this role.

4.9 Remote evaluation

It was noted that all independent evaluators were able to be present at the evaluation sessions in Brussels.

4.10 The evaluation tool

The online submission and evaluation system appeared to have functioned effectively, for the most part. A bug in the software was noticed midway through the evaluation panel, which resulted in incorrect weighting for one of the evaluation criteria. The Scientific Officers responded quickly once this it was noticed, and were able to clearly report and confirm that this error had not materially affected the proposal ranking.

The observers were pleased to see that following recommendations from Call 4 Median scoring as well as Average scoring was presented for the provisional ranking, providing a helpful check on variance between the independent evaluators scores.

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

It was further noted that, following recommendations from Call 3 and Call 4, a remote ethics screening stage has be added after the completion of Stage 1. It will be interesting to see the impact of this new process on Stage 2

RECOMENDATION C: Fully QC and sense check the functionality of the remote evaluation tool ahead of each Call.

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

Three 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.
• 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 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.