

H2020-JTI-IMI2-2014-01

Evaluation of Stage 1

9-10 December 2014

Independent Observer's Report

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Abbreviations

CoI	Conflict of Interest
CR	Consensus Report
EFPIA	European Federation of Pharmaceutical Industries and Associations
SP	Short proposal
ESR	Evaluation Summary Report
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
T1DM	Type 1 Diabetes Mellitus

1. Introduction and approach taken by the observer

1.1 Introduction

This independent observer (IO) report is of the first stage evaluation of the Innovative Medicines Initiative-2 (IMI2) call H2020-JTI-IMI2-2014-01. Submissions of proposals were invited in response to the following call identifiers and topics:

- 1) Topic code: IMI2-2014-01-01. The topic scope is 'Translational approaches to disease modifying therapy of type 1 diabetes mellitus (T1DM)' and this topic is under the Research and Innovation Action
- 2) Topic code: IMI2-2014-01-02. The topic scope is 'Discovery and validation of novel endpoints in dry age-related macular degeneration and diabetic retinopathy' and this topic is under the Research and Innovation Action.

The launch of the submission of stage 1 proposals to these topics was 9th July 2014 and the deadline was 12th November 2014. The on-site evaluation took place in Brussels on 9th and 10th December 2014.

1.2. Independent Observer's Tasks and Approach

The Independent Observer's task is to report on the conduct and fairness of the Stage 1 evaluation phase of the two-stage procedure of the H2020-JTI-IMI2-2014-01 call for proposals. These calls were issued on the basis of the IMI2 JU Annual Work Plan 2014: IMI/INT/2014-1260.

The role of the independent observer (IO) is:

- to observe the practical workings of the evaluation process
- to give independent advice on the conduct and fairness of the evaluation sessions and the application of the award criteria;
- recommend ways in which the procedures could be improved,

The independent observer does not express views on the proposals or the other experts' opinions.

The IO's role is to observe that the guiding principles of the evaluation, as outlined below, were followed;

- Excellence. Projects must demonstrate high quality in relation to the topics and criteria set out in the calls.
- Transparency. Funding decisions must be based on clearly described rules and procedures, and applicants should receive adequate feedback on the outcome of the evaluation.
- Fairness and impartiality. All proposals submitted in response to a call are treated equally and evaluated impartially on their merits, irrespective of their origin or the identity of the applicants.
- Efficiency and speed. Evaluation, award and grant preparation should be done as quickly as possible without compromising quality or neglecting the rules.

The IO's role is to give independent observations on the conduct and fairness of all phases of the evaluation, on the application of the award criteria, on the quality, independence and thoroughness of the experts carrying out their role. The IO will assess the practical workings of the evaluation process, the management of the evaluation and observe that the evaluation is done according to the rules and procedures. The IO can make observations on ways in which the procedures could be improved. The IO is not allowed to intervene in the discussions or in the evaluation process.

The IO's approach was to review all written and on-line information supporting the short proposal (SP) evaluation process to this IMI2 call for proposals. The IO attended both days of the on-site briefing, evaluation sessions and panel discussions held in Brussels on 9th and 10th December 2014. The IO spoke with, and obtained feedback from, the experts, the European Federation of Pharmaceutical

Industries and Associations (EFPIA) representatives and the IMI staff. The IMI staff included the IMI Scientific Officers, the supporting secretariat and administrative staff, the IMI lawyers and Professor Michel Goldman, the IMI Executive Director. The IO used the 'Horizon 2020 Independent Report' template provided by IMI staff for the format of this report.

The two topics in this call were evaluated in separate meetings, which were held in parallel, in meetings rooms adjacent to each other. The IO divided her time between both evaluations and was present at all times during both days of the evaluation. Each of the two topics had its own experienced IMI staff member acting as moderator or chairperson of the consensus and panel meetings. Both of these IMI staff members did their role 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 1 evaluation process of these two topics and comments and feedback from the independent experts. It includes recommendations to improve the process for future calls (see section 4.1 for the Summary of Recommendations). These recommendations are to be seen as further improvements in the context of the overall evaluation process, which was observed to be of excellent quality and rigor, and was of the highest international standard of peer review, being transparent, open and fair.

2. Overall Observations and Impression

The IO assessed that 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.

All information related to this call is available at <http://www.imi.europa.eu/content/stage-1-13#Call documents and deadlines>. These guidelines and procedures are available at <http://ec.europa.eu/research/participants/portal/page/home> and are outlined in the IMI2 manual for evaluation, submission and grant award available at http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/Manual_for_submission_evaluation_grant%20award_2014.06.26.pdf.

Other information was found in the H2020 and IMI2 document, the Multi-beneficiary Model Grant Agreement for Innovative Medicines Initiative 2 Joint Undertaking (IMI 2 JU) document ([h2020-mga-imi_en_2014_Important_IMI2_Declarations_Penalties.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/h2020-mga-imi_en_2014_Important_IMI2_Declarations_Penalties.pdf)).

As regards the overall observations and impression, the Independent Observer is entirely satisfied with the excellent quality, fairness and transparency of this short proposal evaluation procedure;

- The IO can confirm the excellent standard of evaluation of all aspects including the management and execution of the evaluation sessions. The IO verifies that the evaluation procedure was in accordance with the evaluation rules and procedures.
- The general organisation and administration of the procedure was underpinned by the expertise, dedication and professionalism of the Innovative Medicines Initiative staff.
- The independent experts (IE) were of excellent quality, with appropriate expertise. The experts approached the task with commitment and professionalism. They were highly positive about the entire evaluation process and they appreciated the high quality of the discussion and the rigor, thoroughness and transparency of the procedure.

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.

- Both the remote evaluation phase and on-site consensus and panel meetings were valued by the experts as fundamental components of the evaluation procedure. The observation of the consensus and panel discussions allows the IO to attest to the impressive and relevant knowledge of the experts which was directly related to the call topics.
- This aspect of Conflict of Interest (CoI) was appropriately addressed. It was particularly assessed during the expert recruitment phase, at the beginning of the procedure, in the selection of the experts by the IMI staff. In a small number of cases, where independent experts, who participated in the on-site evaluation, had a CoI with a particular proposal, the expert left the meeting room while that proposal was being considered. The IO can confirm that all CoIs were handled according to the IMI rules and procedures.
- The electronic exchange system used by IMI is the SOFIA tool for remote evaluation and for the on-site consensus and panel meeting in Brussels. The IO and the experts had no difficulties with using the SOFIA tool throughout the remote and on-site phases. The feedback from the experts that this tool and the IMI IT support worked well throughout the entire evaluation.
- 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 groups for both topics were appropriately composed, with different evaluators' expertise complementing each other. The European Federation of Pharmaceutical Industries and Associations representatives actively participated in both evaluation meetings. They left the meetings during the scoring and ranking of the proposals, in accordance with the rules.
- In both these topics, each independent expert read all the proposals submitted in their respective topic. Each proposal had a separate expert assigned to act as rapporteur of that proposal before coming to Brussels, which gave them time to prepare for this role. The Consensus Reports (CRs) were prepared by the rapporteur, following the discussion and input of all the independent experts at the consensus meeting. The consensus and panel meetings were facilitated expertly by the IMI staff, acting as moderators. The panel meeting discussed the proposals and the CRs and prepared the Evaluation Summary Reports (ESRs). The comments and the scores on the CRs and ESRs accurately reflected the discussions.
- A separate panel report was prepared for each of the two topics evaluated. The panel report was drafted by the IMI staff and verified and signed by the independent experts to report on the outcome of the evaluation process and to give an overview of the evaluation procedure. The two panel reports, for each of the two topics, were given to the IMI Board as an overview of the evaluation.

2.1. Scale of 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). There are three phases to the evaluation process of short proposals. An overview of each phase is summarised below;

Phase 1 — Individual evaluation

Phase 2 — Consensus group

Phase 3 — Panel review

In Phase 1, the individual evaluation phase, each independent expert carries out an evaluation of the proposals remotely, for each of the proposals assigned to the IE 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. In this phase, the proposals are remotely evaluated by the

selected independent experts and by representatives of the companies within the planned EFPIA Consortium for the specific call topics.

In Phase 2, the consensus group phase is held on-site. The individual experts form a consensus group, to come to a common view and agree on comments and scores and they prepare a Consensus Report (CR). The consensus groups for the two topics were held in separate meeting rooms in Brussels and each had an impartial moderator who was an IMI staff member. The EFPIA representatives of the companies within the planned EFPIA Consortium for the specific call topic were present during the consensus meetings discussions of each of the short proposals submitted in response to the respective topic. However, as per the IMI2 JU procedures, the EFPIA representative did not participate in the part of the consensus meeting where the numerical scoring was decided and the EFPIA representative did not participate in the overall ranking of the short proposals.

There was a briefing of the experts on the morning of the first day 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 capably carried out, for the experts of both topics together, by Professor Michel Goldman, the IMI Executive Director. During the briefing, an overview of the evaluation procedure was presented, in addition to the roles of the independent experts, the rapporteurs and the moderators. Questions were encouraged and all questions were answered comprehensively.

In Phase 3, the panel review which was also held on-site, all of the proposals within a call, or part of a call, are assessed to ensure that the consensus groups have been consistent in their evaluations. In this evaluation, the two panels meetings of the two topics were held separately in separate meeting rooms during the on-site evaluation in Brussels. During the panel meetings, there is the option, to propose a new set of marks or comments, and to resolve cases where a minority view is recorded in the consensus report. The final Panel Report is signed by the IMI staff member acting as chairperson, the rapporteur and at least three independent expert panel members. The panel report is given to the IMI2 Governing Board as a report of the outcome of the evaluation procedure.

2.2. Transparency of the procedures

The IO can confirm that the entire evaluation procedure, from the selection of experts to the handling of conflict of interest aspects, to the consensus and panel meetings and writing of the reports proceeded according to the IMI2 JU manual for submission, evaluation and grant award.

All phases and procedures were carried out according to the procedures, and the highest level of fairness, expert evaluation and discussion, openness and transparency was followed. When any issues arose, these were handled in an open and transparent manner, according to the rules and procedures. In addition, they were recorded in the corresponding 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 on-site evaluation of the two call topics took place in parallel, in Brussels on 9th and 10th December 2014. The experts had three weeks for Phase I, the remote evaluation of the proposals and the submission of the Individual Evaluation Reports, with associated scores, for each proposal. Each expert evaluated all proposals for both of the topics evaluated. The feedback from the experts was that they had sufficient time to evaluate the proposals remotely and for the on-site evaluation. One of the on-site topic evaluations was completed in one day, on the 9th December 2014. The other topic in this

call took two full days to complete the evaluation. The overall assessment was that the length of time for the process and evaluation procedure was sufficient.

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

The IO assessed that the procedures were efficiently managed and reliably implemented throughout the evaluation by the IMI staff. This was also confirmed from feedback from the experts. The experts reported that the SOFIA IT tool worked very well for both the remote and on-site consensus and panel meetings. The IT tool was highly efficient, including for accessing the proposals and writing the individual, CRs, ESRs and panel reports and showing the comments and the scores.

The experts noted they had problems initially logging into the SOFIA IT tool with the automatically generated passwords they had received by email, at the very beginning of the remote evaluation. The experts suggested this may be because of the different keyboard systems in different countries. In each case, when the expert emailed the IMI2 and SOFIA support staff, it was quickly addressed. The experts suggested this may be reviewed to address this minor issue.

Recommendation: The experts recommended assessing the minor issue they had logging into the SOFIA IT system, using the automatically generated passwords, at the beginning of the remote evaluation process.

2.5. Impartiality, fairness and confidentiality

The Independent Observer was impressed with the rigor of the procedures to ensure that the selected experts were impartial and how the importance of confidentiality and fairness in the procedure was emphasised. This was explained to the experts in the information provided to them and it was emphasised during the selection procedure, the remote phase, in the briefing and during the on-site meetings. Where experts did have CoIs, they left the room when the particular proposal was being discussed. The experts were fully cognisant and supportive of the importance of impartiality, fairness and confidentiality in the evaluation procedure.

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

The IO can confirm that the remote and on-site evaluation process 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. The web page links for the published H2020 and IMI2 JU supporting information are detailed in section 2. and section 2.1 of this report.

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 can confirm 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 in EU evaluations, including for Framework Programmes, MCSA actions and for the ERC.

The high quality and positive aspects of this evaluation include;

- the experts are assessed and must confirm that they have no conflict of interest at the beginning and throughout the evaluation.
- the evaluators are selected to be highly competent and skilled in the specific area of the topic of the call.
- the remote evaluation requires the experts to submit their evaluation, comments and their scores independently of seeing the evaluation from the other experts. The experts appreciated the openness of the evaluation, when the expert had remotely completed his or her IERs, the expert could see the IERs of the others experts who had also submitted their evaluations for the same proposals.
- the experts appreciated the transparency and openness arising from the presence of independent observers to oversee and report on the evaluation procedures.
- the experts supported the combination of remote evaluation and on-site consensus and panel meetings, which they considered ensured the high quality of this IMI2 evaluation process. There was also general agreement that the excellent discussions during the on-site consensus and panel meetings were a particularly valuable part of the evaluation process, ensuring the high quality, fairness and openness of the evaluation.

2.8. Quality of the evaluation process overall

In the observation and execution of this task, as stated in section 1.1., the Independent Observer (IO) is entirely satisfied with the high quality, fairness and transparency of all phases of the evaluation procedure and the process overall.

The IO can confirm the excellent standard of evaluation from the highly skilled and professional independent experts to the capable management administrative support and execution of the on-site evaluation phases 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 IMI staff provided the experts with all the information about the call in advance of the remote evaluation. The experts were satisfied with the quality of the documentation provided before the remote evaluation and with the SOFIA IT tool. Each of the experts, the IO and each IMI staff member was provided with a very useful printed information pack which had a detailed schedule of planned meetings and room allocation, the printed slides of the briefing, a printed manual which collated all the call documents, including the IMI2 Scientific Priorities for 2014, IMI 2 Summary of most relevant provisions for participating in IMI2 actions, and the IMI2 Manual for submission, evaluation and grant award, in addition to the IMI2 Call for proposals 2014, the evaluation form, the proposal templates and expert contract. This was available on the morning of the first day of the on-site evaluation in Brussels. The documentation was useful and of high quality.

3.2. Quality of the on-site briefing sessions

The on-site briefing was capably given by Professor Michel Goldman, the IMI Executive Director. The briefing was comprehensive, clear and of high quality and was carried out for both topics at the same

time, with all the independent experts, IO and IMI staff together. The experts appreciated the briefing session, which provide clarity on the procedures and the process.

During and at the end of the briefing, there was encouragement for experts to ask questions, if they were unsure of any aspect of the briefing or the evaluation process. All questions were answered comprehensively by Prof. Goldman. If additional information or further clarification was required, this was expertly provided by the IMI staff. The IO was introduced to the experts at the briefing and the role and tasks of the IO were clearly explained.

During the briefing, the Guiding Principles for the evaluation of independence, impartiality, objectivity, accuracy and consistency were explained. The briefing emphasised the importance of the confidentiality of the evaluation procedure and the requirement for experts to declare any Conflict of Interest (Col). It was also noted in the briefing that during the evaluation, if a proposal fails to achieve the threshold for a criterion, the evaluation of the proposal will be stopped at that criterion.

There was an opportunity, following the briefing, for discussion of the experts and IMI staff of the IMI strategy, priorities and the rationale for the two topics being evaluated in this call. The experts were actively involved in the discussion of the topics and the current and future issues in both of these important areas.

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

Based on reading the comprehensive IERs and the observation of the detailed and high level discussions and deliberations in the consensus and panel meetings, the experts demonstrated a thorough understanding of the IMI2 JU and Horizon 2020 procedures and the specific context and topics of this call. In addition, they had a thorough understanding of their pivotal role in the evaluation process, and of the award criteria and scoring scheme.

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 proposals. The main selection criterion of the experts is the appropriate scientific 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 was provided by the IMI staff for the two topics combined in this call, for the 14 independent experts. 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) or the EFPIA and IMI2 Associated Partner representatives. It was noted for one of the topics that two experts who participated in the remote evaluation were unable to take part in the panel review.

- skills, experience and knowledge

The skills, experience and knowledge of the experts were excellent, and included experts in senior positions. The skills and knowledge of the independent experts were specific and highly relevant to each of their respective call topics.

- geographical diversity:

There were 12 (86%) experts from the EU-28, 1 (7%) expert was from an Associated Country and 1 (7%) expert was from a third country.

- gender:

Of the 14 independent experts;

- o 11 (79%) were male
- o 3 (21%) were female.

Two of the independent experts who carried out the remote evaluation but were unable to participate in the on-site evaluation were females. This resulted in only one female expert present during the on-site evaluation.

- where appropriate, the private and public sectors:

The IO used the classification of the data for the 14 independent experts as provided by the IMI staff. All 14 independent experts participated in the remote evaluation, 12 participated in the on-site evaluation.

. The IO can confirm that the experts used were highly skilled and experienced in the two topic areas of this call.

- o Of the 14 IEs, 10 (71%) independent experts were from the public sector (or categorised under 'science' in the data provided to the IO). This included experts from universities, research institutes, hospital clinicians; one IE was a professor/provider of consultancy, (classified as 'owner') and one was from an SME (classified under science and not industry)

- an appropriate turnover from year to year:

This information was not provided for the 14 independent experts. From speaking with the experts, the IO ascertained that many of the experts were highly skilled and experienced evaluators, with extensive experience of national and EU evaluations.

Regarding the geographical distribution, feedback from the experts recommended that having more experts from outside the EU would be valuable to contribute to the understanding of what was happening outside Europe in call topic areas.

Recommendation: Regarding the geographical distribution of the IEs, feedback from the experts recommended that having more experts from outside the EU would be valuable to contribute to the understanding of what was happening outside Europe in call topic areas.

Regards the gender distribution, of the 14 independent experts selected to participate in the evaluation, 11 were male (79%) and 3 (21%) were female. Of the three females, two of them were unable to participate in the on-site evaluation. This resulted in only one female independent expert present during the on-site evaluation. It is recommended that for future evaluation panels, the goal of having 40% of each gender on the evaluation panel is achieved.

The target of 40% of the under-represented gender in panels and groups is one of the H2020 objectives to ensure gender balance in decision-making and at each stage of the research and innovation cycle, subject to the situation in the field of research and innovation concerned (article 16) (http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/gender/h2020-hi-guide-gender_en.pdf). Similarly, in the IMI2 model grant agreement, there is an obligation to aim for gender equality in implementation of the action (article 33.1) ([http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2%20JU%20Model%20Grant%20Agreement%2012%20JAN%202015%20-%20agreement%20EFPIA_EC_IMI%20\(1\).pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/IMI2%20JU%20Model%20Grant%20Agreement%2012%20JAN%202015%20-%20agreement%20EFPIA_EC_IMI%20(1).pdf)).

Recommendation: Of the 14 independent experts selected, 11 were male (79%) and 3 (21%) were female. As outlined in the H2020 objective, it is recommended that for future evaluation panels, the goal of having 40% of each gender on the evaluation panel is achieved.

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

In both topics in this evaluation, following screening of the experts for CoIs, the experts remotely completed the individual evaluations of all the short proposal using the SOFIA IT tool. In this evaluation of both topics, each proposal was assigned a separate rapporteur. The rapporteurs were appointed 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 the consensus meeting, with the rapporteurs for the proposals taking notes of the discussion of the proposal and preparing the draft CR based on the consensus group discussion. The draft CR was then distributed to the other experts, who give their feedback and there was further discussion and scoring of each CR. In the two topics of this call, all independent experts evaluated all SPs. Ethical assessment will be performed during the Stage 2 evaluation. This process was excellently facilitated by the IMI staff acting as moderators of the meeting. The rapporteurs and experts signed the CR to attest that it reflected the discussions, scoring and views of the experts.

The rapporteur's tasks involved giving an introduction to the proposal in the consensus meeting and giving an overview of the proposal under discussion and a summary of their comments. The other experts, each in turn, then give their views, comments and evaluation on the proposal for each criterion, which is then followed by a general discussion of the proposal and the score is determined for each criterion. Based on the discussion, the rapporteur drafts the Consensus Report following the discussion and scoring of the proposal at the consensus meeting. The EFPIA representatives for each of the two topics made expert and active contributions to the discussions. The consensus meetings were expertly facilitated by the IMI staff acting as moderators.

For the on-site evaluation, for both of the topics in this evaluation, each of the two topics had an EFPIA representative. In the on-site evaluation, at the beginning, each expert (and the IO) had the opportunity to briefly introduce themselves. Similarly, the EFPIA representatives had an opportunity at the beginning to present in detail their perspective on the topic. The scores provided by the EFPIA representatives did not contribute to the final consensus evaluation scoring used to rank the short proposals. The IMI concept of joint development of topics and Stage 2 proposals with Industry and the role of the EFPIA representatives during Stage 1 was understood well by the experts. They were fully aware that during Stage 2 that the proposal ranked first would be development with the EFPIA to a Full Proposal which would be evaluated during Stage 2 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 first day 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 also reviewed the consensus reports and the feedback was welcomed and appreciated by the experts. The experts had questions on the review procedure which was ably explained. However, the experts would have preferred that the details of the review procedure be included in the briefing.

In this first-stage evaluation of proposals under a two-stage submission procedure, the threshold for each individual criterion is 3 and only the criteria 'excellence' and 'impact' are evaluated. There is no overall threshold. For the first stage evaluation of excellence and impact, only the aspects in **bold** below are considered (http://www.imi.europa.eu/webfm_send/1463)

1. Excellence (Score 1)

Note: The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the IMI2 annual work plan:

- **Clarity and pertinence of the objectives;**
- **Credibility of the proposed approach;**
- **Soundness of the concept, including trans-disciplinary considerations, where relevant;**
- **Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art;**
- **Mobilisation of the necessary expertise to achieve the objectives of the topic and to ensure engagement of all relevant key stakeholders.**

2. Impact (Score 2)

Note: The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level:

- **The expected impacts of the proposed approach listed in the IMI2 annual work plan under the relevant topic;**
- Enhancing innovation capacity and integration of new knowledge;
- **Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;**
- **Improving European citizens' health and wellbeing and contribute to the IMI2 objectives ;**
- Any other environmental and socially important impacts;
- Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.

For the evaluation of the second-stage proposals under this two-stage submission procedure; all three criteria are evaluated and the threshold for each individual criterion is 3. The overall threshold, applying to the sum of the three individual scores, is 10.

3. Quality and efficiency of the implementation* (Score 3)

Note: The following aspects will be taken into account:

- Coherence and effectiveness of the project work plan, including appropriateness of the allocation of tasks and resources;
- Complementarity of the participants within the consortium (where relevant);
- Clearly defined contribution to the project plan of the industrial partners (where relevant);
- Appropriateness of the management structures and procedures, including risk and innovation management and sustainability plan.

*Experts will also be asked to 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 meetings for both of the topics in this call were very well organized. The IT systems for reviewing the consensus reports and evaluation summary reports were efficient, showing the

comments and the scores on large screens, and printed versions of all the CRs were available for all participants.

Information on the objectives and the procedure to be followed for the panel meeting were clearly presented by the IMI moderator and chairperson. The consensus meeting (and panel meeting), in both cases of the two topics evaluated in this call, were expertly guided by a panel moderator, which was an IMI staff member. In both evaluations of these two topics, the respective IMI staff members were professional, highly competent in their roles as moderators of the consensus meetings and chairs of the panel meetings, with in depth knowledge of the IMI evaluation processes and procedures. The IO can confirm they both ensured a transparent, fair and equal treatment of the proposals.

The panel was tasked with reviewing the text of the draft consensus reports (CRs) in order to ensure that comments on each criterion and the scores reflect the discussion and consensus reached by the experts. During the panel meeting, the text of each individual consensus report for each proposal was displayed on the screens and each participant had at their disposal the printed version of all CRs. Time was devoted for reading and commenting on each CR, in turn, followed by approval of the CR or a discussion on any suggested modifications by the experts.

The separate panel meeting for each of the two topics checked the consistency of the comments and the scores of the award criteria. Based on these discussions, the final CRs were prepared, and were reviewed by the experts and the IMI staff (for readability, removal of any factual errors or inappropriate comments). The final CRs were signed by the experts and were attached to the panel report.

It was noted that modifications of scores can be performed during the panel meeting but only in exceptional cases, and with the input and agreement of the independent experts. Where proposals had the same scores for each of the two criteria, the proposals were discussed one by one, until consensus was reached about the final ranking order. This process worked very well and was handled entirely professionally by the IMI moderator acting as chairperson of the panel meeting.

The panel went on to rank the proposals according to a set procedure outlined in the call documentation, Excellence was the first criterion and Impact is the second criterion. The panel meeting was entirely fair and transparent and ensured openness and consistency of the entire evaluation. The panel ranked the proposals on the basis on the overall score in the ESRs. The full panel ranking list was included in the annexes of the panel report, which included the proposals that equalled or passed all thresholds, in addition to the list of proposals that did not meet the overall threshold and/or did not meet one or more of the individual thresholds, in addition to the list of proposals found to be ineligible during the evaluation.

Both panel meetings were well organized. 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 each of the proposals receiving an in depth and fair review. The Independent Observer was impressed by the quality and critical fairness of the discussions and the ranking procedure within the panel meeting.

In the resulting panel report for each of the two topics evaluated in this call, any modification on scores and/or comments following the discussions in the panel meeting, were detailed in the panel report and its annex. In both of the panel reports, each panel were of the opinion that the outcome of the ESR step of the evaluation was consistent with the award criteria, the scores and the comments. Issues related to operational capacity in the CRs were confirmed.

The IMI staff drafted the panel report directly following the discussions during the panel meeting and the panel report was read and discussed by the rapporteurs and independent experts. The panel report gives an overview of the evaluation process and outcome. The panel report includes a brief overview of the topic under evaluation and contains details including a list of proposals passing all thresholds, along with a final score, called the panel ranked list. The panel report includes an overview of Conflict of Interest and any specific issues that arose and need to be mentioned from the evaluation. The panel report was signed by the IMI staff member acting as chairperson, the rapporteur and at least three independent expert panel members to affirm it reflected the outcome of the

discussions and the evaluation procedure and the accuracy of the final scores and final ranking list of proposals. This two panel reports, for each of the two topics, were given to the IMI Board as an overview of the evaluation

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.

In each of the two panel reports for the two topics the following information was provided, both as the number of proposals and in percentage terms;

- Total number of proposals submitted to the call (in the scope of the report)
- Number of proposals found to be inadmissible
- Number of proposals found to be ineligible before the evaluation
- Number of proposals found to be ineligible during the course of the evaluation
- Number of proposals having failed the overall or any individual evaluation threshold
- Number of proposals equal or above the overall and all the individual evaluation thresholds

In one of the topics, it was reported in the corresponding panel report that there was one proposal where consensus could not be achieved and where minority voting was required in the consensus meeting. The IMI lawyer was also consulted in relation to the correct procedure to be followed. The information from the lawyer was entirely according to the rules and this information was appreciated and followed by the experts. Following a detailed discussion by the experts, it was noted in the panel report that a vote was required, where the minority view was one expert. Details of the voting result and a descriptive indication of the minority view was included in the panel report.

During the panel meeting, the expert panel found it 'inadequate' that the top ranked consortium only received a 'yes' as feedback. The experts were informed that the number one ranked consortium did not receive any written feedback and did not receive the Stage 1 ESR until after the Stage 2 evaluation. It could be considered whether this procedure should be changed to provide some written feedback to the consortium that is ranked first. In the panel report, there is a section for 'Additional Comments and Recommendations', and in one of the panel reports, it was noted by the experts, that it should be considered to provide more written feedback to the top ranked consortium.

Recommendation: It was noted that the experts considered it 'inadequate' that the top ranked consortium did not receive written feedback following the Stage 1 evaluation. The top ranked consortium does not receive the ESR from the Stage 1 evaluation until after the Stage 2 evaluation. The experts recommended considering providing some written feedback to the consortium that is ranked first.

In the other panel meeting, the panel report included that a conflict of interest was reported by one expert. The expert did not evaluate the proposal concerned nor took part in any panel review where the proposal was discussed. In this topic, it was also noted that two experts who participated in the remote evaluation were unable to take part in the on-site evaluation.

An additional issue arose in this evaluation, which is described in section 3.10. below and which was also detailed in the panel report.

Additional feedback from the experts after the consensus and panel meetings was that they found it 'frustrating' to assess some of the proposals as specific information, which would have been expected in the proposals was absent while there were sections which were repetitive, vague and insufficiently detailed. The experts recommended not lengthening the page limits of the short proposals but instead, where relevant to the topic that specific headings in the guide to applicants would be required information in the proposal. They gave examples (where relevant to the topic) such as detailed information on access to clinical trial data, study design, sample size, statistical analysis, health technology assessment and regulatory aspects.

The experts felt this recommendation would improve the evaluation of the proposals if more specific and detailed information was included on aspects (as related to the topic) such as; access to specific data, details on the statistical analysed to be used, more information on the clinical samples and/or numbers of samples and/or to clinical trials, specific details on access provisions for access to third party data, samples or clinical trials.

The experts' recommended that confirmation should be required to be provided by consortia to confirm that all the relevant ethical and consent aspects, data protection, regulatory and legal requirements and compliance issues had been met to verify critical statements in the proposal, such as access to critical data or clinical trials. This detail should also confirm that all the relevant ethical and consent aspects, data protection, regulatory and legal requirements and compliance issues had been met to allow this statement to be included in the proposal. The experts felt that this requirement to verify such important aspects of the proposal would facilitate the assessment of the short proposal and evaluation, particularly under the Excellence criterion, and the credibility of the proposed approach.

Recommendation: The experts felt in some cases insufficient specific evidence was provided in the proposals to substantiate pivotal statements which were critical for the credibility of the proposed approach. They recommended the consortia should be required to provide specific and detailed information in the proposal to justify such statements, even at the short proposal stage. The experts gave examples where this should be required, such as in relation to access to specific and critical data, essential samples or large sample numbers, statistically powered studies, statistical methodology and calculations, clinical trials, access to third party data, or access to third party samples or clinical trials.

To expedite this recommendation, the experts suggested, for example, that IMI should add a template, with required section headings, such as specific details on access to data, access to sufficient samples, cohorts with verifiable references to ethical approval and third party access. The experts felt this would require consortia to be more specific and avoid vague descriptions in the proposals.

Recommendation: The experts recommended that where a clinical trial is included in the topic, that the IMI in the Guide for Applicants should require consortia to include in the SP a detailed statistical analysis, including the methodology and rationale for the numbers of subjects to be used in the clinical trial, even at the short proposal stage.

For ease of evaluation, the experts recommended that IMI devise a standardised table format in the short proposals, on one page, with the key information for each participant, such as; participant number, the name of the university, research institute or industry participant, the name of the principal investigator or participant and their role the university, research institution or industry partner. While this information can currently be found, the experts found the various formats used in the proposals made the evaluation difficult and having a standardised table format would be helpful, such as in the example below;

Participant Number	Name of Institution or Industry and country	Name of Principal Investigator/ Participant	Role of PI or Participant in Institution or Industry e.g. Head of Department
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The experts further recommended that in the SP, the consortia would be asked to identify key participants and to write a clear justification for their role and responsibility and contribution to the proposal. As in some SPs, the experts felt there were many participants who received only a fraction of the budget and whose role in the consortium was not identified and was not sufficiently clear.

Recommendation: The experts recommended that IMI devise two standardised tables with the following information for each proposal on one page of the Stage 1 proposals; participant number, the name of the university, research institute or industry participant, the name of the principal investigator or participant and their role the university, research institution or industry partner. The experts recommended a second table that would give an overview of the key participants, the specific responsibilities for each participant and the total budget allocated to each participant. The experts

further recommended that in the short proposals, the consortia would be asked to identify key participants and to write a clear justification for their role and responsibility and contribution to the proposal. As in some SPs, the experts felt there were many participants who received only a fraction of the budget and whose role in the consortium was not identified and was not sufficiently clear.

The consensus and panel meetings were very well organized. The experts, rapporteurs, EFPIA representatives and the moderators worked very well together. The high quality discussions indicated that the consensus groups were well composed, with different experts' expertise comprehensively complementing each other. Discussions were of high quality, with the short proposal each 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 were no hearings. It was noted by some experts, that the option of having a hearing to clarify such issues, would have been valuable and they suggested that it could be considered to re-introduce the option to have hearings in the evaluation of short proposals. A minority of the experts were not supportive of the return of hearings.

Recommendation: It could be considered to re-introduce the option to have hearings as part of the evaluation of the short proposals.

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

In one of the topics in this call, a specific issue arose during the evaluation in relation to a proposal which had been ranked first by the panel. The scientific part of the proposal included a statement, which could appear to be against the spirit of the IMI2 programme and its call process. This aspect was extensively discussed by the independent experts during the consensus and panel meetings. Since the statement could not be verified during the evaluation, the IMI staff recommended that the panel focus its assessment on the pure scientific merit (excellence, impact) of the proposal without taking into any consideration the statement. The Executive Director and IMI legal staff explained to the panel that IMI would immediately take steps to confirm that the proposal was in compliance with the overall IMI principles.

It was recommended by the experts to provide even further clarity for consortium coordinators and participants submitting proposals to future IMI2 JU calls, that they should confirm, for example in a statement of honour, that no arrangements have been made with EFPIA participants and companies in the preparation of, or during, the Stage 1 phase.

To ensure openness and transparency, the experts deemed it appropriate to report this statement in the panel report in the section for 'Additional Comments and Recommendations'. As per the normal procedure, the panel reports from the evaluations would be sent to the IMI Board.

The independent observer can attest that the independent experts and IMI staff handled this issue with professionalism and fairness and the rules and procedures were followed. The independent observer can confirm that reporting this aspect in the panel report ensured the openness and transparency of the evaluation procedure and demonstrates how specific issues are addressed when they arise during the evaluation.

Recommendation: It is recommended to provide additional clarity to those participants and consortium co-ordinators submitting proposals to IMI2 JU that they should confirm no arrangements

have been made with EFPIA participants and companies in the preparation of, or during, the Stage 1 phase.

3.11. The quality of evaluation summary reports

The rapporteurs, experts and IMI moderators worked very well together, for the evaluation of both topics in this call. The process of writing the Evaluation Summary Reports (ESRs) was efficient and accurately reflected the discussions and the contributions of the experts. The criteria under evaluation and the scoring scheme were well understood and the ESRs were comprehensive, fair, accurately reflected the evaluation and scoring and were of high quality.

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

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

3.13. Infrastructure and working conditions for evaluators

The briefing, consensus and panel discussions were held in Brussels on 9th and 10th December 2014. 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 infrastructure and working conditions were of a very high standard. 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 short proposals and 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 experts were satisfied with the reimbursements in relation to the workload for this Stage 1 evaluation. It was observed also that the reimbursement of expenses was performed efficiently by the IMI administrative and support staff throughout the two days of the evaluation. There were no waiting periods for experts to complete the appropriate administrative forms, as the IMI2 administrative staff were present during both days of the evaluation and were efficient, helpful and professional throughout.

4. Summary of Recommendations

4.1. Summary of Recommendations

In general, the evaluation was carried out entirely according to the H2020 and IMI2 JU rules, processes and procedures and was fair, rigorous and transparent. In this context, the recommendations below comprise areas for further improvements of this evaluation procedure, which is already of a high standard.

Recommendation: The experts recommended assessing the minor issue they had logging into the SOFIA IT system, using the automatically generated passwords, at the beginning of the remote evaluation process.

Recommendation: Regarding the geographical distribution of the IEs, feedback from the experts recommended that having more experts from outside the EU would be valuable to contribute to the understanding of what was happening outside Europe in call topic areas.

Recommendation: Of the 14 independent experts selected, 11 were male (79%) and 3 (21%) were female. As outlined in the H2020 objective, it is recommended that for future evaluation panels, the goal of having 40% of each gender on the evaluation panel is achieved.

Recommendation: It was noted that the experts considered it 'inadequate' that the top ranked consortium did not receive written feedback following the Stage 1 evaluation. The top ranked consortium does not receive the ESR from the Stage 1 evaluation until after the Stage 2 evaluation. The experts recommended considering providing some written feedback to the consortium that is ranked first.

Recommendation: The experts felt in some cases insufficient specific evidence was provided in the proposals to substantiate pivotal statements which were critical for the credibility of the proposed approach. They recommended the consortia should be required to provide specific and detailed information in the proposal to justify such statements, even at Stage 1. The experts gave examples where this should be required, such as in relation to access to specific and critical data, essential samples or large sample numbers, statistically powered studies, statistical methodology and calculations, clinical trials, access to third party data, or access to third party samples or clinical trials.

Recommendation: The experts recommended that where a clinical trial is included in the topic, that the IMI in the Guide for Applicants should require consortia to include in the SP a detailed statistical analysis, including the methodology and rationale for the numbers of subjects to be used in the clinical trial, even at Stage 1.

Recommendation: The experts recommended that IMI devise two standardised tables with the following information for each proposal on one page of the Stage 1 proposals; participant number, the name of the university, research institute or industry participant, the name of the principal investigator or participant and their role the university, research institution or industry partner. The experts recommended a second table that gave an overview of the key participants, the specific responsibilities for each participant and the total budget allocated to each participant. The experts further recommended that in the short proposals, the consortia would be asked to identify key participants and to write a clear justification for their role and responsibility and contribution to the proposal. As in some SPs, the experts felt there were many participants who received only a fraction of the budget and whose role in the consortium was not identified and was not sufficiently clear.

Recommendation: It could be considered to re-introduce the option to have hearings as part of the evaluation of the short proposals.

Recommendation: It is recommended to provide additional clarity to those participants and consortium co-ordinators submitting proposals to IMI2 JU that they should confirm no arrangements have been made with EFPIA participants and companies in the preparation of, or during, the Stage 1 phase.

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 IO role.

4.3. Conclusion

In conclusion, the Independent Observer fully acknowledges that this Stage 1 evaluation procedure was excellently carried out by the experts and the IMI staff. During the entire evaluation, the procedures and process laid out in the rules were entirely followed by the IMI staff. All the IMI staff had an in depth understanding, knowledge and awareness of all the rules and procedures of IMI2 JU and of H2020.

The IO can confirm 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. The entire evaluation was well organised with the dedicated commitment of all the participants, from the independent experts to the IMI staff.