



Answers of the IMI Executive Office to the recommendations from the Independent Observers' reports for Call 6 (Stage 2)

Recommendation A: Consideration should be given to ensuring that the timeline for preparation of the FPP following the ranking of Expressions of Interest after Stage 1, should be commensurate with the work required for initial coordination of the academic/SME and EFPIA partners. A minimum period should perhaps be stipulated, especially over the summer months when a number of parties may be away.

IMI comment:

The timelines for Call 6 were short considering the exceptional characteristics of the AMR Call. The duration for the preparation of the FPP usually range between 2.5 and 3 months.

Recommendation B: Though it is recognized that face-to face time is limited, it is recommended that the Consortia Members be given a greater length of time to prepare for the questions posed by the review panel. This would allow for more thought to be given to both the questions and hopefully produce both fuller and more insightful answers. Where multiple Topics are reviewed, one solution might be to collate questions to Topics on one or more days and ask Consortia Members to attend a hearing on a second day, giving them either the proceeding morning or afternoon to prepare.

IMI comment:

At stage 2, the consensus panel meeting lasts one day. The hearing is organised to allow an interaction between the consortium and the panel. The consortium is given the opportunity to present the full project proposal as submitted thus giving the panel opportunity to ask for clarifications. Although there is little time available between the definition of the questions to be asked to the consortium and the hearing itself, IMI will consider sharing those questions with the consortium prior to the hearing.

Recommendation C: It is important that the Chairperson ensures all questions are answered fully and hearing timelines kept to. If questions remain unanswered at the end of the hearing they should be carried over and a written response requested. Consideration should be given to requesting that all questions posed by the review panel receive formal written responses. This is important both for clarity and to ensure that any concerns are fully addressed prior to an agreement between the IMI and Consortia.

IMI comment:

The role of the rapporteur in leading the hearing, supported by the IMI SO moderator is obviously important. This will be reinforced during the briefing to the experts. The current timing for the evaluation process does not allow IMI to handle responses in

writing. The experts provide recommendations to the consortium in the consensus evaluation report and it is responsibility of the IMI allocated scientific manager that these are addressed during the negotiation and prior to the signature of the grant agreement.

Recommendation D: Given the welcome presence of both scientific and ethical review experts at the same venue, it is recommended that time is set aside to allow the ethical reviewers to present any concerns to their scientific colleagues and for the scientific reviewers to ask any ethics based questions they may have.

IMI comment:

Further to recommendations made at Call 4, the process has been reviewed to improve the way the ethical review was conducted. In this exercise, IMI took on board comments made previously by experts in ethics and consulted with the EC. This resulted in the introduction of the ethical screening at the end of stage 1, as well as having a separate ethics panel review. Call 6 Stage 2 was the first call following this new approach. The suggestion to organize a joint discussion between the scientific and ethical panels will be considered for the next evaluation session.

Recommendation E: Consideration should be given to allowing the ethical review panel to draft questions for the Consortia Members and ask these either at a separate hearing or preferably at joint hearing with the scientific review panel. The ethical and scientific aspects of the proposals should not be viewed as separate entities either by the panels or the Consortia Members.

IMI comment:

See answer to previous recommendation

Recommendation F: Consideration should be given to delaying a " go / no go" decision on a proposal until all questions requested by the review panels prior to the formal hearings have been formally addressed in writing by the Consortium (Recommendation C) and reviewed by a majority of Members on the original Hearing Committee.

IMI comment:

The panel in the final consensus evaluation report may provide recommendations or conditions to be fulfilled during the negotiation phase for grant award. During the negotiation, the IMI Scientific officer verifies that these recommendations are fully addressed in the final project description of work. It has already happened in the past that a proposal was recommended for funding under the condition that specific recommendations are addressed, and the updated description of work is reviewed by members of the panel during the negotiation phase. The possibility therefore exists and it is applied when requested by the panel, if needed.

In addition, each project undergoes a mid-term review carried out by independent external experts, including at least one expert from the original evaluation panel.

Recommendation G:

Given the importance of the financial and “in-kind” contributions made by both the EFPIA Members and the European Commission, consideration should be given to an independent review of the financial viability of the individual Work Packages and the Call’s overall funding, prior to the “face to face” meeting. Any comments made under this review would not need to be binding on the evaluation group’s decision to accept the proposal, but would help to guide them as to the project’s viability.

IMI comment:

Among the tasks of the expert panel, it is indeed the assessment of the project viability, to be intended as the IMI JU and EFPIA contributions against the planned activities. IMI already provides guidelines to applicant consortia and to experts to respectively provide and assess the financial aspects of the proposals. Furthermore during the negotiation phase the soundness of the use of resource in the different work-packages is again verified. Nevertheless, IMI will further reflect on how to improve the briefing of the experts and guidance to applicant consortia on these aspects.

Recommendation H: As referred to in the 4th Call, the coordinators of the FPPs should be required to generate a series of (4-5) ‘High Level’ Deliverables, relating to the objectives in the Call Topic. These should form a basis against which the project’s progress will be reviewed at the time of the interim review.

IMI comment:

IMI will consider this suggestion, keeping in mind that the mid-term review will focus on the degree of achievement of the project work plan for the relevant period, including for all the related deliverables.