

IMI – 11th Call 2013

Evaluation of Stage 2 Topic 7

December 2014

Addendum to the Evaluation of Stage 2 October 2014 Independent Observers' Report

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1. Background

This is the report of the Independent Observer (IO) for Stage 2 of the 11th Call for proposals by the Innovation Medicines Initiative 2 (IMI) for ND4BB Topic 7: Development of novel inhaled antibiotic regimens in patients with cystic fibrosis (CF) and patients with non-CF Bronchiectasis (BE)

Following the evaluation of eligible EoIs submitted in Stage 1 of the IMI 11th Call for proposals which took place from May 13th to 16th 2014, the IMI launched Stage 2 of the Call process. The first-ranked applicant consortia from Stage 1 were invited to form Full Consortia with the corresponding EFPIA participants and to prepare and submit Full Project Proposals (FPPs) to IMI2 JU by September 9th 2014. In agreement with the IMI, the application deadline for the FPP for ND4BB Topic 7 was extended until November 1st 2014.

The submitted FPP was then remotely evaluated from 14 November until December 2nd 2014 by Independent Experts (IEs). During this period, the IO had also remote access to the submitted FPP.

The IEs were then brought together in Brussels on Monday 8th December to finalise the Stage 2 evaluation process with a plenary session, panel discussions and hearings with the consortium members,

The morning agenda was devoted to a general briefing and an introduction by Michel Goldman, the IMI Executive Director, then discussion of the FPP by the IEs and preparation of the questions for the hearing. The afternoon was devoted to the hearing and discussion between the IE panel and the consortium members followed by the finalisation of the Consensus Evaluation Report by the IEs only.

2. Overall observations

The Stage 2 evaluation for the ND4BB Topic 7 FFP evaluation was, in the view of the IO, conducted professionally, fairly and with commitment from all participants, ensuring an impartial and thoughtful assessment.

The on-site briefing for IEs took place on the morning and was conducted similarly to the Stage 2 of the 11th Call that took place in October (described in Evaluation of Stage 2 October 2014 Independent Observers' Report). The briefing for the IEs clearly outlined key objectives of the Stage 2 evaluation emphasising their role, the importance to declare potential conflicts of interest, the necessity to ensure equity, integrity and confidentiality throughout the entire peer review assessment.

In the IO's opinion:

- There were no violations against the rules of the published evaluation guidelines.
- The IEs were of a high quality and possessed the relevant expertise for the evaluation of the topic.
- The evaluation of the FPP, panel discussions and questioning of the applicants, were fair and transparent.
- The rapporteur and all IEs contributed to a fruitful discussion with the representatives of the consortium
- Experts and ethics reviewers demonstrated high quality of expertise
- A consensus was reached by all the IEs on the scoring of the proposal.
- The final Consensus Evaluation Reports represents the consensus opinion of the panel.

3. Working method of the independent observer

The IO followed all phases of the evaluation session and had access to all written and on-line information supporting the Stage 2 evaluation process and attended all day sessions starting with the briefing, followed by panel discussions, applicant's hearing and ending after the signature of the final Consensus Evaluation Report.

During the meeting in Brussels, the IO spoke individually with several of the IEs and IMI employees. These included the Scientific Officer who acted as moderator, the supporting Secretariat, IMI lawyer, the IT support specialist and Professor Michel Goldman, the Executive Director of the IMI.

4. Observations and Recommendations

As already stated in the evaluation of Stage 2 October 2014 Independent Observers' Report, the IO wishes to emphasize that the IMI assessment procedures follow a set of core principles for good practice in peer review that are gold standards as stated by the European Science Foundation in the European Peer Review guide published in March 2011¹. The IMI rules are in conformity with international best practice for a transparent, inclusive, independent and impartial process.

A positive point is that the evaluation meeting is moderated by the IMI Scientific Officer and not chaired by an IE. This allows the discussion to be conducted professionally, fairly and with commitment from all and also ensures that the IEs can express themselves with liberty and with no constraints.

As the Stage 2 evaluation of the ND4BB Topic 7 FFP was conducted in a similar way as for the 7 other topics of the IMI's 11th Call and the same IO was present in both Stage 2, this **Addendum to Stage 2 October 2014 Independent Observers' Report** will just focus on major points (1 to 3), and few minor observations during the process (4 to 10).

The IO observed:

1. That IMI Scientific Officers during Stage 1 and Stage 2 sessions were very knowledgeable in different biomedical fields and with high organizational and managerial capacities.

RECOMMENDATION: Continue to have the evaluation meetings moderated by an IMI Scientific Officer to ensure that all IEs express their opinion and help them to reach the consensus. Moreover, the role of the IMI moderator during the writing Consensus Evaluation Reports is crucial in order to ensure consistency between the scoring and the phrasing.

2. The IMI Secretariat, the lawyers and the IT Staff gave considerable support to all involved parties.

RECOMMENDATION: The presence of such support staff is required as each of them help the moderating Scientific Officers throughout the session. Their presence is required to ensure compliance with applicable rules and the success of the assessment.

3. The evaluation of the FPP was carried out in full accordance with the IMI rules and published evaluation guidelines.
4. Five of the same well qualified experts who conducted the review of Eols at Stage 1 were invited for the remote evaluation of the FPPs and took part in the onsite process for Stage 2 as IEs. One additional expert joined the Stage 2 assessment.
5. None of the IEs was subject to any kind of conflict of interest.

¹ European Peer Review Guide – Integrating Policies and Practices into Coherent Procedures : <http://www.esf.org/publications.html>

6. The gender parity of the panel meeting IEs was respected.
7. Questions from the scientific and ethics IEs were provided to the representative of the consortia one hour before the hearing.
8. During the hearing the rapporteur of the ethics panel joined the meeting by telephone conference. Due to the distance from presenter to the microphone, the rapporteur could not always clearly hear the consortium's oral presentation.

RECOMMENDATION: Telephone conferences should be avoided as they can be ineffective when a large number of participants are present on-site.

9. A small logistic point was brought to the attention by an IE: It could be useful to have access to the FPP in electronic format during the panel evaluation.

RECOMMENDATION: Alert the experts that the FPP and evaluation documents will not be available after remote evaluation dead-line, even during the meeting in Brussels.

10. The final Consensus Evaluation Report represents the consensus opinion of all IEs present in the panel.

5. Acknowledgements

The IO was helped in her task by all participants in the Stage 2 consensus meeting. The IO wish to thank the Independent Experts and Consortium members for being amenable to being 'observed' and to thank the Independent Experts for the conversations that helped formulate this report. The IO would like to particularly thank the IMI staff for their help and hospitality before, during and after our stay in Brussels for the consensus evaluation meetings.

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