IMI2 JU INDEPENDENT OBSERVER'S REPORT

Call ID: H2020-JTI-IM2-2015-03

IMI-2 3rd Call for Proposals

Stage 2 Evaluation

H2020-JTI-2015-03

Date of evaluation:

October 20th - 22nd 2015

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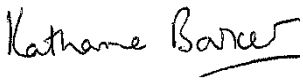
Present at the evaluation: October 20th - 22nd 2015

Signature and date



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Abbreviations

EFPIA	European Federation of Pharmaceutical Industries and Associations
EoI	Expression of Interest
IE	Independent Expert
FPP	Full Project Proposal
SOFIA	Submission OF Information Application
IMI	Innovative Medicines Initiative
IO	Independent Observer
SP	Short Proposal

1. Introduction and approach taken by the observers

The evaluation was followed to observe and report on the practical workings of the evaluation process, on the conduct and fairness of the evaluation sessions, on the application of the award criteria and on the procedures and their implementation, including IT tools. Based on their observations, the observers give independent advice for improvement of the evaluation process[1].

At the first stage of the IMI-2 Third Call, 35 proposals (short proposals respectively) had been submitted. In each of the 6 topics proposals passed were ranked and those ranked first were recommended to proceed to full proposals. In the second stage these 6 proposals were evaluated over the period of 3 days (1 full working day for each of the topics, 2 topics in parallel). As in stage 1, a pair of independent observers worked together. In advance of the evaluation there has been a short telephone briefing, where questions could be raised. The IMI call co-ordinator also provided a set of links to all relevant documents about the programme and the present and previous calls. Both observers had full access to the proposals and to the combined advance assessments of all the expert panels through the electronic tool "Submission OF Information Application" (SOFIA).

During the 3 days of the evaluation the panel meetings were followed by the observers. They sat in on different panels and regularly conferred with each other. The observers had previously introduced themselves to the independent experts (IEs) during the initial briefing meetings for experts and made it clear that they were keen to receive any comments during and after the evaluation, in person or in writing.

They were able to obtain clarifications from IMI officers and panel moderators during the evaluation. The observers were present throughout the 3 day evaluation period.

An ethics audioconference with two ethics IE followed on the 26 October, without participation of the IO.

2. Overall impression

The six panels covered the following call topics:

- Topic 1 Remote assessment of disease and relapse (RADAR Programme), Topic 1 CNS
- Topic 2 Assessing risk and progression of prediabetes and Type 2 diabetes to enable disease modification
- Topic 3 Linking clinical neuropsychiatry and quantitative neurobiology
- Topic 4 The consistency approach to quality control in vaccine manufacture
- Topic 5 Pertussis vaccination research
- Topic 6 Knowledge repository to enable patient focused medicine development

The on-site evaluation (2nd stage of a two-stage procedure) was well structured and the procedure was followed identically in all six panels:

- On each of the days two panels were active. The independent experts first were briefed jointly by the newly appointed executive director Pierre Meulien, who outlined

[1] This is the abbreviated version of the explanations given in the "Code of Conduct for Observers"

the key concepts of IMI, recalled the two stage selection of proposals and gave an overview of the current evaluation, noting in particular that in IMI2 as part of H2020 the proposals had to be evaluated "as is".

- The onsite evaluation then divided into two separate meetings (for each topic there has been one meeting) and started with a first debate of the IEs, where they discussed the proposal on the basis of their remote comments and marks and then together formulated a list of questions. These meetings were moderated by IMI scientific officers.
- This list of questions was then forwarded to the representatives of the consortium, who met in a separate room and had one hour's time for preparation.
- After a break the consortium representatives were invited to join the meeting, to outline their full proposal and to answer the questions of the IEs, starting with those from the list. In one case there had been far reaching changes in the composition of the proposal. The hearing allowed the addressing of these changes in depth.
- The meeting then again was restricted to the IEs. After due discussion and in light of of the evaluation criteria the Consensus report was jointly written, the Report of the panel review prepared, comprising of the minutes of the hearing and finally the ESR was formulated.

For the first general briefing a well-designed set of slides was used which summarized the scope and the aims of the task of the independent experts and thus served as a good introduction to the work ahead. At the same time it was an opportunity to clarify final questions.

The experience, diversity and commitment of independent experts appointed were found to be very good. 40 independent experts had been appointed (including two ethics evaluators) from 22 countries (1 independent expert of an associated country and 5 from overseas), 22 female, 18 male.

The high standard of the expertise of the evaluators and the professionalism and dedication of the IMI scientific officers ensured an independent, impartial, and fair review process. We are satisfied that the procedures strictly followed the rules as laid down in the relevant IMI Annual Work Plan 2014, call topic text, and the respectiveIMI2 Manual for Submission, Evaluation, and Award. .

Our conclusion is that the evaluations have been carried out in a fair, transparent, and unbiased manner.

The evaluation procedure was developed over a number of years. In its present format and execution it is - according to our observations - a mature tool and we do not have any recommendations for improvement.

The full project proposals are complex documents which outline large collaborative projects encompassing basic research, pre-clinical and clinical studies and which are working across disciplinary boundaries. Some involve regulatory authorities, some combine biomedical research with information technology and all seek to put industry and public sector researchers together to achieve the overall aims of the call. The task for the independent experts is demanding therefore. The process is made easier by, in most cases, the expert panel being the same as for Stage 1, except where a conflict of interest required the replacing of an expert.

During Stage 1, each panel recommended one proposal to be developed further for Stage 2. The observers had wondered whether the Stage 2 proposals would be "nodded through". This was very far from the case. Both the observers were impressed by the detail of the remote evaluations, the detail and robustness of the debate within the panel meetings and by the way in which the project representatives were questioned during the face to face hearings. We make some remarks below about the hearing questions. The fact that one proposal did not pass the threshold and was not recommended for funding, having been selected at the previous stage , while unfortunate for that consortium, demonstrates that passing the Stage 2 review is not a given. Proposals not meeting the required quality standards do not go forward.

The observers reviewed the nature of the questions posed and the answers given in the hearings. Many of the questions asked for very detailed clarifications of aspects of the science and technology, for example how a model would be used, what exact definitions were being deployed, what exactly was expected to go on within a particular task. The independent experts asked for clarifications about how different elements of projects were exactly going to be linked. The questions had to be answered in a fairly short time period. The independent experts came back with follow up questions where further clarification was needed. The hearing was not merely a pleasant formality, but required the representatives to demonstrate a thorough knowledge of their proposal.

The observers' report on Stage 1 criticised the slow speed of the SOFIA tool which was seriously inconvenient for the independent experts working remotely and also gave problems during the Stage 1 panel meetings. For Stage 2 we are happy to report that we have seen improvements, whether this is related to the smaller number of proposals we cannot judge. Our critical remarks as regards to the structure of the SOFIA tool (the "menu points") still are valid.

We are grateful to the IMI officials, for their consistently high standard of assistance and information to support us in our tasks.

3. Any other remarks

Technical differences

In our stage 1 report we already stated: "The evaluation overall conformed to the evaluation procedures published for H2020 as presented in the IMI2 Manual for Evaluations, Submissions and Awards with technical differences to the approach and principles of IMI…"

The technical differences are first of all related to the very specific content and structure of the IMI2 topics as compared for example to H2020 "Health"[2]. The result is a **great divergence in the number of proposals in stage 1.**

In IMI2, third Call, with a financial commitment of € 113 million, there have been 35 proposals at stage 1, as compared to Health, Call identifier H2020-PHC-2015-two stage with a volume of 306 million € with 2096 proposals at stage 1.

2 More precisely: H2020 Configuration 'Health, demographic change and well-being', see for example Call identifier: H2020-PHC-2015-two stage, http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/calls/h2020-phc-2014-2015.html

Furthermore, according to the structure of IMI, in the second stage of this Call 6 full proposals had to be evaluated (for each topic one), in Health 506.

Due to the manageable number of proposals at stage 1 consensus and panel meetings at this stage, it has been possible to provide written feedback to the applicants whereby shortcomings are identified. As we have observed, this simple fact has a strong influence on the execution of the second stage. According to our observations the IE at stage 2 - as a rule the same as in stage 1 - are fair but very strict at the same time. The IE are keen to see whether, and how, those shortcomings identified in stage 1 have been addressed.

Full scale of marks above threshold

In addition, with only one proposal to be evaluated at stage 2, they examined it thoroughly and provided detailed written comments (remote evaluation).

A fact, which greatly impressed us, is the rigorous evaluation at stage 2. In case of a "go", the full scale of marks above threshold was used, reflecting minor shortcomings. In addition, as we have seen, there is no guarantee to pass stage 2, once this has been reached. Up to now 3 proposals out of approximately 60 (IMI1 and IMI2) got a "no go" at stage 2.

Identification of Shortcomings

In H2020 a target of 8 months of time from submission of proposal to grant (Time To Grant TTG) has been set. In order to achieve this it had been decided that there are no grant negotiations. The applications had to be evaluated "as is" and short comings may have to be reflected in the score.

As we have observed, this was done according to the rules, but occasionally clarification was needed. In one case a lawyer of the IMI secretariat had to be asked for support in order to explain the implications of this new regulation, including how to handle the identification of shortcomings under the new regime, as opposed to using recommendations as was the previous practice under IMI1.

In the evaluation of stage 1 the identification of shortcomings is of major importance. In particular, since the final composition of the consortium still had to be shaped for the full proposal. The role of this mechanism for the stage 2 evaluation already has been noted.

In the past under IMI1, at stage 2 there have been recommendations too. Some of these were occasionally formulated as requirements to be fulfilled before grant signature. Valuable as this may be, in H2020 this is not according to the rules and this fact needed some time to be accepted by the IEs.

However, there are cases, where the IEs still think it is reasonable to communicate recommendations. On practical grounds they are transferred to the coordinator of the consortium - without impact on the grant preparation - and the general understanding is that they may be helpful for the project leader, who is free to take them into account or not. In addition it was discussed, that these recommendations might come up again at a later stage in the context of interim reviews of the project.

Ethics evaluation and ethical requirements

As the result of clarifying questions we had directed to the scientific officer in charge of the ethics evaluation we got the following concise answer:

> "The proposals were subject to an ethics screening performed by two independent ethics experts. The screening was done remotely between 2 and 14 October 2015 and a consensus audioconfer-

ence was held on 26 October 2015. The final consensus reports were delivered on 27 October 2015. The proposals obtained all conditional ethics clearance, subject to a number of requirements and in some cases additional ethics checks (after 12 months and 24 months) as listed in the individual ethical screening reports. The requirements must either be fulfilled before grant signature or become part of the grant agreement. In some cases additional reporting must be provided together with the periodic reports or through ethics checks"

In other words, in case of the ethics evaluation the situation is a bit different: It is possible that requirements are formulated and it even is possible, that they have to be fulfilled prior to grant signature.

4. Summary of Recommendations

The format of the on-site evaluation is a mature procedure which should not be changed. In particular the face to face hearings, combined with the list of questions, were very valuable for the fairness and robustness of the process.

The fact that the full proposals have to be evaluated "as is" and that there are no grant negotiations implicates - as it is formulated at present - that there are no "recommendations" to be forwarded to the applicants. We recommend using a slightly different wording: that there is no possibility to formulate "requirements" as prerequisites for the grant signature. The possibility to give recommendations to the coordinator of a consortium should be kept.