

**IMI2 JU INDEPENDENT OBSERVER'S REPORT**

**Call ID: IMI2 Call 4 stage 1**

**H2020-JTI-IMI2-2015-04**

**Enabling Platform on Medicine Adaptive Pathways to Patients**

**Coordination and support action**

**Date of evaluation:**

**February 26, 2015**

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**Present at the evaluation: February 26, 2015**

## 1. Introduction

This Independent Observer (IO) report is based on three steps: (i) the review of the overall documentation provided before the evaluation meeting; (ii) the observation of the evaluation session organized on February 26, 2015 in Brussels; (iii) the discussions with the evaluators during the on-site session. Steps (i) and (ii) were respectively aimed at checking the quality and completeness of the materials provided to the experts and assessing that the rules and procedures applied during the evaluation process were fairly followed. The objectives of step (iii) were to collect the comments and suggestions made by the evaluators on this process and to make recommendations on possible improvements.

## 2. Documentation and phone contacts

These documents either obtained by e-mail or via the SOFIA platform, included:

1. The H2020-JTI-IMI2-2015-04-two-stage call text (Coordination and support action)
2. The IMI2 evaluation form for coordination and support actions
3. The summary of the most relevant provisions for participating in IMI2 actions
4. The IMI2 manual for submission evaluation and grant award.
5. The three short proposals submitted (only the applicant consortium whose proposal is ranked first at stage 1 is invited for the second stage)
6. An observer report template

This information was completed by several phone calls with the IMI staff in order to highlight the specific features put in place by IMI, for instance the roles of industry representatives and EFPIA. These exchanges were important and appreciated by the IO. They contributed to a good understanding of the whole procedure.

A few days before the on-site evaluation, two last documents were made available:

1. H2020-JTI-IMI2-2015-04-Aggregated reports
2. The agenda of the evaluation meeting

The information package provided beforehand was considered of very high quality by all parties, experts and IO. It covers all the relevant aspects of the Call, from the initial proposal template to the evaluation criteria. The efficiency and the facilities in use of the SOFIA platform were acknowledged. The availability of the IMI staff for remote questions was also strongly emphasized and is a significant component for preparing experts to the tasks they have to fulfill. The aggregated reports received before the meeting were appreciated by the panel members.

### 3. On-site meeting

The agenda of the meeting was split into the following items:

- Expert briefing by the acting Executive Director of IMI
- Introduction to the panel by the moderator (IMI Scientific Officer)
- Topic presentation by industry representatives
- Discussion of proposals
- Scoring of proposals
- Writing of consensus and panel reports

When opening the session, the acting Executive Director of IMI asked all evaluators and the IO to introduce themselves. This allowed showing that the gender balance was fully respected. The two industry representatives followed the same rule. One expert was solicited for remote evaluation only and another one was unable to attend the meeting for personal reasons but participated by teleconference to the discussions up to the scoring step. The experts were coming from different countries (Belgium, Finland, Hungary, Italy, Poland, Spain, UK and US) and from public institutions (universities), patient organizations and private consultancy companies. Their profiles match very well with the expertise needed. They gather: drug development and safety, regulatory affairs, health technology assessment, pharmacovigilance, epidemiology.

The three presentations (expert briefing, introduction to panel, topic presentation) were excellent. They summarized very clearly the process, the objectives and the guiding principles to follow as stated in the documentation previously received. Emphasis was put on independence, impartiality, objectivity, accuracy and consistency. Confidentiality, conflict of interest, evaluation criteria (within the scope or not, level of excellence and expected impact) and consensus objectives for scoring and reporting were also addressed. Stage 1 and stage 2 goals were also described. All over the presentations, everybody was encouraged to ask questions and they received attention and concise replies.

The discussion of the short proposals was managed by the moderator, assisted by the IMI call coordinator. All experts and the IO received the submitted projects. Each proposal was reviewed by 6 to 8 remote and independent evaluations. The aggregated reports included the scoring of each evaluator for excellence and impact, the “yes/no” corresponding to the “in scope” and to the “conflict of interest” questions. The full texts corresponding to the reviews provided by each expert were also available. The evaluators who had an indirect link with one proposal left the room (for example, when his/her organization, not directly involved in the project, was part of an applicant umbrella organization).

The discussion was initiated by the rapporteur designated before the meeting. He/she summarized the proposal and the different points of view expressed in the reports. Each expert then exposes her/his comments, arguments and explains her/his evaluation. This process was nicely managed by the moderator who requested when needed to better explicit the viewpoints, asked different opinions and

checked if a consensus was reached or not. The distant expert was solicited on a regular basis to be part of the discussion. The atmosphere during the exchanges was open-minded, friendly and constructive. Even if a few differences were observed between the different evaluations, a high coherence appeared through the reports and the individual scorings for the three proposals. Following the discussion, the convergence on the first ranked proposal was straightforward. The industry representatives left the room during the consensus evaluation scoring phase. The deliberations were also well managed by the expert panel without being influenced by the moderator. Final consensus scorings were collectively discussed and unanimously approved. Two proposals failed to pass on the excellence threshold.

The afternoon was devoted to the consensus and panel reports. A couple of experts (including the rapporteur) was solicited by the moderator for each proposal. They worked independently. Their reports were made then available through the SOFIA platform and displayed on a screen. The industry representatives were attending again. The reports were intensively discussed, sentence by sentence, even word after word. The moderator was modifying the report according to the suggestions made in real-time by the panel members. In some cases, previous paragraphs already agreed were reexamined. This process took time and stopped when everybody was satisfied. The industry representatives participated actively in the process without driving it. This evidences the special attention given by the experts to precisely reporting their analysis of the proposals. The panel report followed the same procedure.

## 4. Overall impression

This IO report is based on:

- the reading of all documents provided by IMI through e-mail, by access to the SOFIA platform and at the beginning of the meeting.
- several interactions beforehand by phone and e-mails with IMI call coordinator in order to precise the specific context of IMI calls (and in particular the differences between IMI and EC Calls).
- observation of the evaluation process during all meeting phases (from briefing to reports)
- solicitation of any impressions, comments of the experts and industry representatives on the procedures that was applied , recommendations for improvements
- face-to-face discussions with them (during the breaks and the lunch buffet) and those leaving the meeting room for conflict-of-interest reasons or by application of special rules (industry representatives absent during the scoring step).
- questions asked to the IMI staff in order to avoid any misinterpretation of some comments during the discussions and to get additional information when necessary.

The IO has been part of a number of national committees in Europe (Sweden, Spain, France, etc.) and in the US. He served also several times as IO for the European Commission (6<sup>th</sup> and 7<sup>th</sup> Framework Programme). The guidelines, the procedures and practices seem to me very close to EC ones and are now well established. The process is of high quality as confirmed during the meeting by all the experts.

In the IO opinion, the evaluation was carried out by fully respecting the rules and guidelines publicly available. Experts were of a high quality as it could be observed during the discussion of the short proposals. They had the relevant expertise to allow them analyzing the respective merits of the short proposals and contributing to a well-informed consensus decision and report. The evaluation of the proposals and the on-site discussions were fair and transparent. The final evaluation reports fit very well with the consensus opinion of the panel.

*Scale of complexity of the evaluation task:* no remark was collected during the expert interviews collected on-site mentioning any difficulty in the evaluation of the short proposals. The experts strongly appreciated the exchanges with the IMI staff before the meeting day in Brussels. The fact that only 3 short proposals were under examination facilitated the evaluation. Some experts expressed some concerns with this very low number. However, the industry representatives considered that from their perspective for such topic, it was satisfactory.

*Transparency of the procedures:* when questions were raised regarding any step of the whole process, they were handled very professionally by the IMI staff.

*Throughput time of the process and the efficiency of the procedures:* the only concerns expressed by a few experts were related to (i) the short-time available for the individual remote reporting; (ii) the need to better help the rapporteur in her/his task for those who have not experienced this before.

*Efficiency, reliability and usability of the implementation of the procedures, including the IT-tools:* the management was recognized as of high quality before and during the meeting. The IO shares this appreciation. The IT tools run perfectly both for performing the remote work and for reporting on-site.

*Impartiality, fairness and confidentiality:* these three important features of the procedure were assessed by all experts. The IO confirms that they were fully implemented.

*Conformity of the evaluation process witnessed with the evaluation procedures published in the IMI2 manual for submission evaluation and grant award.:* these procedures were rigorously applied.

*Quality of the IMI2 evaluation process in comparison with the evaluation procedures of national and/or other international research funding schemes:* the IO and the experts assessed that this evaluation process can be favourably compared to many national and international equivalent selection schemes.

*Quality of the evaluation process overall:* very high at all levels. The process features that were unanimously assessed include the evaluation of all short proposals by all non-conflicted experts (i.e.

this allows them being fully part of the all discussions), the access before the meeting to all individual and independent remote reports, the friendly and openness atmosphere during the meeting, the availability of the IMI staff.

## **5. Any other remarks**

All of the evaluation panel members had previously reviewed the short proposals. The quality of the documentation provided was considered as excellent. One expert was unable to attend the on-site meeting but participated and contributed to the discussions and evaluation through teleconferencing. The remote evaluation of the other expert who could not attend was also taken into account. This was managed nicely by the moderator. Panel members were fully aware of the objectives and criteria of the evaluation process, the tasks and the process they had to carry out and to follow, the decisions to be taken, the importance of their ranking, scoring, reporting and their further recommendations on the process itself.

The quality of the briefing sessions introducing the on-site meeting was recognized by experts. The moderation of the session was performed with professionalism and impartiality. It allows respecting the all viewpoints while well ensuring the conduct of the session. Advices were provided when necessary. Conflicts of interest were properly handled. Positive expert comments were received by the IO concerning the role and the contribution of the moderator. The IT tools used were considered as efficient and easily manageable both for remote evaluation and for the on-site writing, modification and completion of the reports.

The facilities offered during the meeting and the responsiveness of the IMI staff were excellent. This comment applies to the registration, the infrastructure and working conditions and the administrative work. All the management of travels and accommodations has been achieved smoothly before and during the session. No claims about the workload and time given to evaluators were received by the IO. The remuneration of the experts (based on the number of short proposals to examine at stage 1) strictly followed the EC rules and was no commented by the experts during the session.

## **6. Summary of recommendations**

Before addressing the recommendations, it must be said that the whole process strictly followed the published guidelines and that the evaluations and debates on the proposal under examination were fair and transparent. The evaluation process is of high quality. The IMI staff operates very professionally. The logistics for all practical affairs were dealt in a smooth and excellent way.

Among the strong points mentioned by the experts and shared by the IO, there are:

- The early and distant phone or e-mail contacts with the IMI staff for questions
- The quality of the documentation provided

- The fact that all experts evaluate independently all proposals and can thus fully contribute to the on-site discussions
- The availability of the individual reports beforehand
- The positive and open atmosphere during the meeting
- The variety of expertise profiles represented in the panel to cover the several lines of the Call
- The possibility for all experts to contribute to the consensus reporting

Some recommendations can however be made. As a minor point, special attention must be put on the deadline to submit the remote evaluation. For example, the remote evaluation deadline was set on Monday, 23<sup>rd</sup> of February. The aggregated individual reports were made available by IMI on Tuesday 24 (a real challenge!). Thus, the rapporteurs had a very short time to synthesize these reports and to prepare for the consensus panel meeting on Thursday 26 February. It was explained at the beginning of the meeting that the timelines for this call are exceptionally tight to ensure this coordination and support action (CSA) is operational promptly. Balancing the need for a faster process while leaving sufficient time for the experts, a solution can be easily found to improve this issue.

Two other points deserve to be considered: (i) advising the rapporteur and (ii) improvement of the consensus reports.

- (i) The rapporteur was chosen before the meeting by the IMI staff. The role of the rapporteur is important in summarizing a proposal and sketching the main features of the remote evaluations. It directly impacts on the discussions occurring later in the panel. If she/he is not familiar with the task to deal with, she/he might be uncomfortable. The recommendation is therefore to give the rapporteur some advice on the ways to prepare her/his intervention. This can be extended also to the preparation of the draft consensus report into which she/he will be involved.
- (ii) Improvement of the consensus reports: although only three proposals were applying to the call, the final writing took much time before being agreed by the panel. The convergence can very likely be improved by advising the experts in charge of the preliminary version of the consensus report (i.e. before discussion with the panel) to organize it according to the items of the evaluation grid: clarity and pertinence of the objectives, credibility of the proposed approach, soundness of the concept, quality of the proposed coordination, mobilization of the expertise, etc.

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