

IMI2 JU INDEPENDENT OBSERVER'S REPORT

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Present at the evaluation: 16-19 FEB 2016

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1. Introduction and approach taken by the observer

The evaluation was followed to observe and report on the practical workings of the evaluation process, on the conduct and fairness of the evaluation sessions, on the application of the award criteria and on the procedures and their implementation, including IT tools.

Based on his observations, the Independent Observer (IO) gives independent feedback on the evaluation process.

This is the report of the Independent Observer for Stage 1 of the 6th Call for proposals by the Innovation Medicines Initiative (IMI2). The 6th Call publication date was 6 October 2015.

Submission of short proposals (SPs) was invited in response to four topics in the 6th Call:

1. QST approaches to improve the understanding of the safety of new medicines.
2. Establishing impact of RSV infection, resultant disease and public health approach to reducing the consequences.
3. Real World Outcomes Across the AD Spectrum (ROADS) to Better Care (Part of the IMI2 Big Data for Better Outcomes Programme).
4. Development of an outcomes-focused data platform to empower policy makers and clinicians to optimize care for patients with hematologic malignancies (Part of the IMI2 Big Data for Better Outcomes Programme).

The IMI JU through its electronic submission tool received Short Proposals (SP) in response to the Call up until the deadline for submission (12 January 2016).

Submitted SPs were then remotely evaluated over a four week period prior to the 16 February 2016, both by Independent Experts (IEs) and representatives of the companies within the planned Industry Consortium for the Call topic. The IO also had remote access to all submitted SPs.

The IEs and representatives of the Industry, were then brought together in the Crowne Plaza Hotel meeting rooms in Brussels from 16-19 February 2016 to finalise the Stage 1 evaluation process. Each evaluation took two days (topics 1 and 2 on February 18-19, topics 3 and 4 on February 16-17). General discussion on the merits of each application, initial rankings and cogent questions to ask each set of applicants, if and when applicable, took place on the first of these days, with the collated questions being asked during a hearing and the evaluations being finalised on, the second day. This resulted in a consensus ranking of the submitted SP for each Call topic.

The ranking will be submitted to the Governing Board for approval in early March 2016 and the result will be communicated to the Applicant Consortia shortly thereafter, concluding Stage 1 of the 6th Call.

The first ranked consortium for each topic will be invited to join the respective Industry consortium to develop a full proposal (FP) which will be evaluated in Stage 2 on 6-8 July 2016.

The IO had access to all written and on-line information supporting the Stage 1 evaluation process and attended all four days of the briefing and evaluation sessions, Panel discussions and hearings held on 16-19 February 2016.

In execution of his task, this IO took the following approach:

- personal observation of each evaluation with allocation of time between panels to ensure visibility and accessibility;
- informal discussions with all participants (IEs, Industry representatives and IMI employees), in groups or individually, mainly during the breaks and at lunch time.

2. Overall impression

While the evaluation task is a complex one, with leading edge science aspects as well as process wise, stage 1 evaluations were conducted professionally, fairly and with commitment from all participants, ensuring an impartial and thoughtful evaluation of all SP. Procedures were implemented efficiently and reliably, the process went on smoothly and transparently. With appropriate management and active support from the moderators, throughput time of the process was in line with time allocated in the agenda.

The need for confidentiality was clearly communicated and understood by all IEs and Industry representatives, as well as conflict of interest rules.

The IMI Team organised the SP submission and evaluation process skilfully. Well qualified professionals were contacted to conduct the evaluations, and take part in the onsite evaluation meetings as IE.

The well-defined evaluation procedures, the high scientific level of IE and the skilled Scientific Officers supported by a very competent staff allowed the proposal of the four calls to benefit from a high quality assessment.

There were no observed violations against the rules of the published evaluation guidelines.

IE were of a high quality and possessed all the relevant expertise for the evaluation of each topic. This was confirmed by Industry representatives, one of whom told this IO *"we have the right experts in the room"*.

All participants approached their tasks with commitment and professionalism.

Evaluation of the SP, panel discussions and questioning of the applicants, were fair and transparent.

When deemed necessary, hearings were organized in an effective manner.

A consensus was reached by the IE on the scoring and ranking of all proposals, in the absence of the Industry representatives.

The evaluation process witnessed conformed to the evaluation procedures published in the IMI2 Manual for Submission, Evaluation, and Grant Award.

This assessment is based on personal observation and interactions with IE and Industry coordinators as well as IMI staff.

3. Any other remarks

The quality of the documentation provided to experts beforehand is fully in line with H2020 guidelines.

One IE mentioned to this IO that he would have liked to have more contextual information on the IMI-specific process, which he could not recover from the publicly available information.

The on-site briefing sessions opened the review of topics and were helpful both to frame properly the evaluations on vision, goals, measure of success, process and guiding principles, as well as remind IE of the confidentiality and conflict of interest rules and make a last check about it, as well as opening the floor for questions.

The understanding by IE of the call (context, topics), of the evaluation process and their role and of the award criteria and scoring scheme was good and there were few clarification questions on these topics.

The balance (gender, geographic, sector), relevance and balance of expertise from IE was good and praised by Industry representatives.

The process of the individual evaluations, consensus meetings, final panel meeting, hearings and the actors involved went smoothly and transparently.

The handling of conflicts of interest was conducted in an appropriate manner.

The quality of evaluation summary reports represent fairly and adequately the consensus opinions of the Panels.

IMI staff have to be thanked for their help, competence, responsiveness and hospitality before and during this IO stay in terms of scientific, organisational, procedural and logistic matters.

Infrastructure and working conditions for IEs were perceived as adequate and buffet setting for breakfast, lunch and breaks was universally appreciated and helped informal interaction.

Workload and time given to evaluators for their work, (remotely and/or on-site, as applicable): the workload was acceptable and time allotted for remote evaluation of the SPs was acceptable.

Remuneration of evaluators (in relation to workload) is perceived to be on the low side but acceptable since it is public money.

Some of the IMI-specifics (like topic focus, large enough amount of information in the application at stage 1 given the size of budget going to applicants...) are not very well taken care of by H2020 rules.

This IO was helped in his task by all participants in the Stage 1 consensus meetings and thank the IEs and Consortia members for being amenable to being "observed" and for the formal and informal conversations that helped formulate this report.

4. Summary of Recommendations

While the key assignment of the IO is to ensure fairness and transparency, suggestions and recommendations for improvement by listening to the team, evaluators and Industry can play a role in further improving the evaluation process.

In one topic, Industry representatives got some questions after their presentation. They were wondering about the possible benefits of a webcast or teleconference to make their presentation before the actual coming together in Brussels.

Industry representatives mentioned the tight timelines for stage 2 preparation, especially for the hematologic malignancies topic, given that the deadline is also the first day of the most important European hematologic malignancies scientific conference. It could be worth checking dates of major medical/scientific congresses to avoid timelines issues.

There were a few discussions around excellence and impact. One IE added a chronological dimension to it, viewing excellence as being grounded in past achievements (publications, notoriety...) and fact-based, while impact is more future-oriented and less fact-based. IEs around the lunch table were interested in having a clearer approach to what was expected and how to score impact in a more factual manner.

A few IE felt bio-breaks could have been offered. They were clearly hesitant to leave the room outside of planned breaks. Clear housekeeping rules communication by moderators at the beginning of the evaluation could help solve this small issue.