



Answers of the IMI Executive Office to the recommendations from the Independent Observers' report for Call 8 (Stage 2)

Recommendation 1

The Independent observers suggest that the IMI and EFPIA engage an external consultant that could do a "proof reading" of all documents related to The Call to ensure that all conditions are realistic and could be accomplished in the timelines defined by the team that prepared The Call. This exercise could take 2-3 days and in principle should not slow dawn the Call launching process.

IMI answer

During the Call Topic Text development, the text is reviewed internally and also by many external stakeholders such as the IMI States Representative Group and the European Commission. Part of this review is to ensure the feasibility of the project with respect to budget and timelines. The IMI will continue to stress the importance of this aspect of the review.

Recommendation 2

Consideration should be given to ensuring that changes made in the budget during preparation of the FPP, in particular those from SME and EFPIA partners, should be aligned with the overall project goals, duration of the project and particular work packages. We recommend that the teams prepare a short document (1-2 pages) describing the budget changes made in the FPP with the explanation of consequences of these changes.

IMI answer

The full project proposal evaluation form which the consortia are asked to consider when preparing their FPP includes a section for the assessment of the consistency of the FPP with the Call Topic and with the stage 1 EoI and consensus evaluation report. The applicant consortia are also instructed to explain any changes made in the budget during the hearing. The briefings to the consortium at the FPP preparation stage and prior to the evaluation hearing will be reviewed with this recommendation in mind.

Recommendation 3

In order to facilitate the onsite preparation of the Hearings, the Independent Observers recommend that IMI Officers ask evaluators to provide 2-3 questions per FPP, as part of their remote evaluation document, so that these questions could be compiled and curated more effectively during the "face-to-face" meeting.

IMI answer

As part of the remote evaluation, the experts are already requested to identify key areas to discuss during the hearing. The instructions to the rapporteur will be amended to ensure that full use is made of these points during the in-house evaluation. However, the final list of questions for the hearing is prepared during the in-house evaluation, and does not, necessarily, include the areas identified during the remote evaluation.

Recommendation 4

Though it is recognized that declaration of Conflict of Interest is the responsibility of each of the evaluators, the Independent Observers consider that the IMI could help ensure that evaluators are well aware of potential conflict of interest that may arise during the FPP evaluations (and were not present at the EOI evaluation). In particular, is recommended that IMI JU officials send to evaluators a document listing the EFPIA partners that are part of the newly created consortia and specifically ask evaluators to check for potential conflict of interest with these companies.

IMI answer:

Potential conflicts of interest between the independent experts and the applicant consortia are checked at several points during the evaluation. During the briefing prior to the remote evaluation, the experts are reminded to check for potential conflicts of interest. In the future, the experts' attention will be specifically drawn to potential conflicts with the new partners from EFPIA companies during this briefing.

Recommendation 5

Though the importance of a detailed Ethical review is recognized, the non-scientific panel could benefit from a multidisciplinary set of experts (Legal, IP, Health Economists, Behavioural scientist, Animal welfare expert, etc.) that could also evaluate other aspects of the FPP such as the competitive advantage, socioeconomic impact, etc.

IMI answer

The panel of independent experts is selected to ensure all aspects of the EoIs and FPPs can be thoroughly evaluated. This can include a broad set of expertise, including those mentioned in this recommendation. However, extra consideration could be given to this recommendation in a future public-private partnership.

Recommendation 6

To increase the value of the non-scientific review, we recommend that both expert panels met for a short period of time (30 minutes) before the hearings, and before questions are sent to the Consortia Members, in order to discuss potential issues of common concern or interest. The ethical and scientific aspects of the proposals should not be viewed as separate entities either by the panels or the Consortia Members.

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IMI answer

While the time of the in-house meetings is already quite limited, this recommendation will be trialled at the next FPP evaluation.

Recommendation 7

Since all experts in the panel and IMI Officers have read the FPP and know the project in detail, we recommend that the Consortia presentation be very short (10 minutes maximum) and focus only on updates, new aspects and changes in the work packages or budget. With shorter presentations more time will be given to the discussion between Consortia Members and the expert panel.

IMI answer

While acknowledging that most experts are already familiar with the project, the IMI Executive Office feels that many experts appreciate a broader presentation on the vision of the project. However, this recommendation is noted and the IMI office will, therefore, trial a maximum presentation length of 20 minutes in future FPP evaluations.

Recommendation 8

Consideration should be given to allowing individuals that are participating in the Hearings by phone. Having the opportunity to call specific Consortia Members (e.g. ethical experts) following the reception of the questions prepared by the panel could increase the value of the discussions.

IMI answer

The IMI Executive Office already facilitates the participation of consortium members to the hearing by phone. From Call 8 onwards, the list of questions for discussion at the hearing is provided to the consortium one hour in advance of the hearing. The consortium will be reminded that they should contact any members with expertise in a specific question during this period of time.

Recommendation 9

Given the changes that were made in the budget between the EOI and the FPP, in particular those associated to the contribution of EFPIA Members, we recommend having an independent financial review of each of the projects.

IMI answer

The responsibility for assessing the continued feasibility of the tasks within the overall budget falls to the independent experts, who are selected with this task in mind. The progress of the projects is also assessed during the interim review. The IMI Executive Office currently feels that sufficient assessment of the financial viability of the projects already takes place. However, this recommendation could be revisited in the context of a future PPP.

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