

IMI2 JU INDEPENDENT OBSERVER'S REPORT

IMI2, Call 7, Stage 2 Evaluation

April 4-7, 2016

5 pages (title page included)

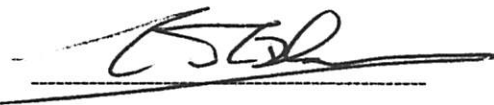
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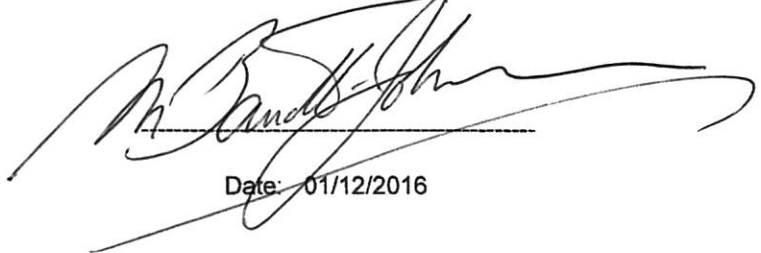
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1. Introduction and approach taken by the observers

The evaluation was followed to observe and report on the practical workings of the evaluation process, on the conduct and fairness of the evaluation sessions, on the application of the award criteria and on the procedures and their implementation, including IT tools. Based on their observations, the Independent Observers (IOs) give independent advice for improvement of the evaluation process.

This is the report of the Independent Observers for Stage 2 of the 7th Call for proposals by the Innovation Medicines Initiative 2 (IMI2). The 7th Call publication date was 18th December, 2015.

Submission of Full Proposals (FPs) was invited from consortia, in response to seven topics in the 7th Call:

1. Validation of translational imaging methods in drug safety assessment (TRISTAN)
2. Identification of druggable targets modulating misfolded proteins in Alzheimer's and Parkinson's diseases
3. Pathological neuron-glia interactions in neuropathic pain
4. Dry age-related macular degeneration: Development of novel clinical endpoints for clinical trials with a regulatory and patient access intention
5. A comprehensive 'paediatric preclinical POC platform' to enable clinical molecule development of children with cancer
6. Coordination and support actions (CSA) for the Big Data for Better Outcomes programme
7. Increase access and use of high quality data to improve clinical outcomes in heart failure (HF), atrial fibrillation (AF), and acute coronary syndrome (ACS) patients

The IMI JU through its electronic submission tool received FPs up until the deadline for submission (6th September, 2016). Submitted FPs were then remotely evaluated over a four week period by Independent Experts (IEs). The IOs also had remote access to all submitted FPs 2-3 days before the in-house evaluation.

The IEs were then brought together as the "panel" in the Renaissance Hotel meeting rooms in Brussels during October 4-7th, 2016 to finalise the Stage 2 evaluation process. Each evaluation was completed in one day (one topic on September 4th, two topics on each of September 5th, 6th and 7th). Following a briefing session by IMI, general discussion on the merits of each FP took place in the morning, along with drafting a set of cogent questions to ask representatives from each set of consortia during the hearing. Having been invited to the Renaissance Hotel in Brussels, consortia representatives were provided with questions at approx. 12 noon,. Following approx. 1 hour to prepare a response, four consortium representatives (typically 2 from EFPIA) were invited into a face-to-face hearing, with the IEs. For each submitted FP a consensus ranking was determined and a Consensus Report prepared. The IE panel resumed to reach a consensus decision, and prepare a consensus report for submission to the Governing Board. Following the Report's approval, it is intended that the conclusions of the Report be communicated to the Applicant Consortia shortly after. This concludes Stage 2 of the 7th Call.

The IOs had access to all written and on-line information supporting the Stage 2 evaluation process and attended all four days of the briefing and evaluation sessions.

In execution of their task, these IOs took the following approach:

- Briefing and formal meetings with IMI;
- Personal observation of each evaluation with apportionment of time between panels to ensure visibility and accessibility;
- Informal discussions with the majority of participants (IEs, Industry representatives and IMI employees), in

groups or individually, mainly during the breaks and at lunch time.

2. Observations and Recommendations

2.1 General Observations

- **Scale and complexity of the FP evaluation task:** Although the number of proposals in Stage 2 is only one per topic, the FPs are complex documents outlining large collaborative trans-disciplinary endeavours. Evaluating these proposals is a demanding task, although whenever possible the use of the same expert panels at Stage 2 as in Stage 1, appears to help and provide continuity.

The IOs were impressed by the Secretariat's organisation and efficient running of the evaluation sessions including the individual remote evaluations. The on-site panel evaluations, including the hearings with the applying consortia (in some cases with remote participation), for seven topics over four days is an impressive achievement by those staff involved.

- **Transparency of the process:** Clear and detailed information, provided as written support material, briefings on the morning of each panel meeting and by the moderators throughout the panel discussions, contributed to a well communicated and transparent process. The professionalism and experience of the IMI JU staff, and the high quality and dedication of the IEs, made all the on-site meetings smooth and efficient.
- **IT-tools:** The IOs did not receive any major comments or complaints from either the IEs or staff on the implementation of the procedures or IT-tools, save the size and font type used. The small font and formatting of the text makes the composite IERs difficult to read.
- **Impartiality, fairness and confidentiality:** No deviations from the rules set out under the IMI procedures were observed regarding these three areas. The independent observers did not see or record any deviations from the published evaluation procedures.
- **Quality of the IMI evaluation process in comparison with other international research funding schemes:** The independent observers consider the quality of the evaluation process to be at least at or above the quality of the evaluation procedures of National and other International research funding schemes.

2.2 Specific Observations

Complexity and Scale of Call 7 and Topics: This was the seventh Call launched under IMI2 (since its launch in July 2014), with all seven Topic Stage 2 panel meetings completed over the 4-day period. This represents a very significant logistical exercise, and the smooth way in which this was managed and executed is a considerable credit to the IMI JU team.

On this occasion, several of the FP projects had a significantly smaller duration and smaller budget to those previously reviewed, although the logistical effort required to process and review these is much the same. While the experience of the IEs selected was of a high standard, one Topic panel had only 3 IEs and another 4 IEs; close to the required minimum.

Role of the Rapporteur: The quality of the Rapporteur role was noted to vary from one IE panel to another. Both IOs received a number of comments from IEs questioning why the role of Rapporteur (which at Stage 2 is only one person) wasn't specifically contracted for e.g. an additional half day. This would allow the Rapporteur to prepare more formally for their role in advance of the meeting in Brussels. This would also ensure that all IERs are read and understood, and a summary of IER comments prepared beforehand to act as a basis for the meeting discussions etc.

Consensus Reports: The IMI rules, as highlighted during the IMI Director's briefing, require that CRs must not make Recommendations, save to recommend the Project for funding (yes/no).

It was the IOs observation that in many or most of the IE panel meetings, the IEs wished to make meaningful recommendations, which may have improved the quality of and reduced risks associated with each Project. These would have included recommending an early engagement with regulators and in some cases, the benefit of a 1 year review meeting.

3. Summary of Recommendations

Recommendation 1: Consider the number and frequency of Calls and Topics, relative to the logistics required to ensure that the highest levels of quality are maintained.

Recommendation 2: Consider formalising and recompensing the role of the Rapporteur, in order to make the role more accountable to expectations and provide better support and guidance to the IE teams.

Recommendation 3: Consider the merits of allowing limited IE CR recommendations. Allowing for additional IE input at Stage 2 may improve the quality of Projects, given that no additional independent input will be provided following a "Go / No Go" decision.

Recommendation 4: Consider increasing font size and layout size for the and formatting for the composite IER generated through the IT tool to make easier to read.