

IMI2 JU INDEPENDENT OBSERVER'S REPORT

Call ID: Call 6 S2

Date of evaluation: 06-07 JUL 2016

Number of pages in this report (title page included): 5 (five)

MARC CZARKA, MD, FBCPM

Present at the evaluation: 06-07 JUL 2016

Signature and date



01/12/2016

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 advice for improvement of the evaluation process.

This is the report of the IO for Stage 2 of the 6th Call for proposals by the Innovation Medicines Initiative (IMI2). The 6th Call publication date was 6 October 2015.

Short Proposal (SP) submission took place on 12 January 2016 and evaluation on 16-19 February 2016.

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

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 the FPs up until the deadline for submission (14 June 2016). Submitted FPs were then remotely evaluated over a fourweek period prior to the 6-7 July meetings, by Independent Experts (IEs). The IO also had remote access to all submitted FPs.

The IEs were then brought together in the Crowne Plaza Hotel meeting rooms in Brussels on 6-7 July to finalise the Stage 2 evaluation process.

Each evaluation took one day (topics 1 and 3 on 6 July, topics 2 and 4 on July 7). Each day started with a briefing that included a clear presentation of context, objectives and processes as well as detailed information on the IMI's rules and procedures regarding conflicts of interest.

The purposes of the evaluation meetings are to agree on consensus scores for the full proposal against the criteria in the evaluation form, to provide the applicant consortia with fair and clear feedback justifying the consensus score and, last but not least, to provide the IMI Governing Board with an overall go/no go recommendation on the FP.

General discussion on the merits (excellence, impact, quality and efficiency of the implementation) of each FP and formulation of questions to ask applicants took place in the morning of each day, with the collated questions being presented at 12:30 pm to consortia which had one hour to prepare their answers to be delivered orally during consortia hearings. The IEs discussed answers and other considerations. This resulted in a consensus recommendation of the submitted FP for each Call topic. If positive, grant agreement signature will take place in Q4 2016.

The IO had access to all written and on-line information supporting the Stage 2 evaluation process and attended the two days of evaluation sessions, Panel discussions and hearings held on 6-7 July 2016.

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

- personal observation of each evaluation with partition of time between panels to ensure visibility and accessibility;
- informal discussions with all participants (IEs and IMI Team), 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 2 evaluations were conducted professionally, fairly and with commitment from all participants, ensuring an impartial and thoughtful evaluation of all FP. Procedures were implemented efficiently and reliably, the process proceeded 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, as well as conflict of interest rules. The IMI Team organised the FP submission and evaluation process skilfully. Well qualified professionals were contacted to conduct the evaluations, and take part in the onsite evaluation meetings as IEs.

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

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

IEs were of a high quality and possessed all the relevant expertise for the evaluation of each topic.

All participants approached their tasks with commitment and professionalism

Evaluation of the FP, panel discussions and questioning of the applicants, were fair and transparent. Hearings were organized in an effective manner. A consensus was reached by the IEs on the scoring of all FP.

The evaluation process witnessed conformed to the evaluation procedures published in the IMI2 Manual for Submission, which reflects the H2020 rules.

This assessment is based on personal observation and interactions with IEs as well as the IMI Team.

3. Any other remarks

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

The on-site briefing sessions opened the review of topics and were helpful to frame properly the evaluations on vision, goals, measure of success, process and guiding principles, as well as remind IEs of the confidentiality and conflict of interest rules and make a last check about it, as well as opening the floor for questions. No conflicts of interest were brought up.

The understanding by IEs of the call (context, topics), of the evaluation process, their role and of the award criteria and scoring scheme was good and there were no clarification questions on these topics.

The general balance (gender, geographic, sector), relevance and balance of expertise from IEs were good.

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

The IMI Team has 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. This was also recognised by IEs who expressed publicly their views on the excellence of the organisation and moderation work performed by Scientific Officers and IMI staff.

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 FPs was acceptable.

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

This IO was helped in his task by all participants in the Stage 2 meetings and thanks the IEs and the IMI Team 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 play a role in further improving the evaluation process.

One IE felt bad about having to select only one SP at Stage 1 to progress to FP while there were a couple of other SPs that could also have brought value and innovation and was wondering whether there should not be an option to merge two or three SPs into one consortium with industry to progress to FP. This seems a valid thought when it comes to building the strongest possible FP.

One IE questioned this IO about IMI's policy regarding access to data and results derived from IMI's funded projects and wanted to be reassured about the ability to freely access these data as he could not find the information straight away on IMI's website. This question could be considered for a future update of the website or as a specific item in new/amended document/FAQs.

As during Stage 1, a couple of IEs felt more 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.