

IMI2 JU INDEPENDENT OBSERVER'S REPORT

Call ID: H2020-JTI-IMI2-2017- 13 - two stage

IMI-2 13th Call for Proposals

Stage 1 Evaluation

Date of evaluation:

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Present at the evaluation: March 19-22nd 2018

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1. Introduction and approach taken by the observers

Our role was to listen, observe and report on the work of the panels as they went through the overall process of discussing the applications and coming to a final decision as to the one selected to go to the next stage. As such we paid particular attention to the conduct, transparency and fairness of the evaluation sessions, and the rigour as to how the scoring criteria were implemented.

- We had a very useful telephone pre-briefing from the Head of Scientific Operations (IMI2 programme office) on March 15th, which provided the background to and purpose of the IMI 2 JU funding concept i.e. a public-private partnership between academia and pharma leading to the improvement of health outcomes. The aims and strategic concept of the IMI were summarised and the sharing of the financing between the public and private explained. The evolution of the evaluation process and its current operation were also described. We were given useful advice as to how we might work in the panel sessions.
- The 12 panels were convened over a four-day period with two days allocated to assessment of each topic. All expert panel members and both observers attended a pre-briefing presentation by the IMI2 programme office.
- The IMI office provided us with hard copies of all the proposals and the aggregated expert panel comments for each proposal. These summaries formed the basis of some of the discussions within the panel, and eventually the final consensus reports for each proposal. We were also given a dedicated room for confidential discussions between panel meetings
- We shared attendance across the panels throughout the two days that each of them met. On occasion we attended the same sessions, but ensured that we attended all the panels on our own at some point. In summary, we independently observed examples of panels' discussions, telephone hearings, agreement of scores/consensus reports and final selection during the overall process.
- Both observers informally discussed the panel procedures with some expert panel members and with panel moderators during coffee and lunch breaks.
- Whilst we attended most of the sessions at different stages of the process, this meant that we observed a 'snap-shot' of what was going on, so some of our comments may only relate to a particular event rather than hold true across the board.

The details of the 13 call topics are given below (2 of the original topics received no applications):

- **Topic 1:** Assessment of the uniqueness of diabetic cardiomyopathy relative to other forms of heart failure using unbiased pheno-mapping approaches
- **Topic 2:** Genome-Environment Interactions in Inflammatory Skin Disease
- **Topic 3:** The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use
- **Topic 4:** Mitochondrial Dysfunction in Neurodegeneration

- **Topic 5:** Support and coordination action for the projects in the neurodegeneration area of the Innovative Medicines Initiative
- **Topic 6:** A sustainable European induced pluripotent stem cell platform
- **Topic 7:** Linking digital assessment of mobility to clinical endpoints to support regulatory acceptance and clinical practice
- **Topic 8:** Human tumour microenvironment immunoprofiling
- **Topic 9:** ConcePTION – Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now
- **Topic 10:** Improving the preclinical prediction of adverse effects of pharmaceuticals on the nervous system
- **Topic 11:** Translational Safety Biomarker Pipeline (TransBioLine): Enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease
- **Topic 14:** Pilot programme on a Clinical Compound Bank for Repurposing: Neurodegenerative diseases
- **Topic 15:** Pilot programme on a Clinical Compound Bank for Repurposing: Rare/orphan diseases

Topics 1,5,7,8,10 and 11 were evaluated on 19/20th March , and Topics 2,3,4,6,9,14-15 on 30th March 21/22nd 2018. Topics 14 and 15 were dealt with by a single panel.

2. Overall impression

The IMI2 JU scheme is novel, imaginative and timely and, as far as we could judge, all involved with it, both IMI staff and expert panel members, are highly supportive of the concept of a private/public resource shared programme.

The IMI staff we encountered were highly committed and professional, and very concerned to help with any problems that arose. We would like to thank the IMI administrative team for their support to all the experts and observers during the 4 days of the meeting. This was provided in an exemplary fashion.

The infrastructure and IT facilities provided for the panels were excellent. The coffee corners and lunch dining room enabled many informal discussions to take place, which is essential to the working of any successful funding organisation. One thought we had is that some sort of small social gathering at the end of the Day 1 might be welcomed by the experts, many of whom have travelled long distances to attend the meetings.

The panels were professionally managed by the IMI Scientific Officers who acted as moderators. The moderator pre-selected a rapporteur for each proposal who collated a

summary document based on the scores and comments from the experts provided ahead of the meeting. This was modified according to the discussions in the panel and formed the basis for the final consensus report. We felt that the rapporteurs worked well with the moderator and other panel members in presenting the projects and in developing the final consensus report. However, several panel members felt that the time they were given to review the applications before submitting their preliminary scores and comments was too short. In particular, the rapporteurs were placed under considerable time pressure to have their draft consensus reports ready for the meeting.

Inevitably, the concept behind IMI funding and the operational process leading to funding a project is very different to that found in more conventional academic funding bodies. This brings its own challenges but the experts understood what was needed and engaged in the process with vigour and commitment. Some commented that representation from the industrial partners at the panel meeting would help in assessing the suitability of the projects for funding, particularly with regard to judging the possible 'impact' of the proposal. We endorse this view and suggest that they may be Experts from the pharmaceutical industry who are fully retired and no longer active in the commercial sector.

The expertise of the panel experts was appropriate to the panel they were appointed to and they performed their role in a fair and unbiased way. The selection of experts was excellent and the panels had a good balance between academics and reviewers from industry and clinical institutions. The gender and country balance of panel members was in all cases appropriate. The way in which the final selection of the 'top' project was made was balanced and conscientiously handled.

We noted that there was some variation in the way the role of the moderators was performed in the different panels. In some the moderator took a more proactive 'Chairman like' approach in guiding the panel, whilst others had a more administrative style. Having said that, all the moderators encouraged the experts to engage in the very fair discussions of each proposal that we observed. They were even-handed, allowing the panel members time to make their points. In some cases, when a panel member could only be available by telephone, the moderators ensured that they were integrated into the discussion. Overall the workings of the panel were conducted with a high level of professionalism and in a transparent and courteous manner.

We recognise that the final consensus reports are necessary to explain the scoring of the projects against the scoring criteria and they provide important feedback for the applicants. However, in some panels, but not all, the development of the consensus document by the whole panel live and, in some cases, online was time-consuming and spread over both days. In our view, this limited the time for discussion of the quality and relevance of the projects for IMI funding in some panels, not helped by the fact that some had to deal with 7 projects and some only 1.

We were particularly impressed by the way in which the 'hearings' were handled. The moderators and panel members were fully engaged in developing the questions, and the teleconferences held on day 2 were a model of fairness to the applicants. The hearings were extremely helpful to the panel discussions and decision-making for scoring and for producing the final consensus report.

In summary, we felt that the panels were professional, committed and performed their tasks in an objective and transparent way.

3. Specific comments

The agenda for the meetings sets aside most of day 1 to the discussion of the merits of the projects and day 2 to the scoring, ranking of the projects and the finalisation of the consensus reports.

Some panels spent a lot of time on day 1 revising the rapporteurs' summary documents together in great detail. This was time-consuming, particularly when the panel had more than 4 projects to consider, and meant that the experts were spending time 'wordsmithing' live which inevitably resulted in there being less substantial discussion. While we can see that using the summary document as the basis for discussion has value, particularly if the rapporteur formally leads the discussion, revising it at this early stage seems premature, particularly as there is a dedicated session on finalising the consensus documents scheduled for day 2. It may be beneficial to the process that most of Day 1 were to be clearly dedicated to discussion of all of the proposals, as outlined in the agenda for the meetings, prior to the development of the consensus reports. The panel may wish to refer to the call documents and the application as required, but we advise that the rapporteurs' reports are not viewed on screen during the discussion phase. We also wondered if the whole process of writing the consensus report might be better done after the meeting by the rapporteur (maybe with the help of one other panel member) and the moderator rather than monopolising the whole panel.

There were a number of proposals with lower scores, which are unlikely to be successful. IMI might wish to review how they are handled, particularly if the panel has many projects to consider. If there is an early consensus in the panel that a proposal will not go forward, the time given to discussing could be limited and the final consensus document handled post-panel by the moderator and rapporteur. This would allow more time for discussions of the better applications.

Some of the panels only had 1 project to deal with and, in this case, it seems reasonable and in the interest of consistency across topics that there is a time limit placed on the discussion so that it is more in line with the average time spent discussing proposals overall. A further benefit to this is that the panel with few projects could have a more focused evaluation and that proceedings could be close to finishing in one day. We were present at 2 panels when there was only one proposal. In one, more time was spent on the wording of the consensus document from the start of the panel meeting, and in the other, the first hours of the meeting were entirely devoted to discussing the project, as planned in the agenda; we felt that the latter approach was preferable. Having said that, in both panels the amount of time spent on detailed changes to the consensus paper was far more than that possible in those dealing with more proposals. IMI should consider how to enable improved consistency between topics in the review and formulation of reports.

We know from our own experience that chairing/moderating panels is difficult. We feel that IMI could establish greater consistency in that role by sharing the expertise of experienced scientific officers to establish guidelines for good practice.

4. Summary of recommendations

1. We recommend that the IMI management work with the moderators to encourage discussion of the best practice for moderating/chairing panel sessions and establish consistent guidelines across all the panels. Clearly there must be room for flexibility, bearing in mind that the number and type of proposals in each panel varies so much, but the general principles concerning the management of the panel should be agreed.
2. The Agenda for each meeting seems entirely sensible to us and clearly sets out the order of business. For the reasons outlined earlier, we feel that the drafting of the consensus documents should be left until after all the proposals have been adequately discussed, scored, ranked, and following any 'hearings' The final report should be formally led by the rapporteur and moderator, perhaps supported by another panel member. We feel it may help if the rapporteur is given an hour after lunch on Day 2, to re-write the consensus document in the light of the panel deliberations, and then bring it back to the panel for final agreement on the content. The rapporteur and moderator could finalise formulation of the consensus report together at the end of the meeting, and if necessary in the following days off-line.