



January 2014

Answers of the IMI Executive Office to the recommendations from the Independent Observers' report for Call 9 (Stage 1)

General Recommendations

Recommendation

Some Independent Experts (IEs) felt that the expressions of interest (EoIs) were lacking important details while fully in-scope. Instructions in the Guide for Applicants regarding this point are not very detailed but for the request to keep the project plan, including all WPs description, to three pages, which, according to some IE, is not enough. *This probably deserves attention in order to further enhance the quality of the information provided to IE for their remote and on-site appraisals.*

IMI answer

The stage 1 evaluation focusses on the scientific and/or technological excellence of the EoIs, the excellence of the partnership, and the work plan outline with weightings of 5, 3, and 1 respectively. The applicants are expected to focus their EoI on the higher weighted categories, and only provide an outline work-plan of maximum 3 pages. The importance of the weightings is already emphasised to the IEs during the briefings prior to the evaluations. It is to be stressed that the full consortium (EFPIA & Public consortium) must develop and submit a detailed workplan at the full project proposal stage.

Recommendation

Despite the fact that a full information package on how the Call was developed was available to the IEs before they started their evaluation, we did observe that there was still a slight confusion for a couple of IEs on the full process (Stage 1 EoIs and Stage 2 FPP and the decision-making process in between and after Stage 2) as well as how exactly the text of the Call was developed. *This probably deserves attention in order to further enhance the understanding of the process by IEs prior to attend the Panel discussion.*

IMI answer

The briefing to the experts will be reviewed to ensure that full information on the call topic development and evaluation processes is well understood.

Recommendation

While the IOs noticed and received feedback that there was generally a good balance and helpful contribution from the EFPIA representatives, in one group a few IEs had the feeling that the EFPIA representatives were too present with their comments. In particular, the discussion revolved about the need for innovation, even in clinical development and the fact that public money should go hand in hand with more risk taking in terms of innovation. It provided for a moment of intense discussion, which took considerable moderator effort to achieve a resolution. *This underlines the need to have both IMI Scientific Officers at all times in the room, so that, if need be, one can moderate, while the other continues to take care of the process and the scientific content of the Panel discussion.*

IMI answer

The IMI JU tries to ensure that 2 scientific/legal officers are present during each in-house evaluation to allow for effective moderation. The briefing to the EFPIA representatives will be re-visited with this recommendation in mind. This recommendation will also be highlighted to the IMI Founding Members for consideration in a future PPP.

Recommendation

A small logistic point was brought to the attention of the IOs: the potential usefulness to have access to the EoIs in electronic format during the Panel evaluation, either on-line or off-line. This was raised in particular by IEs who had not saved the EoIs on the hard-drive of their laptops. *This probably deserves attention in order to further help IE during the Panel discussion.*

IMI answer

This recommended feature will be added to the SOFIA software tool during a future release.

Recommendation

We observed that special care was taken in giving the same time allocation (30') to each EoI for the hearing. The applicants received the questions the evening of the day before the Hearing, together with information on when they must be available for the Hearing itself. Some IEs thought that 30' was not always sufficient to gather the appropriate discriminating information. *This probably deserves attention in order to further help IE during the Panel discussion: when less than 4 EoIs are selected for a hearing, could IMI JU envision increasing the allotted time for Hearings for each EoI? Fairness here would mean an identical allotment of time for each EoI going through the hearing in a specific topic.*

IMI answer

While the guidelines to the moderators of EoI evaluations suggest that the hearings should last approximately 30 minutes per applicant, these timings are only recommendations. Should the independent experts decide otherwise during the preliminary discussions, it is already possible to adjust this time so long as all EoI consortia are granted the same time and that there is sufficient time available for all hearings to take place.

Recommendation

The user-friendliness and usefulness of SOFIA were pointed out by several IEs. One IE mentioned a small malfunction; another one contacted the help desk which was able to solve the issue. *Both were browser-related and could be avoided in the future by providing guidance on browser compatibility.*

IMI answer

The automated emails inviting the independent experts to begin the evaluation process will be amended with this recommendation in mind.

Recommendation

We noted Scientific Officers had to juggle between software tools on top of SOFIA (Word and Excel). *Having some of the simple capabilities of these software tools built in SOFIA could simplify the process and avoid possible mistakes related to copy-and-paste or retyping activities, especially when topics have been popular with applicants and provided for 10+ EoIs.*

IMI answer

The SOFIA software platform is frequently updated to include new features and improve existing processes. This recommendation will be considered in future

updates.

Specific Recommendations to enhance Stage 1 selection process

5.1 Applicants and EoIs

Attracting applicants

In cases where science in healthcare is only part of the topic, could the publishing and publicising of the call by the IMI team towards new and less well-known targets be improved to reach a sufficient number of EoIs?

IMI answer

The IMI JU already makes considerable effort to publicise the Calls as widely as possible including to organisations outside the healthcare sector when appropriate, relevant multiplier organisations, and horizontal stakeholders such as the IMI States Representative Group. These communications take many forms including press releases, webinars, and conference presentations. The IMI JU will continue to expand on these communication efforts.

Nature of projects

Some topics are more conducive to quantum innovation than others and even incremental innovation can lead to improvement in healthcare.

While we understand that innovation is probably more difficult to implement in late clinical development, Panels should still strive to include meaningful, even if riskier, attempts to innovate, like new biomarkers.

IMI answer

This recommendation will be forwarded to the topic writers for future calls. The Executive Office will also highlight it to the Founding Members.

Including other stakeholders

As already discussed in the IOs' report from Call 7 – Stage 1, the broader aim of IMI is to make strategic changes in the entire sector. Other stakeholders than the usual projects partners (academics, SMEs, EFPIA members) should be involved more deeply in the projects where appropriate and mechanisms to do so should be explored and implemented.

In particular, for the WEBAE theme (Leveraging emerging technologies for pharmacovigilance), one specific key organization (e.g. EMA) has to be present/be invited into all competing consortia. The same situation arose with ND4BB's topic 4 and ECDC.

IMI answer

The IMI JU is aware of this issue and is currently investigating potential solutions for a future PPP.

5.2 Independent Experts

IE pool and proactivity

Having a larger pool of IEs, as well as selecting more IEs per call and topic, as well as being even more proactive using appropriate means could probably help in this matter.

IMI answer

When forming the panel of experts, the IMI JU already aims to select sufficient IEs to ensure having a minimum of 5 experts per topic. The late withdrawal of an

IE from an expert panel due to the late identification of a conflict of interest (despite measures in place to anticipate this) or due to unexpected unavailability may nonetheless occur, necessitating the invitation of another IE at the last minute. The IMI JU is currently considering increasing the recommended number of experts to invite to evaluation panels to ensure that, even following last-minute withdrawals, a minimum panel of 5 IEs is always available.

Potential conflicts of interest

Expert panels are crucial to the success of IMI JU, both in quantity and quality. Healthcare is a small world and even smaller in the EU, meaning that finding IE without any CoI is becoming increasingly difficult. This is especially true with very successful Calls attracting numerous EoIs, tying up a large proportion of the expert population.

We questioned the IMI legal team who confirmed the rules are not IMI-specific but the Commission's rules.

One may wonder whether general rules are fully applicable to IMI or whether full disclosure, like in peer-reviewed healthcare publications, would not be sufficient, as long as no IE benefits directly or indirectly financially of a decision.

Additionally, having Panel consensus provide an additional safety belt as it is unlikely just one individual will tip the whole group towards an Applicant for which the IE would have disclosed a (potential) CoI.

If possible at all, we recommend addressing the question with the appropriate stakeholders and decision-makers at the Commission level.

IMI answer

The Executive Office will highlight this recommendation to the Founding Members.