IMI2 JU INDEPENDENT OBSERVER'S REPORT

Call ID: H2020-JTI-IMI2-2016-09-two-stage

IMI-2 9th Call for Proposals
Stage 1 Evaluation
Date of evaluation:
September 13-16 2016

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

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Present at the evaluation: September 13-16 2016

Signature and date

October 28th 2016
1. Introduction and approach taken by the observers

This report constitutes the observations and recommendations of two independent observers who followed the evaluation of proposals for stage 1 of the 9th call of IMI-2. The call was published on April 27th 2016 with the deadline for submission of proposals being 26th July 2016. The call encompassed 6 topics, which were all Research and Innovation Actions with a two-stage submission and evaluation process.

Following the completion of remote evaluation and scoring using the SOFIA tool, the evaluation panels met for two days each between 13th and 16th September 2016, with the exception of one topic, which was finished within one day. They discussed the proposals and came to a consensus on a ranking and on the content of the evaluation reports. IMI scientific officers moderated the panel workings and IMI secretariat staff provided logistical support. EFPIA representatives introduced each panel in order to explain the call rationale and the industry perspective regarding the research and innovation outlined in the call document.

The observers worked together in the following ways:

- They viewed the results of the remote evaluations via the SOFIA tool
- They attended the overall panel briefings given by executive director Pierre Meulien at the start of each topic evaluation, and here introduced themselves to the independent experts
- They observed the panel workings, in particular for fairness and for adherence to the principles of evaluation set out in the IMI-2 Manual for Submission, Evaluation and Grant Award
- They informally discussed the views of the independent experts and EFPIA representatives of the respective industry consortium on the practical workings of the evaluation process, including 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
- They invited all independent experts to contact them after the evaluation with any observations or concerns.

Both observers were present for the four days, and this gave them the opportunity to share experiences from different panels, to gain a good coverage of parallel sessions and to discuss the findings and recommendations.

The call topics were as follows:

- Topic 1: Addressing the clinical burden of *clostridium difficile* infection (CDI): evaluation of the burden, current practices and set-up of a European research platform (part of the IMI new drugs for bad bugs (ND4BB) programme)
- Topic 2: Development of immune tolerance therapies for the treatment of rheumatic diseases
- Topic 3: Data quality in preclinical research and development
- Topic 4: Next generation of electronic translational safety – NEXGETS
- Topic 5: Identification and validation of biomarkers for non-alcoholic steatohepatitis (NASH) and across the spectrum of non-alcoholic fatty liver disease (NAFLD)
- Topic 6: Joint influenza vaccine effectiveness studies.

Topics 1-4 were evaluated on September 13th and 14th, and topics 5 and 6 on 15th and 16th September 2016, in the Renaissance Hotel, Brussels.

2. Overall impression

The observers are fully confident that the evaluation conformed to the procedures published in the IMI-2 Manual for Submission, Evaluation and Grant Award and in line with the H2020 Grants Manual. All participants adhered to the published rules and were ably guided by the IMI scientific officers. The evaluation process is mature and was expertly implemented by IMI staff. Overall, it was a very high quality evaluation.

The independent experts were well chosen to give the right expertise for the complex project proposals. The panels valued the contributions of the EFPIA representatives in explaining the context of the call topics and the industry perspectives. Panels reached a consensus and collaborated in preparing the consensus reports. Panels with the support of the legal team efficiently addressed some minor concerns regarding potential conflicts of interest in accordance with the rules governing expert participation. With one exception (concerning the very small font size, which could not be adjusted) there were no remarks about the SOFIA tool, suggesting that this has worked smoothly; in addition, it was announced that in the near future the H2020 evaluation tool, SEP, would replace the SOFIA tool and thus further updates were not planned. The independent experts had performed their remote evaluations giving explanations of the remote scores.

3. Any other remarks

In this section we will focus on a few items. Call 9 brought in some changes in the submission and evaluation of proposals. First, the stage 1 proposal length has been increased from 15 to 30 pages, in order to allow a better elaboration of project ideas by the applicants. It seemed from the topic panel discussions that most of the proposals had sufficient detail to make a robust judgement, and so this can be taken as an indication of a successful change. However, the experts frequently expressed the view that the remote evaluations took a great deal longer than half a day. The complexity of the projects in response to complex calls required the experts to read all proposals in full at least twice before starting to complete the remote reports.

Adding in the criterion of implementation forced the applicants to pay attention to it, despite the stage 1 being before any consortium is put together. The panel discussions showed that some applicants did not allocate sufficient attention to implementation, despite it being on the form and in the guide for submission. It does not have a threshold level, unlike “excellence” and “impact” and so this may explain the lack of attention from some applicants.
Thirdly, the panels needed to give feedback on all criteria even when below threshold. They acknowledged this task to be a suitable reflection of the effort and resource needed to mount a proposal.

Finally, the panels continued to avoid giving recommendations through re-phrasing their concerns as shortcomings, reflected in the score. The IMI officers gave guidance on this point throughout the report writing, and the legal officers also checked the final wording of consensus reports.

In IMI2 as in H2020, proposals have to be evaluated "as is": there is no chance to make recommendations or to formulate requirements, which in earlier Framework Programmes then could have been considered and taken into account in the preparation of the grant.

This exactly is the case in the second stage of two-stage evaluations and it has been invented in order to speed up the time from submission to grant (TTG).

In the first stage of a two-stage evaluations however, there is a chance to inform applicants of possible improvements, in particular when there are consensus meetings at stage one, and carefully written consensus reports as in this IMI-2 evaluation. The provisions for this are:

1. In case the evaluators identify shortcomings, it is not only expected to reflect this in a lower score, but in addition to clearly write them down in the consensus report.
2. The IMI2 Call 9 evaluation form offers an additional (fourth) section, called "Any other remarks on this proposal which may be of assistance to the applicants if it is selected for Stage 2 evaluation".
3. As confirmed by the moderators (and as seen in former evaluations), there is some continuity in the persons, acting as evaluators in stage 2. The independent experts were interested to see whether these remarks were taken into account or addressed by the applicants.

We consider it an advantage, that in IMI-2 the number of proposals is limited - due to the very detailed topic descriptions – and that this allows the panels to identify shortcomings and formulate remarks in the consensus meetings. Due to the nature of the application process, where the full consortium is forged only after stage 1, this is an excellent opportunity for the applicants to take advantage of the knowledge of the independent experts.

The panel moderators (IMI scientific officers take this role) worked to an agenda and standard briefing notes. This was a good addition in the process, promoting panel consistency across call topics.

Hearings were not held by most of the panels but one panel that did so found the hearing to be informative and to provide clarification that was very useful to the scoring process. The hearings were conducted fairly and adhered to the guidelines where they took place.

Several experts were new to IMI and had not acted for H2020 either. It was reassuring to observe how they quickly picked up the principles for IMI-2 evaluation, regarding the nature of the call, of the industry participation and the need for good quality feedback to applicants. Here, the role of the briefings, first to the panels by phone and then in person by the
executive director of IMI-2 at the start of each 2 day evaluation, remains vital to the proper working of the process. Several experts who missed the panel briefings by phone found they were fully informed by the pre-evaluation expert briefing held at the hotel.

The industry representatives were satisfied with the quality and mix of independent experts. The independent experts were highly appreciative of the industry perspective and contribution to the discussion. The scoring and ranking in the next step was done without industry representatives. In one topic area, however, there was some tension between independent experts and industry mainly due to a clash of communication styles. In the end there was not a disagreement about the ranking.

This leads to a further observation about the time taken by some panels to produce consensus reports. One panel worked for an additional 5 hours, while another one took a long time to produce reports. We note that previous independent observers have raised this issue, suggesting that the role of the rapporteur needs to be clarified (IO report call 7) and noting the time needed for participatory, jointly produced consensus reports (IO call 8). Here, the role of the IMI panel moderators is crucial. However, we observed that they kept to their role of moderating, asking experts to summarise and checking agreement – they did not take over the drafting. Our view is that the process can be lengthy but needs to remain as it is. Technical support with printing and language could help a little.

The surroundings, refreshments and meals and support from the secretariat and scientific officers were excellent and contributed to the smooth running of the evaluation.

4. Summary of Recommendations

We opened with our views that the evaluation of Call 9 of IMI-2 was conducted in a fully proper way. Several of our recommendations underline the importance of maintaining these aspects of the evaluation process:

- The panel briefings by phone and the in-person briefings with all the experts before they split up into topic groups.
- The mix of expertise in terms of basic research, clinical research and application
- The standard working of the panels including in the management of hearings
- The presence and contribution of EFPIA members
- The collaborative production of consensus reports by the independent experts.

A strong plea from many experts is noted: that to evaluate the proposals properly takes much longer than half a day. Experts did not complain as such about their remuneration, but we recommend that the allocation be increased or that a flat rate per proposal is given.
5. Acknowledgements

We acknowledge the helpful inputs from the independent experts, the EFPIA representatives and IMI staff.