

IMI2 JU INDEPENDENT OBSERVERS' REPORT

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

IMI-2 13th Call for Proposals

Stage 2 Evaluation

Date of evaluation: Sept 25-28th 2018

Number of pages in this report (title page included) 6

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Present at the evaluation: Sept 25th – 28th 2018

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 process of discussing the application, agreeing the consensus document, scoring the proposal and coming to the decision as to recommending funding or not. We paid particular attention to the conduct, transparency and fairness of the evaluation sessions and the rigour as to how the scoring criteria was implemented. Both observers had been present at the Stage 1 evaluation in March 2018 and were familiar with the overall IMI processes.

- We had a briefing with the Head of Scientific Operations and the Call Coordinator (IMI2 programme office) on September 25th 2018 which provided the background to and purpose of the 2nd evaluation stage. Stage 2 is entirely devoted to the consideration of whether the top proposals identified in Stage 1 should be funded or not. We discussed the importance of the ‘Hearings’ in which the industrial and academic partners proposing the projects are questioned by the Expert Panel members.
- The 13 panels were convened over a four-day period with each panel having a full day to evaluate the proposal allotted to them. All expert panel members and both observers attended a pre-briefing presentations by the IMI programme office.
- The observers received a link to the full proposals 12 days before the meeting and an aggregation of the written expert evaluations of the proposals, one week before the panel meeting. The IMI office also provided us with hard copies of the proposals and the aggregated expert panel comments for each proposal. We were given a dedicated room for confidential discussions between panel meetings
- For the Stage 2 process we elected to attend panel meetings separately. Both of us attended at least one full meeting from beginning to end but ensured that between us we attended all the panels at some point. We independently observed examples of panels’ discussions, face to face hearings, agreement of scores/consensus reports and the final decision as to recommend funding or not.
- Both observers informally discussed the panel procedures with some expert panel members and with panel moderators at various stages of the evaluation process

The details of the call topics are given below:

Topic code	Topic name
IMI2-2017-13-01	Assessment of the uniqueness of diabetic cardiomyopathy relative to other forms of heart failure using unbiased pheno - mapping approaches
IMI2-2017-13-02	Genome-Environment Interactions in Inflammatory Skin Disease
IMI2-2017-13-03	The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use
IMI2-2017-13-04	Mitochondrial Dysfunction in Neurodegeneration
IMI2-2017-13-05	Support and coordination action for the projects in the neurodegeneration area of the Innovative Medicines Initiative

IMI2-2017-13-06	A sustainable European induced pluripotent stem cell platform
IMI2-2017-13-07	Linking digital assessment of mobility to clinical endpoints to support regulatory acceptance and clinical practice
IMI2-2017-13-08	Human tumour microenvironment immunoprofiling
IMI2-2017-13-09	ConcePTION –Continuum of Evidence from Pregnancy Exposures, Reproductive Toxicology and Breastfeeding to Improve Outcomes Now
IMI2-2017-13-10	Improving the preclinical prediction of adverse effects of pharmaceuticals on the nervous system
IMI2-2017-13-11	Translational Safety Biomarker Pipeline (TransBioLine): Enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease
IMI2-2017-13-12	Pilot programme on a Clinical Compound Bank for Repurposing Cardiovascular diseases and diabetes
IMI2-2017-13-13	Pilot programme on a Clinical Compound Bank for Repurposing Respiratory diseases
IMI2-2017-13-14	Pilot programme on a Clinical Compound Bank for Repurposing Neurodegenerative diseases
IMI2-2017-13-15	Pilot programme on a Clinical Compound Bank for Repurposing Rare/orphan diseases

2. Overall impression

Rather than repeat much of what we wrote in the Stage 1 evaluation in March 2018, suffice to say that having now experienced both stages of this Call, we reiterate that the IMI 2 JU scheme is novel, imaginative and timely and is well served by a dedicated highly professional staff. The expert panel members are highly supportive of the concept of a private/public resource shared programme. We 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.

- We were pleased to see that a number of the recommendations we and other Expert Observers have made have been acted on and implemented.
- Inevitably, the Stage 2 assessment had a very different ‘feel’ to it compared to Stage 1. As each proposal had a full day devoted to it, there was far more time to consider it in a calm and considered way which is entirely appropriate when making decisions about awarding large amounts of tax-payers’ money.
- Each panel had four to six expert panel members who between them had the appropriate level of expertise and experience to assess their assigned proposal in a conscientious and rigorous way.
- Overall the panels were professionally chaired by a scientific officer as a moderator, supported by a second IMI staff member. Each panel had pre-selected rapporteurs who, working closely with the moderator, were responsible for the initial drafting of

the consensus reports and of the questions to be put to the applicants during the face-to-face hearings. These drafts formed the basis of the final consensus report and list of questions for the hearings following extensive discussions with the full panel membership. The working relationship between the moderator and rapporteur is the key to the smooth running of the session.

- We felt that the quality of the discussion and assessment of each proposals was high and handled in a collegiate and fair way by the members. The fact that many of the experts were involved in the Stage 1 assessment meant that there was a continuity between Stages 1 and 2. Their experience from the 1st Stage would have helped in the way they approached the writing of the final consensus report, the scoring and the funding recommendation in Stage 2.
- We were particularly impressed by the way in which the face to face ‘hearings’ were handled. The moderators and panel members were fully engaged in developing the questions, and the meetings with the applicants in the afternoon of the panel meeting were conducted politely and fairly. These hearings were extremely helpful to the panel discussions in producing the final consensus report, the scoring and decision as to recommend funding or not.
- In summary, the workings of the panel were conducted with a high level of professionalism, commitment and transparency. 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. IMI and their staff are to be congratulated on both the innovative nature of the scheme and the manner in which they run it.

3. Any other remarks

Choosing the Rapporteur

The Rapporteur and his/her working relationship with the moderator are the key to the smooth running of the panel meetings. Establishing a cohort of people who can perform this challenging role has its difficulties but getting it right is important to ensure the smooth running of the meeting. This will help alleviate some of the time constraints experienced by the panels so that they can use their time on assessing the sometimes very large and complex proposals presented to them. Having attended many of the panel meetings now, we have seen just how beneficial it is to have a Rapporteur who works closely with the IMI staff and knows what is expected of them before and during the meeting.

IMI’s excellent information sheet on the ‘Role of the Rapporteur’ clearly explains what is expected but such a skill mix is not possessed by all. It is not sufficient to be an expert in the field. Good English skills and an ability to distil the main points from multiple reviewers’ comments are essential. IMI may wish to think about our suggestions in building such a cohort, some of which it may already be doing. Further, it might consider appointing dedicated Rapporteurs rather than choosing one from the expert panel members, who may not have the required skills.

- As the IMI scheme has been running for a decade now, the staff have had the opportunity of working with some of the finest experts in the world. Amongst these people some are excellent rapporteurs spanning a wide range of specialities. It would be worth identifying who they are and also taking advice from them as to who else may be able to fulfil the role.
- IMI could review, as part of the de-briefing after each set of meetings, who performed the task well and who else of the panel members seemed to have the appropriate skills to act in this capacity.
- IMI might consider setting up a series of workshops, run by those experts who have proven expertise in the role, to train people. Such experts can also act as mentors to others who are at an earlier stage in the careers but look as if they may have the skills to become excellent Rapporteurs.
- IMI is already working with other major European funders, and these organisations may be able to help in identifying suitable people capable and willing to assist in fulfilling this important role.

Some Thoughts on Running the Panel

We have been thinking about the way in which the panels are working and have had a few ideas that may help facilitate the overall process, particularly in the writing of the consensus report and the formulation of the questions which will be put to the applicants at the hearings. It may be that some of these ideas are already being considered. What we suggest below is based entirely on what we observed and on conversations with the IMI staff, the Rapporteurs and panel experts. Some of what we are suggesting does take place in some of the panels, but we feel that in the interests of best practice, it would be good if the same procedures are used by all the panels. To that end we have outlined a 'roadmap' of the whole process which IMI might find useful.

A. Actions to be taken before the Panel meeting

- The panel members receive the final proposal about 2-3 weeks before the panel meeting. Using the Call Document for guidance and as the reference text, they should be asked to write a 1-2 page summary of their opinion of the project in addition to filling in the individual evaluation form. The summary should include 3 or 4 key questions which they would like the applicants to answer.
- We suggest that the moderator forwards on the individuals' summaries in addition to the aggregated individual evaluation reports to the Rapporteur. Currently, this happens about 5 days before the panel meeting, giving the Rapporteur a tight time schedule to draft the consensus paper and questions. If at all possible, the Rapporteur should be given a couple of extra days to complete this key task. The draft consensus report and hearings' questions are then shared with the panel ahead of the meeting as is current practise.
- It would be useful for the Rapporteur and moderator to meet the day before the panel meeting, if possible. In our experience with other funding agencies, such meetings are very helpful as they give the moderator and Rapporteur an opportunity to brief each other from the IMI perspective (moderator) and project evaluation

perspective (rapporteur). It will also allow minor revisions to be made to the consensus report and hearings' questions so that the drafts presented to the full committee are optimised such that they facilitate the final formulation of these key documents.

B. The Panel Meeting

- After the welcoming remarks, we suggest that the moderator should name the Rapporteur and explain his/her role in preparing for the panel session and within the panel meeting. The Rapporteur should then introduce her/himself, followed by the moderator asking all the attendees to introduce themselves. We suggest that the moderator should then go round the experts in turn, asking each of them to briefly summarise their view of the proposal, drawing on the summaries written before the meeting.
- The next stage on the agenda is the discussion of the proposal and agreeing the list of questions. The latter should be prioritised in order of importance as far as possible. The draft list of questions, previously prepared by the Rapporteur, should be displayed on screen and used as the basis of the discussion as it already reflects the overall views of the experts. These discussions will also provide insight into the re-drafting of the consensus paper, which we feel should only start after the hearings have taken place and as per the Agenda for the meetings. It would be useful if the IMI staff member supporting the moderator takes notes during the discussion to aid the re-drafting of this key document after the hearings. The panel also has available the text of the Call Topics and the full proposal to refer to as required.
- Once the final list of questions, prioritised in order of importance, has been agreed, they are given to the applicants so they have time to respond before the afternoon session. We feel that to be fair to both the panel and applicants, the number of questions should be such that there is appropriate time for adequate discussion. Further, the questions should be prioritised so if time is running out the key ones are able to be responded to by the applicants.
- The applicants should be given clear instruction as to the amount of time they have for their formal presentation, which in our opinion should be 10 minutes. The applicants should be held to this limit.
- Once the hearings are completed, we suggest that the Rapporteur and moderator/support staff member have 30-45 minutes together so they can revise the consensus document ahead of it being finalised by the full committee. This will reduce the amount of 'wordsmithing' by the full committee.
- The scoring of the proposal should be performed once the final version of the consensus paper has been agreed. This is best done by the moderator asking each expert in turn for their score(s). This is best practice and we applaud its use by IMI.
- The moderator should formally confirm the panel's recommendation as to whether the proposal be funded or not and remind the panel of the final steps in the process.