



Answers of the IMI Executive Office to the recommendations from the Independent Observers' report for Call 7 (Stage 2)

Recommendation 1

It would be useful if the winning consortium produced a written document as an Appendix outlining their response to the reviewer's comments showing how they tried to address them if they are not covered in the FPP.

IMI answer:

When briefing the consortium during the first face-to-face meeting, the IMI scientific officer asks to join such document in the Full Project Proposal (FPP) to help the experts in their evaluation. IMI will consider reinforcing this request by including it in the guidance to applicants for the preparation of the FPP.

Recommendation 2

Consideration should be given to the comments of the ethics panel on the automated tool and possible solutions implemented.

- In terms of the ethics report form having only a 'Yes' or 'No' the ethics panel felt that these two categories were not enough - there needs to be the opportunity to grade the response in the same way as the expert scores are (good/fair etc) and qualify them.
- It was also mentioned by that panel that in the Stage 1 ethics review there were no subcategories which might be helpful in giving more specific feedback if issues were identified at that stage.

IMI answer:

IMI JU is currently using the FP7 approach. Considering the particularities of the topics, the IMI JU will consider how the ethics review report as well as the form developed for the ethical screening at Stage 1 might be improved to take on board these comments.

Recommendation 3

Could the IMI give some consideration to having a 'pool' of reviewers which have already been briefed, ahead of time, to the IMI processes and, for groups like patient groups, some education in the nature of the scientific review process. For Topic 2, one of the panel members, who

was there as a patient group representative, felt the time allowed for review was too short and much underestimated especially for people new to the process. This is especially so when projects are of a general nature and not focused on a specific therapy area.

IMI answer:

The experts are chosen primarily based on their expertise. Most of the selected experts are already familiar with IMI and/or FP7 evaluation process. However, as a good practice, all experts are briefed by the IMI scientific officer at the start of the evaluation (by teleconference and in-house briefing). Further considerations will be given for a more targeted one-to-one briefing for those experts new to the process.

Recommendation 4

It would be desirable for the scientific experts to have sight of the draft ethical review ahead of the hearing with the Consortia, especially if there are ethical issues

IMI answer:

Before the consensus panels, all experts receive both the evaluation form and ethics review report aggregating in an anonymised way the comments made, during remote evaluation, by the individual scientific and ethical experts respectively. At stage 2, scientific and ethical panels are running in parallel, offering the possibility for interaction if needed (including the possibility for clarification with the consortium). This interaction will be further reinforced for the next evaluation, in particular through the ethical rapporteur.

Recommendation 5

The separation of the ethical and scientific review panels worked well for working up issues and the consensus document, but it would be good to have the ethics panel or at least the relevant ethics rapporteur to sit in on the discussion with the Consortia.

IMI answer:

See answer to previous recommendation.

Recommendation 6

As per the independent observers report for Stage 2 of the 6th Call, it would be good to continue the practice of allowing the Consortia some early sight of the questions on the day – even for 15-30 minutes, especially where there are lot of issues. Could any major ones be flagged even earlier since the evaluator reports come in some days beforehand?

IMI answer:

The hearing is organised to allow an interaction between the consortium and the panel. For this Call 7, the consortia were informed by the IMI scientific officer in advance of the hearing on areas identified by the individual experts during the remote evaluation, as a starting point for the discussion at the hearing. It is nonetheless during the consensus panel that the experts discuss together on the questions that the consortia should answer during the hearing.

IMI will further reflect on how to share those questions with the consortium prior to the hearing, although there would little time available between the definition of the questions to be asked to the consortium and the hearing itself.

Other Comments

(as already recommended in the Call 7 stage 1 report): as the broader aim of IMI is to make strategic changes in the entire sector, it is clear that other stakeholders than the usual projects partners (academics, SMEs, EFPIA members) should be involved more deeply in the projects where appropriate. For example, dissemination of new methodology will not ensure adoption and implementation of those methodologies in practice. Also, they need to be recognized by the regulators as valuable and eligible in the regulatory process. Moreover, these innovations need to be to the actual benefit of the patients, HTA schemes need to recognize the added value for Healthcare Outcome and national reimbursement schemes need to be ready and willing to pay back. This goes towards recognition that Innovation is needed beyond the product or service level with clinical value, but involves also a focus on socio and economic parameters that affect uptake and market.

The 2 topics under Call 7 already move in that direction in which CROs, patient organizations, regulators (EMA, ECDC) and HTA organizations were specifically mentioned in the call text and invited to participate in the consortia. Practical problems could arise if one specific key organization (e.g. EMA) then has to be present/be invited into competing consortia in order to be eligible for receiving funding. An alternative option could be to set aside a special budget line (of a few %?) from the IMI budget, not from its overheads and separate from the call funds and at the discretion of the IMI Board, to be allocated to support the active involvement of such key stakeholders to the consortia that go through the first stage evaluation (top up their project budget). Flexibility to include non-traditional participants if required might also be necessary e.g. if diagnostics or medical devices become important for a particular proposal.

IMI answer:

The current IMI rules do not allow for this. However, IMI JU will pass on this suggestion for further consideration under Horizon 2020.