

H2020-JTI-IMI2-2014-01

Stage 2 Evaluation

19th May 2015

**Translational approaches to disease modifying
therapy of type 1 diabetes mellitus (T1DM)**

Independent Observer's Report

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Abbreviations

CoI	Conflict of Interest
CR	Consensus Report
EFPIA	European Federation of Pharmaceutical Industries and Associations
ESR	Evaluation Summary Report
FP	Full Proposal
H2020	Horizon 2020
IMI	Innovative Medicines Initiative
IE	Independent Expert
IO	Independent Observer
IER	Individual Evaluation Report
IMI2 JU	Innovative Medicines Initiative 2 Joint Undertaking
SP	Short Proposal
T1DM	Type 1 Diabetes Mellitus

1. Introduction and approach taken by the observer

1.1 Introduction

This independent observer (IO) report is of the Innovative Medicines Initiative-2 (IMI2) call H2020-JTI-IMI2-2014-01. The topic in this stage 2 evaluation is IMI2-2014-01-01: 'Translational approaches to disease modifying therapy of type 1 diabetes mellitus (T1DM)' and this topic is under the Research and Innovation Action. The first stage short proposals for this topic were evaluated in Brussels on the 9th and 10th December 2014. The Full Proposal (FP) stage 2 evaluation of this topic took place in Brussels on 19th May 2015.

1.2. Independent Observer's Tasks and Approach

The Independent Observer's task is to report on the conduct and fairness of Stage 2 of the two-stage evaluation procedure of the H2020-JTI-IMI2-2014-01 call for proposals. The call was issued on the basis of the IMI2 JU Annual Work Plan 2014: IMI/INT/2014-1260.

The IO for the first stage evaluation of this topic is also the IO for this stage 2 evaluation. The IO fulfilled all aspects of the role to observe the practical workings of the evaluation process, to give independent advice on the conduct and fairness of the evaluation sessions, the application of the award criteria and to recommend ways in which the procedures could be improved. The IO did not express views on the proposal or the other experts' opinions. The IO confirms the evaluation followed the guiding principles of excellence, transparency, fairness, impartiality, efficiency and speed.

The IO reviewed all written and on-line information supporting the full proposal (FP) evaluation and attended the on-site briefing, evaluation sessions and panel discussions held in Brussels on 19th May 2015. The IO confirms IMI staff members and independent experts fulfilled their roles with great expertise, professionalism, dedication and efficiency and with a comprehensive understanding of the evaluation rules and procedures. This Independent Observer's¹ report is based on the observations of the stage 2 evaluation and comments and feedback from the independent experts. It includes recommendations to improve the process for future calls (see 4.1 Summary of Recommendations).

2. Overall Observations and Impression

The IO observed the procedures followed during the evaluation were entirely as set out, or referred to, in the IMI 2 Manual for evaluation, submission and grant award.

- The IO can confirm the excellent quality and rigor of the evaluation and confirms with the evaluation was transparent, open, fair and in accordance with the evaluation rules and procedures. The independent experts (IE) were of excellent quality, with appropriate expertise. Aspects of Conflict of Interest (Col) were appropriately addressed. The general organisation and administration of the procedure was underpinned by the expertise, dedication and professionalism of the Innovative Medicines Initiative staff. The experts had no difficulties with using the SOFIA tool throughout the remote and on-site evaluation phases.

¹ As such, observers shall have at their disposal Chapter IV of the H2020 Vademecum as background material. They are encouraged to enter into informal discussions with the staff of the Commission/Agency/Joint Undertaking involved in the evaluation sessions and, if relevant, to suggest to the call coordinator any possible improvements that could be put into practice immediately. They should refrain from interfering in any manner in the conduct of the evaluation by experts and staff. In the framework of their work, they should not express views on the proposals under evaluation or on the experts' opinions on the proposals.

2.1 Scale and complexity of the evaluation task

The scale and complexity of the evaluation task is described in the IMI2 manual for submission, evaluation and grant award (http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-jti-imi2-2014-02-single-stage/1630122-h2020-guide-pse-imi-ju_en.pdf) and as detailed in the IO's report of the stage 1 evaluation of this topic.

- Each expert remotely prepares an 'Individual Evaluation Report (IER)' with their evaluation of whether the topic is in scope, their comments and scores for each criterion, which are submitted remotely in SOFIA. In stage 2, one full proposal was evaluated in this one topic. As industry participates in the consortium in the stage 2 evaluation, there was no EFPIA representative or participating industry expert during any part of this stage 2 evaluation..
- In stage 2, as in stage 1, during the individual remote evaluation phase, each independent expert carries out an evaluation of the one proposal remotely using the SOFIA IT tool. Each expert prepares an 'Individual Evaluation Report (IER)' with their comments and scores for each criterion and submits it in SOFIA. The experts also indicate whether the proposal is within the scope or falls outside the scope of the respective call topic.
- The on-site consensus and panel meetings were well organized. The experts' discussions were of high quality and comprehensive, with all proposals receiving a thorough and fair review. The expert group for this topic was appropriately composed, with different evaluators' expertise complementing each other. The one proposal in this stage 2 evaluation had one expert remotely assigned to act as rapporteur of the proposal before coming to Brussels.
- The Consensus Report (CR) was prepared by the rapporteur, following detailed and in depth discussions of the full proposal with input from all the independent experts at the consensus meeting. The consensus and panel meetings were facilitated expertly by the IMI moderator. The panel meeting discussed the proposal and each of the criteria, the CR, the scores and prepared the Evaluation Summary Report (ESR). The comments and the scores on the CR and ESR accurately reflected the discussions.
- The panel report was drafted by the IMI staff with the rapporteur and the independent experts. The panel report was verified and signed by the rapporteur and independent experts to report on the outcome of the evaluation process to the IMI Board as an overview of the evaluation.

2.2. Transparency of the procedures

The IO confirms the entire evaluation procedure, from the selection of experts to handling of conflict of interest aspects, to the consensus and panel meetings and writing of the reports proceeded entirely according to the IMI2 JU manual for submission, evaluation and grant award. The evaluation was carried out to the highest level of fairness, expert evaluation and discussion, openness and transparency. Any issues were handled according to the rules and procedures and were recorded in the panel report which is given to the IMI Board and are included in this IO report.

2.3. Throughput time of the process and the efficiency of the procedures

The publication of this IMI2 call for both topics and the launch of the submission of Stage 1 proposals was 9th July 2014 and the deadline for submission of Stage 1 proposals was 12th November 2014. The stage 1 evaluation of the two topics in this call took place in Brussels on 9th and 10th December 2014. The second stage Full Proposal for this topic was submitted on 14th April 2015 and the stage 2

evaluation of this topic took place in Brussels on 19th May 2015. The independent experts' feedback was that the length of time for the process and the remote evaluation procedure was entirely sufficient.

2.4. Efficiency, reliability & usability of the implementation of the procedures, including IT-tools

The experts reported that the procedures were efficiency managed and reliably implemented throughout the evaluation by the IMI staff. The experts related that the SOFIA IT tool worked very well for both the remote and on-site consensus and panel meetings, including for accessing the proposals and writing the IERs, CRs, ESRs and panel reports and showing the comments and the scores.

2.5. Impartiality, fairness and confidentiality

The IO was impressed with the rigor of the procedures to ensure the selected experts were impartial, did not have CoIs and the importance of confidentiality and fairness throughout the evaluation.

2.6. Conformity of the evaluation process witnessed with the evaluation procedures published in the Horizon 2020 (H2020) Grants Manual

The IO observed that the remote and on-site evaluation process for the stage 1 and this stage 2 evaluation was carried out according to the procedures published in the IMI2 manual for submission, evaluation and grant award and according to the H2020 and IMI2 JU evaluation procedures and rules.

2.7. Quality of the IMI2 evaluation process in comparison with the evaluation procedures of national and/or other international research funding schemes

The IO confirms that the IMI2 evaluation process compares entirely favourably with national and international research funding schemes. This IO has experience of evaluation in the national systems of five European countries (Ireland, UK, Germany, Sweden and Belgium), in addition to being an expert evaluator for over 10 years for EU Framework Programmes, MCSA actions and for the ERC.

2.8. Quality of the evaluation process overall

In the observation and execution of this task, the Independent Observer confirms the excellent standard of evaluation from the highly skilled and professional independent experts to the capable management, administration and support provided by the expert and dedicated IMI staff. The IO verifies that the evaluation was done entirely according to the rules laid down.

3. Additional Observations

3.1. Quality of the documentation provided to experts beforehand

The experts and the IO were entirely satisfied with the quality of the documentation provided for the second stage evaluation of this topic. Each of the experts, the IO and each IMI staff member was provided with a useful printed information pack for the on-site evaluation.

3.2. Quality of the on-site briefing sessions

There was a briefing of the experts on the morning of the evaluation to inform the experts of their roles and obligations and to give them an overview of the evaluation procedures. The briefing was comprehensive and was expertly carried out by the IMI Acting Executive Director Irene Norstedt. The IMI moderator of the evaluation was Magda Gunn assisted by Colm O'Carroll. IMI lawyers were available if requested for clarification on any aspect by the independent experts.

The briefing was comprehensive, clear and provided clarity on the evaluation procedures and the process. There was a thorough discussion of conflict of interest (COI). The difference between stage 2 from the stage 1 evaluation were highlighted, including that there is no competition in stage 2 as there is only one proposal in the stage 2 evaluation. The briefing explained that in this stage 2 evaluation of the Full Proposal, the threshold for each of the three criteria is 3 and the overall threshold for the full proposal (FP) is 10. The briefing detailed that there is a separate ethics panel, which assess ethics aspects and produce an Ethics Screening Report. It was noted, that as industry organisations are part of the consortium in the stage 2 full proposal, there is no industry expert as part of the stage 2 evaluation or no representatives from the European Federation of Pharmaceutical Industries and Associations (EFPIA). Questions were encouraged and all were answered comprehensively.

The experts suggested it would have been useful for them to have had the briefing presentation before coming to Brussels in order to be better prepared for the evaluation.

Recommendation: The experts suggested it would have been useful for them to have had the briefing presentation before coming to Brussels in order to be better prepared for the evaluation.

3.3. The understanding by experts of the call (context, topics), of the evaluation process and their role and of the award criteria and scoring scheme

The independent experts demonstrated a thorough understanding of the IMI2 JU and Horizon 2020 procedures. The IEs were expertly informed of the specific context of this call and the topic which was demonstrated by the detailed and comprehensive discussions in the consensus and panel meetings, and the rigor the experts took in evaluating each criterion and in deciding and awarding the scores.

3.4. The allocation of experts to proposals: balance (gender, geographic, sector), relevance and balance of expertise

The experts were selected by the IMI staff based on their expertise and relevance in the call topic. The experts are selected to ensure they did not have a conflict of interest with the submitted proposal. The main selection criterion of the experts is the appropriate competencies related to the topic. Other criteria include a balance of experienced and new experts, the distribution of regional origins of the

experts, a balance between academic and industrial expertise and users and a reasonable gender balance. The data and information below applies to the 6 independent experts for this stage 2 evaluation of this one topic. The numbers and analysis below for the independent experts does not include the IO (who is a female, from the EU-28 and from academia);

Table 1 presents an overview of the gender, geographic origin and affiliation of the experts involved in this evaluation exercise.

Gender	Geographic Origin	Affiliation
M	United Kingdom	Academic
F	Spain	Academic
M	United States	Academic
F	Ireland	Industry
M	Norway	Academic
F	Ireland	Academic

For this evaluation 6 independent experts were contracted:

- 3 out of the 6 experts (50%) were women,
- 5 (83%) came from universities and research institutes - public or private
- 1 (17%) were from private commercial firms

- An appropriate turnover from year to year:
 - Of the 6 independent experts;
 - o 3 experts evaluated stage 1 of this topic
 - o 3 experts are new to this stage 2 evaluation
- skills, experience and knowledge
 - The skills, experience and knowledge of the experts were excellent and included experts in senior positions and highly relevant to the call topic.

Regarding gender representation, it is welcomed that the female independent experts has been increased from 21% in the stage 1 evaluation to 50% in the stage 2 evaluation of this topic. In the IO report of the stage 1 evaluation of this call, it was recommendation in that the female representation has been increased from 21% to 40%. This recommendation is to comply with one of the H2020 objectives to ensure 40% of independent experts are from each gender is achieved (article 16) (http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/gender/h2020-hi-guide-gender_en.pdf).

3.5. The process of the individual evaluations and the participants involved

In this topics, following screening of the experts for CoIs, the experts remotely completed the individual evaluations of all the short proposal using the SOFIA IT tool. The proposal was assigned a rapporteur before coming to Brussels, which gave them time to prepare for this role.

3.6. The process of the consensus meetings and the participants involved

The experts participated in detailed and in depth discussion during the consensus meeting, with the rapporteur preparing the draft CR based on the consensus group discussion. The draft CR was then

distributed to the other experts, and there was further in depth discussion of each of the criteria and the scores. As there was one proposal in this evaluation, all independent experts evaluated the full proposal (FP). The ethical assessment is performed separately during the stage 2 evaluation. This process was excellently facilitated by the IMI staff acting as moderators of the meeting. The rapporteur and experts signed the CR to confirm that it reflected the discussions, scoring and views of the experts. As industry participates in the consortium in the stage 2 evaluation, there was no EFPIA representative or participating industry expert during this stage of the evaluation.

3.7. Criteria and scoring scheme: appropriateness, completeness, relevance, clarity, consistency in application

The evaluation criteria, the scoring scheme and how to assess them was explained in detail during the briefing on the morning of the evaluation in Brussels. It was clear from observing the evaluation, that the experts clearly understood the evaluation criteria and the scoring scheme and their importance and relevance to the assessment. The high quality of the discussions on the criteria and on their deliberations on the scores given during the consensus and panel meetings was evidence of the thoroughness of the assessment and the understanding of the process by the experts. The IMI moderator and legal staff gave feedback on the CR which was welcomed and appreciated by the experts. The experts had questions on the review procedure which was ably explained.

In this second-stage evaluation of this one proposals, the threshold for each of the three individual criterion is 3 and the overall threshold for the proposal is 10. Experts also assess the operational capacity of applicants to carry out the proposed work.

3.8. The process of the final panel meeting and the participants involved

Overall, the panel meeting for the topic was very well organized. The IT systems for reviewing the consensus reports and evaluation summary reports were efficient, showing the comments and the scores on a large screen and a printed version of the CR was available for all participants.

The consensus meeting and panel meeting was expertly guided by an IMI staff member as moderator. The panel meeting checked the consistency of the comments and the scores of the award criteria. The final CR and ESR were signed by the experts and were attached to the panel report.

The experts worked well together and the discussions indicated that the evaluators' expertise comprehensively complementing each other and were entirely related to the topic. Discussions were thorough, with the proposal receiving an in depth and fair review. The Independent Observer was impressed by the quality and critical fairness of the discussions.

The outcome of this panel meeting was a consensus that the scores for each of the three criteria were above threshold and the overall score was above the overall threshold, this proposal was recommended for funding.

The panel report was signed by the rapporteur the independent expert panel members and by the IMI staff member acting as chairperson, to affirm this outcome accurately reflected the discussions and the evaluation procedure. This panel report is given to the IMI Board.

Both the remote evaluation phase and on-site consensus meetings were valued by the experts as fundamental components of the evaluation procedure. The observation of the consensus and panel meeting discussions displayed impressive knowledge of the experts of their respective subject areas.

The consensus and panel meetings were very well organized. The independent experts, rapporteur and the IMI moderator and staff worked very well together. The high quality discussions indicated that the consensus group were well composed, with different experts' expertise comprehensively complementing each other. Discussions were of high quality, with the proposal receiving a thorough, expert and fair review.

3.9. The process of the hearings (if any) and the participants involved

In this evaluation procedure, there was no hearing. It was noted by the independent experts, that the option of having a hearing would have been valuable. The independent experts recommended to have a hearing as part of the evaluation, in order;

- to have the opportunity to clarify aspects and issues that arose during the evaluation,
- to hear an overview of the project
- to clarify questions related to the proposal,
- to better inform the evaluation.

The independent experts recommended re-introducing the option to have hearings in stage 2 evaluations. This recommendation was also made during the stage 1 evaluation of this topic.

Recommendation: The independent experts recommended re-introducing the option to have hearings in stage 2 evaluations. This recommendation was also made during the stage 1 evaluation of this topic.

3.10. The occurrence and handling of specific issues (if any) such as conflicts of interest

There were no specific issues that arose during this evaluation which had to be addressed.

3.11. The quality of evaluation summary reports

The independent experts, rapporteur and IMI moderators worked very well together. The process of writing the Evaluation Summary Report (ESR) was efficient, thorough and accurately reflected the discussions of the experts. The criteria under evaluation and the scoring scheme were well understood and the discussions were of high quality, comprehensive and fair.

3.12. Overall conduct of staff: responsiveness, hospitality, competence

During the entire evaluation, the IMI staff were highly expert with a thorough knowledge and understanding of the evaluation procedures and rules. At all times, the IMI staff showed great professionalism in carrying out their roles and were courteous and responsive to all the questions and requests of the independent experts and the IO.

3.13. Infrastructure and working conditions for evaluators

The briefing, consensus and panel discussions were held in Brussels on 19th May 2015. The infrastructure and working conditions during the evaluation were of a high standard. The IMI staff had

their administrative rooms adjacent to the evaluators' meeting rooms. The Independent Observer had a private room to read, with access to the internet, computers and printing facilities and to meet with independent experts and IMI staff. The experts and the IO were accommodated in the same hotel where the evaluation took place.

3.14. Workload and time given to evaluators for their work (remotely & on-site)

The feedback from the independent experts was that they had sufficient time to review the full proposals and to submit their remote independent evaluation. They considered the workload and time given for the remote and on-site evaluation sufficient.

3.15. Remuneration of evaluators (in relation to workload) and reimbursement of expenses for Experts

The reimbursement of expenses was performed by IMI administrative and support staff throughout the day of the evaluation and the IMI2 staff were efficient, helpful and professional throughout. The experts were not entirely satisfied with the remuneration in relation to workload for this stage 2 evaluation. The experts recommended being reimbursed for two days for the remote evaluation, instead of one day, as the experts took over two days for the remote evaluation of the Full Proposal.

Recommendation: The experts recommended being reimbursed for two days for the remote evaluation, instead of one day, as the experts took over two days for the remote evaluation of the Full Proposal.

4. Summary of Recommendations

4.1. Summary of Recommendations

The IO confirms the evaluation was carried out entirely according to the H2020 and IMI2 JU rules, processes and procedures. The IO can attest that the evaluation was of an excellent standard, of high quality and was fair, rigorous and transparent. There was one recommendation for further improvements of this evaluation procedure, which is already of a high standard;

Recommendation: The experts suggested it would have been useful for them to have had the briefing presentation before coming to Brussels in order to be better prepared for the evaluation.

Recommendation The independent experts recommend re-introducing the option to have hearings in stage 2 evaluations. This recommendation was also made during the stage 1 evaluation of this topic.

Recommendation: The experts recommended being reimbursed for two days for the remote evaluation, instead of one day, as the experts took over two days for the remote evaluation of the Full Proposal.

4.2. Acknowledgements

The Independent Observer wishes to sincerely thank all the independent experts for their assistance, support, valuable comments and constructive feedback during the evaluation. Their recommendations for on-going improvements for the benefit of the evaluation procedure will ensure transparency and openness and the continuing high standards and excellent quality of this evaluation procedure.

The Independent Observer expresses her sincere appreciation to all the IMI staff for their helpful and professional assistance throughout the entire evaluation procedure and who fully supported her in performing her role.

4.3. Conclusion

In conclusion, the Independent Observer fully acknowledges that this stage 2 evaluation procedure was excellently carried out by the experts and the IMI staff according to the H2020 and IMI2 JU rules, processes and procedures. The IO can confirm the independent experts and the evaluation was of an excellent standard, rigorous, impartial, fair and transparent, where issues of conflict of interest and confidentiality was carried out according to the rules and procedures. All the IMI staff and independent experts had an in depth understanding, knowledge and awareness of all the rules and procedures of IMI2 JU and of H2020. The entire evaluation was well organised with the dedicated commitment of all the participants, from the independent experts to the IMI staff.