# IMI2 JU INDEPENDENT OBSERVER'S REPORT

**IMI2, Call 7, Stage 1 Evaluation**

**April 19-22, 2016**

5 pages (title page included)

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Date: 2/7/2016

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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 1 of the 7th Call for proposals by the Innovation Medicines Initiative 2 (IMI2). The 7th Call publication date was 18th December, 2015.

Submission of short proposals (SPs) was invited 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 Short Proposals (SP) in response to the Call up until the deadline for submission (17th March, 2016). Submitted SPs were then remotely evaluated over a four week period by Independent Experts (IEs).Two EFPIA representatives per Call topic also accessed the SP. The IOs also had remote access to all submitted SPs.

The IEs were then brought together as the "panel" in the Crowne Plaza Hotel meeting rooms in Brussels during April 19-22nd, 2016 to finalise the Stage 1 evaluation process. At this meeting also EFPIA representatives attended. Each evaluation took two days (topics 1-3 on April 19-20th and topics 4-7 on April 21-22nd). General discussion on the merits of each application, initial rankings and cogent questions to ask each set of applicants, if and when applicable, took place on the first of each two-day session, with the collated questions being asked during a hearing on the second day. For each submitted SP a consensus ranking was determined and a Consensus Report prepared. The EFPIA representatives participated in panel discussion except for the determination of the consensus scores and ranking. The ranking will be submitted to the Governing Board for approval and the result will be communicated to the Applicant Consortia shortly thereafter, concluding Stage 1 of the 7th Call. The first ranked consortium for each topic will be invited to join the respective Industry consortium to develop a full proposal (FP) which will be evaluated in Stage 2.

The IOs had access to all written and on-line information supporting the Stage 1 evaluation process and attended all four days of the briefing and evaluation sessions, held on April 19-22nd, 2016.

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

- 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

- All Stage 1 evaluations were conducted professionally and fairly and in accordance with established procedures and regulations, resulting in an impartial, transparent, thorough and high quality evaluation of all SPs;
- Highly qualified reviewers were selected and each panel had the appropriate expertise for the topic covered and worked well together;
- The opinions of all panel members (IEs) and EFPIA representatives were fully taken into consideration during the discussion and evaluation;
- All panel members actively participated in the drafting of the Consensus Reports under the moderation of the Scientific Officers (SO);
- Panel meetings were well organized and supported, with the role of moderator seen as being very important;
- A consensus on scoring and ranking was achieved by the IEs for each SP, in the absence of the EFPIA representatives;
- The expert reviewers unanimously expressed their appreciation and support for the very balanced and helpful role that the EFPIA representatives played in the discussions.

## 2.2 Specific Observations

**Instructions to Participants:**

In general, all participants (IEs, EFPIA representatives and IOs) were provided with appropriate and comprehensive documentation and instructions in a timely and fulsome manner. From discussion with the IMI team, we learned that a series of webinars are run for both experts and EFPIA representatives at which IMI go through the process, roles and requirements. IMI often also provide one-to-one support to help explain the process or facilitate access to the tools and address any issue the experts might have. However, there were small inconsistencies across panels and a number of participants flagged the following areas for possible improvement.

- The review process might be facilitated if once on-site the identity of the IE reviewers was un-blinded on the IER reports, instead of continuing to use numbers. In addition, it might be helpful to have lists and brief bios of panel members provided on-site particularly of those members of the panel who perform their assessment remotely;
- Information and instructions provided in advance of the meetings could be clearer in the guidance given on the role of the rapporteur in the development of the Consensus Report;
- On this particular occasion, the IOs would have benefitted from receiving schedules for each review topic in advance of the meetings, allowing them to better organize and prepare for the review.

**Hearings:**

There is a requirement that the panel must evaluate each SP based solely on what is written in the application and that new or additional information should not be provided by the applicants during the hearing. Panel members found it difficult to identify points of “clarification” that would not result in additional information being provided. In addition, concerns were raised that a particularly charismatic consortium spokesperson might influence the panel in a positive way, giving them an advantage over the other applicants (and vice versa).

On occasion, there seemed to be some confusion with respect to the guidance provided on the use of hearings, leading to potential for inconsistencies and variation in how the hearings and their usefulness might be presented to the different panels.

**Conflict of Interest:**

The IMI is rigorous in its policy of identifying conflicts of interest; not only those that are readily apparent, but also those which may be considered as conflicts of interest, whether major or minor. Such situations are carefully scrutinised on their individual circumstances. This assessment is done both before the panel hearing and, when necessitated by occasion, at the hearing itself.

For this panel, a small inconsistency was observed in the case of one expert who, having declared a situation which could be considered a conflict of interest in advance of the panel meetings had been advised as a consequence not to complete remote evaluation for the SP in question.

However, on arrival and following discussion within the panel and advice of the moderator and IMI lawyers, this potential conflict of interest was assessed such that the expert was able to contribute to the discussion (albeit not the scoring). This incident highlighted the potential need to review conflicts of interest rules and procedures and form a common practice by the moderators.

**Consensus Report and Role of Rapporteur:**

The Consensus Reports are extremely important as they are the record of the panel discussion and justification for the ranking provided.

We need note that on occasion quite an amount of time was taken to write the Consensus Report; not because of disagreements on the assessment of the application or its ranking. Rapporteurs are assigned for each SP from the experts, ahead of the panel meetings, but in some cases the Rapporteurs either did not seem clear on their role or else were not being used to their full potential.

**IT Tool (SOFIA):**

Many of the experts who were interviewed, had negative comments relating to the challenges of using SOFIA both for writing their remote reviews and when preparing the Consensus Report.

**Role of EFPIA Representatives:**

The IOs strongly support the attendance of EFPIA representatives at the review meeting. When asked, all IEs and moderators expressed their support as well, noting that the EFPIA representatives added significant value to the process and in no way interfered or exerted any influence on the decisions of the IEs. The IEs specifically appreciated the presentation of the Call Topic by the EFPIA representatives and indicated that it would have been even more helpful to have this presentation more clearly highlighted in advance of their remote review.

One expert, questioned whether, and if not why not, the EFPIA partners also should be asked to disclose any conflict or potential of interest in a similar way to the IEs.

# 3. Summary of Recommendations

***Recommendation 1:*** IMI should continue to provide detailed briefing about the goals of IMI and the review process to panel members (IEs) and EFPIA representatives in advance of the remote review and again on-site. Information on panel members should be made available to each other and the IOs once on-site. IMI might consider revising or communicating better the role of the Rapporteur in drafting Consensus Reports, to improve efficiency and reduce the time taken.

***Recommendation 2:*** A review of the use of hearings in general is recommended, especially in light of possible format changes in the future extending the size and content of the SP. If hearings do continue into future Calls, then it is recommended to provide clearer guidelines for moderators and panel members and for these to be adhered to consistently.

***Recommendation 3:*** On-going review of conflicts of interest rules and procedures, to form a common practice by the moderators and also to consider disclosure of conflicts of interest by EFPIA representatives..

***Recommendation 5:*** Consider investigating the use of an alternative IT tool for doing remote and Consensus Reports.

***Recommendation 6:*** The participation of the EFPIA representatives should be continued.