

IMI2 JU INDEPENDENT OBSERVERS' REPORT

Call ID: H2020-JTI-IMI2-2018-16-SINGLE-STAGE

IMI2 JU 16th Call for Proposals

Single Stage Evaluations

November 14-16, 2018

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Present at the evaluation: November 14-16, 2018

Summary of call and response

Call 16 was directed towards the discovery and development of new preventions and treatments to address antimicrobial resistance (AMR). Supporting AMR research is challenging due to the low return on investment (RoI) for the pharmaceutical sector. The aim of this call was to accelerate AMR research through the development of a pipeline of potential medicines to treat patients with resistant bacterial infections or to prevent infections from occurring. To best support the wide-ranging series of projects, the AMR Accelerator will provide a single operational structure to help ensure that synergies can be realised and to minimise duplication of effort¹.

To this end, the AMR Accelerator programme consists of three pillars:

- Pillar A: Capability Building Network (CBN)
- Pillar B: Tuberculosis Drug Development Network (TBDDN)
- Pillar C: Company-specific Portfolio Building Networks (PBNs)

Topic 7 and 8 of the two-stage IMI2 JU Call 15² will launch Pillars A and B of the AMR Accelerator. IMI2 JU Call 16 targeted Pillar C. Applicants were able to submit proposals to multiple topics under the different pillars. It was made clear in the call guidance that in the case that more than one topic was being applied to, separate proposals should be submitted.

The call for proposals for Research and Innovation Actions under Pillar C was opened on July 18, 2018 and closed on October 24, 2018. In total, six proposals were submitted to the call and reviewed by the panel of independent experts.

Remote evaluation took place from October 25th to 11 November. Onsite evaluations took place in Brussels from November 14th-16th, 2018. There were 11 experts participating in the evaluations. There was a good balance between male and female experts involved. Experts were drawn from across Europe and beyond.

The table below summarises the number of proposals received in response to the call topics:

Topic ID	Proposals
IMI2-2018-16-01: Progress new assets (one pre-new molecular entity (preNME) and one first-time-in-human (FTIH) start) for tuberculosis (TB) that act synergistically with bedaquiline, cytochrome bc or cytochrome bd inhibitors	1
IMI2-2018-16-02: Progress novel assets (one FTIH start) for non-tubercular mycobacteria (NTM) that may act synergistically with bedaquiline and cytochrome bc drugs	1
IMI2-2018-16-03: Discover and progress novel assets with new mechanisms of action (one preNME for TB and one preNME for NTM) and biomarkers for TB and NTM infection	1
IMI2-2018-16-04: Determination of gepotidacin levels in tonsils and prostatic tissue	1
IMI2-2018-16-05: Infection site targeting, antibiotic encapsulated in nanoparticles for treating extracellular bacterial infections	0
IMI2-2018-16-06: Functional Ethionamide boosters: a novel combination for tuberculosis therapy	1
IMI2-2018-16-07: Intravenous treatments of serious infections (urinary tract infections (UTI), intra-abdominal infections (IAI) & hospital-acquired pneumonia/ventilator associated pneumonia (HAP/VAP)) caused by Gram(-) bacteria (Enterobacteriaceae +/- Pseudomonas and/or Acinetobacter)	1
Total	6

¹ IMI2 Call 16 text http://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/open-calls/IMI2_Call16_CallText.pdf

² IMI2 Call 15 text http://ec.europa.eu/research/participants/data/ref/h2020/other/call_fiches/jtis/h2020-call-fiche18-15-imi2-ju_en.pdf

Approach taken by the observers

Prior to the on-site evaluation, the observers were provided with a wealth of helpful documentation about the call and associated procedures including the call text, FAQs, and links to call-specific webinars. All important documents were made available to the observers via SEP. Printed versions of proposals were also made available during the consensus and panel meetings. In addition, the observers participated in a conference call with the Head of Scientific Operations and the Call Coordinator to ensure that any questions about the call or procedures could be raised prior to the on-site evaluations.

The on-site observations for IMI2 Call 16 started with attendance at the general briefing meeting on the morning of November 14, 2018. The experts received a review of the evaluation procedures and were once again reminded to declare any conflicts of interest or potential conflicts of interests that may be identified during the on-site evaluations. The observers were introduced to the experts who were encouraged to provide feedback and suggestions on the process at any time.

In addition to joining the evaluation discussions, the observation was supplemented through conversations with individual experts, rapporteurs, moderators (IMI scientific officers) and members of the secretariat and the legal teams. Daily notes were taken to form the basis of this report. The observers were invited to meet with the Head of Scientific Operations and the Call Coordinator on the afternoon of November 15 to share early insights and to seek any clarifications needed.

Overall impression

The observers were very impressed by the overall efficiency and excellent organisation of the evaluation process – both with regards to the remote evaluations and the on-site evaluations. The IMI website provides all relevant call documents and provides links to detailed guidance. The observers were struck by how easy it was to find the relevant information via the IMI website. It is clear that significant time and effort has gone into making the website as user-friendly as possible. The general atmosphere of the evaluations was one in which professional debate was encouraged and every expert's voice was given the same weight.

Scale of complexity of the evaluation task

Call 16 (single stage evaluation) was assessed from November 14-16 in parallel to the evaluation of Call 15 which is a two-stage procedure. This required that the briefing for experts on the 14th of November covered two types of evaluation processes. The information presented in both briefings was comprehensive and consistently described. The timing of the evaluations was well planned to maximise best use of time with the availability of experts.

Transparency of the procedures

The observers were impressed by the level of transparency applied to all stages of the call and subsequent evaluation process. Discussions with many of the experts during the three days of the on-site evaluations confirmed that there is high confidence in the fairness, professionalism and transparency of the overall evaluation process.

The call information is very detailed and provided a high-level of transparency on IMI, the nature of the public private partnership with industry represented by EFPIA, and it was very easy to find related documents to support applicants. However, the actual process of how specific call topics are defined could be made more visible to support transparency.

Despite the independent observers being introduced during the briefing session, some experts were still unclear as to the relationship between the independent observers and IMI. In future it might be helpful to stress that independent observers are not IMI staff during the briefing(s).

Efficiency, reliability and usability of the evaluation process and documentation

During the onsite evaluations, the observers were impressed by the IMI moderators' knowledge on all aspects of the call and the general rules. This knowledge was essential to keep experts focussed on relevant discussion areas.

On a technical note, the video conference and beamer apparatus that were made available to link in experts joining remotely did not always work properly.

All evaluation-related documents are shared using SEP. However, once the Consensus Report has been collectively drafted, it tends to be shared via email with onsite IMI actors for review prior to being finalised in SEP. The observers recommend that rather than sending draft CRs between the moderators and the IMI actors on site via email that a mailing feature within SEP might be implemented to ensure data security. The observers are fully aware that adding new functional within a system such as SEP will not be immediate and will depend on many factors. However, we recommend that this functionality be suggested with SEP developers at an appropriate juncture.

Impartiality, fairness and confidentiality

Moderators provided a good overview of the process at the outset of the panel and were diligent in their efforts to ensure that no single voice dominated the discussions – often seeking input directly from those experts who were not as vocal to ensure that all views were shared and considered. A brief tour de table was carried out in the panel which is a good idea to make clear the specific areas that each of the participating experts represents.

The moderators for this panel were very careful to ensure that the evaluation criteria were consistency applied. In many cases, experts also demonstrated a keen self-awareness of the need to be consistent and fair in their comments and subsequent scoring of each proposal. In all cases, comments were agreed first and then scores agreed on the basis of the strengths and weaknesses identified for each. Moderators were careful to stress that the call text must always be considered when providing comments. Indeed, at several points the moderators referred experts back to the call text by sharing their screen to make sure that the discussion points reflected the exact call specifications.

The invited experts clearly had extensive subject knowledge and demonstrated professionalism throughout the process. Through a review of selected Individual Evaluation Reports (IERs), it was clear that the experts had thoroughly reviewed each proposal assigned to them and adhered to the principles of the assessment.

The evaluation panel gave due consideration to all criteria – not just scientific excellence. In most cases, the three criteria were considered as independent parameters and both moderators and experts were careful to avoid penalising a proposal twice for the same issue. It was, however, difficult for some experts to imagine how a good impact or implementation of a given project might be realised in the event that the scientific excellence was not optimised. The confirmation of the principle of criteria independence should therefore be maintained or emphasized during the briefing meetings or by the moderators.

One expert participated in the discussions remotely via Webex. Overall, this approach worked relatively well however the moderators often had to remind the expert to speak loudly and directly into the microphone to ensure that he was audible.

Any other remarks

The evaluation participants praised IMI staff for always being visible, approachable and highly knowledgeable. IMI staff also took care to provide a helpful reminder to experts on their last day about how to claim for their remote and onsite evaluation activities and encouraged experts to get in touch if they experienced any difficulties in uploading items in the system for reimbursement. The working conditions were very comfortable and effective for the onsite discussions. The continuous provision of coffee, teas and a range of snacks for experts was highly appreciated by all participants.

Due to the interdisciplinary nature of the call topic, experts from a variety of backgrounds were invited to participate. This is a strength in general but does in some cases introduce a risk that one expert can influence the evaluations if they are deemed the only one with the specific knowledge on a particular issue (e.g. animal to human testing feasibility). It may not be possible, but for future evaluations it may be good to try and have more than one expert for various areas. However, given the very niche nature of some of the expertise required the observers recognise that this may not be feasible.

With regard to how calls are defined, some experts felt that the process of getting buy-in from several big pharma partners can result in calls that are too prescriptive in some respects and too general in others. Indeed, while the documentation provided via the website describes the process of topic identification and refinements very well, some experts were still unclear as to how specific call topic texts were arrived at. There is an infographic explaining how IMI call topics are generated which is very informative. However, it is currently only visible in a pop-up box that cannot be expanded requiring the reader to scroll through the image to see the various stages making it difficult to get a full sense of the workflow. The observers suggest making this image more easily viewed in its entirety on the IMI website and suggest that it might also be included on the wall in evaluation rooms to serve as a visual reminder of the specific IMI co-creation model.

Summary of Recommendations

The evaluations were very well administered and there are just a few minor modifications that we can suggest to optimise the process. These are outlined below.

- To provide a visual reminder of the co-creation call process in each evaluation room that experts can refer to if needed. In addition, it would also be helpful to optimise its visibility via the IMI website in full screen mode rather than as a scrollable image.
- Despite the independent observers being introduced during the briefing session, some experts were still unclear as to the relationship between the independent observers and IMI. In future it might be helpful to emphasise that independent observers are not IMI staff during the briefing(s).
- Investigate new functionality in SEP that will facilitate the sending and amending of CR text between moderators and the IMI actors on site to improve the security of the information contained within the CRs. However, the observers recognise that this will not be a quick fix.
- Wherever feasible, avoid remote participation by experts which depend upon technology working well. However, the observers realise that due to the very niche expertise required to evaluate the call proposals, this will not always be possible.