

IMI - 1st Call 2008

Evaluation of stage 2,
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Independent Observers' Report

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Abbreviations

EFPIA	European Federation of Pharmaceutical Industries and Association
EMM	Expert Management Module
EOI	Expression of Interest
FP	Framework Programme
IMI JU	Innovative Medicines Initiative Joint Undertaking
PPP	Public Private Partnership
SME	Small and Medium sized Enterprises

1. Introduction

The first Call (IMI_Call_2008_1) was published 30 April 2008¹ with a deadline for submission of Expressions of Interest (EOIs) 15 July 2008. The EOIs of stage 1 of the Call have been evaluated in September 2008 in Brussels². As a result of the peer review, ranked lists with up to 3 Expressions of Interest were established for each of the 18 topics of the Call.

Stage 2 of the Call was launched 23 October 2008, where the highest ranked EOIs for each topic from Stage 1 have been invited to form Full Consortia with the corresponding EFPIA project participants in order to prepare and submit one "Full Project Proposals" per topic to the IMI JU with a deadline of 20 January 2009.

This is the report on the evaluation procedure for stage 2 of the first Call.

At present IMI JU is still managed under the responsibility of the European Commission in collaboration with EFPIA³. It is foreseen that it will become fully autonomous in 2009. The first Call therefore is managed by the IMI JU Interim Executive Director, supported by a team of staff from Commission and EFPIA companies.

The evaluation procedure as applied in this Call – including the appointment of Independent Observers - is based on that of the Framework Programmes (FPs) in the theme "Health"⁴ and has been adapted to the needs of IMI as a Public Private Partnership (PPP). The IMI two stage procedure is, however, somewhat different as compared to other two stage procedures in the FP.

"The role of the independent expert acting as an observer is to give advice to the IMI JU on the conduct and fairness of all phases of the evaluation process, ways in which the experts acting as evaluators apply the evaluation criteria, and on ways in which the procedures could be improved"⁵.

2. Summary of Major Observations and Recommendations

The "Rules for submission, evaluation and selection of Expressions of Interests and Proposals", which have been published with the Call have been followed thoroughly. In a few cases there have been quite vivid discussions on how to interpret these rules and in particular the role and tasks of evaluators in the stage 2. The scientific officers, acting on behalf of IMI JU have been given clear cut advice and left no doubt on how to make use of the rules. We again have been impressed by the conduction of the process as a whole as well as the evaluation facilities in Covent Garden.

¹ see http://www.imi.europa.eu/calls-01_en.html, select IMI 1st Call - stage 1

² see Independent Observers' Report: http://www.imi.europa.eu/docs/imi_call1_ior-2008_10_24_en.pdf

³ European Federation of Pharmaceutical Industries and Associations

⁴ see <http://cordis.europa.eu/lifescihealth/src/evaluation.htm>

⁵ Text from Annex 1 of the Contract of the Independent Observers

These discussions, which we consider an integral part of the process, are a further indication that IMI JU is a new effort, bringing together public and private funds, involving industry, SMEs, and non-profit research institutions.

Accordingly the evaluation procedure in this Call - and in particular in stage 2 - is unique as compared to others, where the stage 1 evaluation procedure followed more familiar ways. It has been designed in order to serve particular needs of IMI JU.

The scoring system in stage 1, which we considered excellent, was fine graded and easy to handle by the evaluators (see independent observers' report, ref. 2). In stage 2 the system was changed⁶, instead of fine grades, there were three scoring values "acceptable (excellent)", "acceptable (subject to specified adjustment)" and "not acceptable". It turned out, that this was a **heavy burden for the evaluators**, because a proposal not acceptable in one of the three categories ("scientific and/or technological excellence", "project implementation" and "consistency with the Call topic and stage 1") immediately would mean failure. The reason for this was simple: with only one full proposal per topic - as foreseen by the "Rules" – a rejection would mean no financial support for an important topic of the work programme for some time.

Thanks to consensus meetings (following individual remote assessment) and the fact, that there was ample time for discussions, the evaluators finally were able to reach a decision in 16 of the 18 topics. 14 proposals have been recommended for funding, two proposals have been rated as "not acceptable" and in two cases - up to now - it was not possible to reach a decision.

In summary, it definitely was a peer review and it was a demanding one for the evaluators.

We wish to propose the following recommendations which, according to our opinion, could improve the procedures:

In order to facilitate the task for the evaluators in the future - without changing the whole Call procedure - we recommend to change the scoring system for stage 2. The excellent scoring system of stage 1 should be adapted to the needs of stage 2 in order to implement a **finer grading**. The **decision on funding or no funding then should be made in a final step** on the basis of scores either at the end of each of the consensus meetings or in an additional, final panel meeting, where all topics are discussed together.

With one exception all successful proposals have been accepted with **adjustments**, some of them far reaching. It became clear, that the evaluators would have felt much more confident with a well defined follow up by experts in place. We strongly recommend to **implement a follow up which is more extensive than a midterm review**, and to take advantage of the expertise of the evaluators, which have tracked the proposals in the course of the two stage evaluation. When asked, there was readiness to participate in such follow ups.

⁶ see rules "Rules for submission, evaluation and selection of Expressions of Interests and Proposals"

Finally we deliberate a possibility to invent "more competition" into stage 2. This should be considered carefully however, because there have been and there still are good reasons to invite only one merged consortium for the final funding decision

3. Independent Observers: Role and Approach Taken

3.1 Role of the Independent Observers⁷

"The role of the independent expert acting as observer is to give advice to the IMI JU on the conduct and fairness of all phases of the evaluation process, ways in which the experts acting as evaluators apply the evaluation criteria, and on ways in which the procedures could be improved. (...)"

"The observer shall examine the management and execution of evaluation sessions. As such, the observer verifies that the procedures set out or referred to in the "Rules on Submission of proposals, and the related evaluation, selection and award procedures" are adhered to, and report to the IMI JU on ways in which the evaluation process could be improved. The observer is encouraged to liaise with the IMI JU officials involved in the evaluation sessions and to make observations on any possible improvements that could be put into practice immediately. However, in the framework of his/her work, the observer shall not express views on the proposals under evaluation or the experts' opinions on the proposals."

"To this end, the observer is also invited to be present from the beginning of the evaluation process, especially when the experts acting as evaluators are briefed by the IMI JU. (...)"

In addition the observers had to sign a declaration of confidentiality and a declaration that there is no conflict of interest.

3.2 Approach taken to perform the task

The independent observers received written information well in advance of the evaluation procedure, together with the text of the Call and all relevant written briefing documents. The independent observers attended experts' briefing sessions and most of the consensus meetings, either together or individually. Wherever requested the independent observers had access to all documents.

There have been interviews with moderators, experts and representatives of the EFPIA consortia. In addition there was ample time for discussion with the IMI JU staff as well as with the Executive Director

4. Observations and Recommendations

The IMI JU is a new Public Private Partnership which in addition is in its setting up

⁷ Texts from Annex 1 of the Contract of the Independent Observers

state, where the Interim Executive Director is supported by staff from both the Commission Services and EFPIA companies. Both independent observers are not sure whether despite or due to this the proposal evaluation process has been remarkably professional, efficient and fair. Having said this, there nevertheless are some points, where according to our understanding improvements should be made.

4.1 General Design of the Evaluation Process

As a result of the peer review of the first Call stage 1, ranked lists with up to 3 Expressions of Interest were established for each of the 18 topics of the Call.

Stage 2 of the Call was launched 23 October 2008, where the highest ranked EOIs for each topic from Stage 1 have been invited to form Full Consortia with the corresponding EFPIA project participants in order to prepare and submit one "Full Project Proposals" per topic to the IMI JU with a deadline of 20 January 2009.

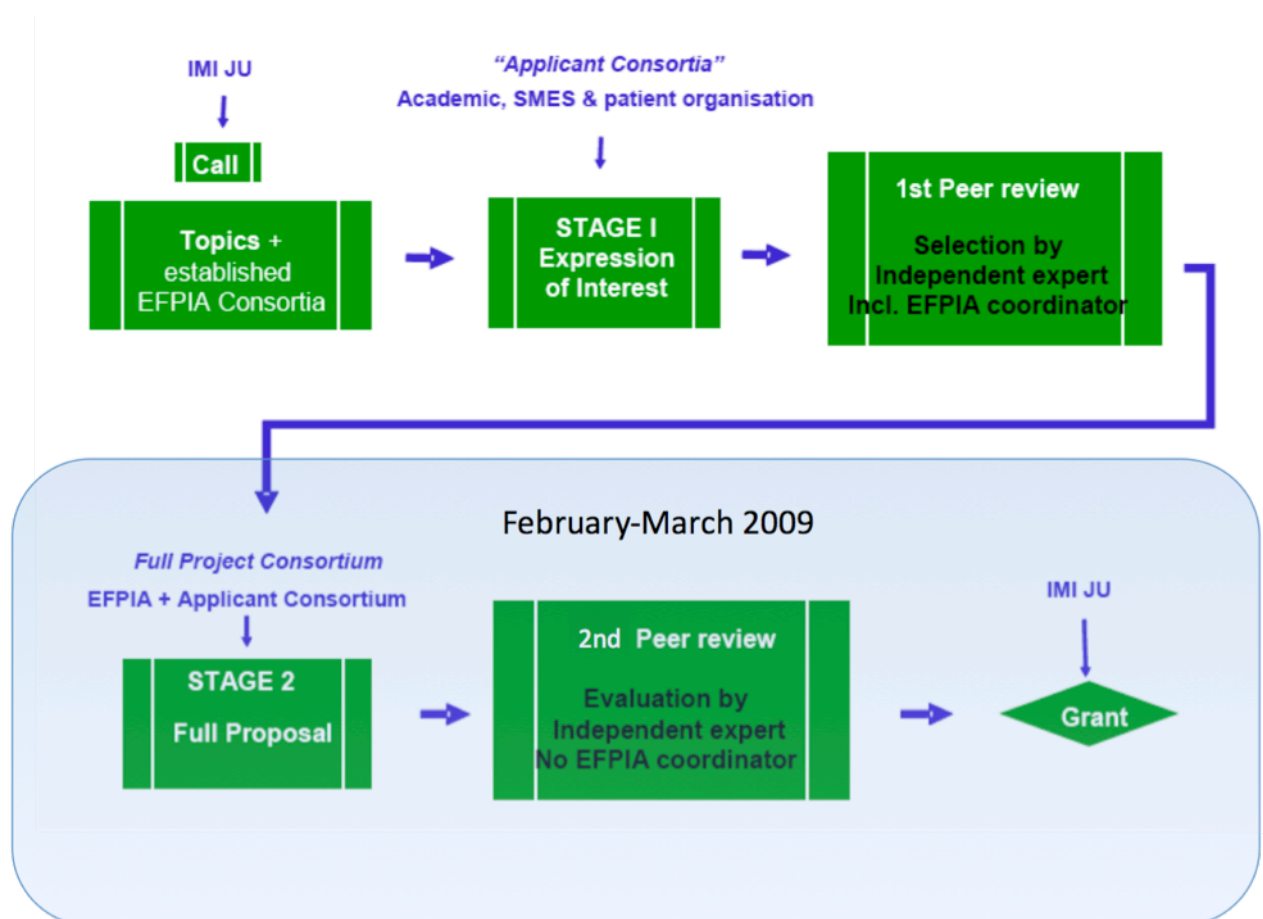


Figure 1⁸: The various steps involved in submission, evaluation and selection procedures, as outlined in the "Rules for submission, evaluation and selection of Expressions of Interest and Proposals". The IMI stage 2 procedure is highlighted.

18 full proposals have been submitted in time and have been found eligible. It turned

⁸ taken from IMI-GB-021v2-24042008-rules for submission.doc and slightly modified

out, that indeed the EOIs, ranked number 1 in the first stage, had been merged with the EFPIA consortia without exception. (see our remarks in the previous "Independent Observers" Report on stage 1).

These full proposals have been sent to the same panel of evaluators as in case of stage 1 for remote assessment. There were some replacements and additions of panel members, notably this time EFPIA consortium members have been excluded from the evaluation and two additional ethical experts included. The consensus meetings were convened in Brussels in February-March 2009.

This evaluation procedure clearly is unique. There was "no competition" as it was phrased by a number of evaluators and there was ample time for them, to read and discuss the full proposals as compared to more familiar evaluation procedures, where (as a rule) up to 10 proposals have to be read and compared. All proposals were read and evaluated by all panel members remotely and independently before the consensus meeting.

The Call documents were consistent and self explanatory, but compact and required a careful reading, in particular, as this Call, as already stated, differs from standard FP Calls and evaluation procedures, which in the meantime are well known in the European scientific community. In relation to this some experts expressed their concern that they had the impression, that not all applicants had clearly fully grasped the nature of the Call and especially the requirement to address all points in the Project Description and all Key Deliverables. The large number of strict Key Deliverables in some Calls were in some cases considered to have contributed to the problem. In addition it was conceded, that the close collaboration of a number of big EFPIA industries in one consortium is something new and demanding as compared to "standard Calls", where competition between these companies is the rule. The observers suggest somewhat more thorough guidance in the following Calls due to the unique nature of IMI.

In particular there was concern about the "absence of competition", whenever there was no doubt, that the whole evaluation procedure had been designed this way from the very beginning and this was published as part of the "Rules for submission, evaluation and selection of Expressions of Interest and Proposals", also see figure 1. In spite of that some experts found themselves not fully adjusted to the situation initially. However, the matter was fully clarified by briefing and guidance in the consensus meeting (see also below).

4.2 Selection and Briefing of experts, 1. Call, stage 2

The evaluators, selected for stage 1, had been invited again, in addition, for each of the panels two ethics experts have been selected too. The observers found this arrangement beneficial; experts were familiar with the subject and aware of the specific expertise of each other. In contrast to stage 1, this time EFPIA representatives were excluded and replaced by additional experts.

As in case of stage 1, approximately 90% of the (remote) evaluators attended.

Prior to the on site evaluation, the evaluators had received written instructions, re-

garding their duties and responsibilities, including instructions on well defined evaluation criteria. An oral briefing was provided in addition prior to the consensus meetings in Brussels.

Since the evaluation procedure IMI stage 2 is quite different as compared to "standard evaluation procedures" it turned out, that some of the evaluators were not fully aware of their role in relation to procedural matters. That was especially true as regards to the handling of their recommendations and adjustments (follow up) when negotiating the Agreement, and in an exceptional case as regards to the consequences of the outcome of the peer review, in the sense, that a non acceptable indeed meant no funding. However, in all cases panels took all efforts to stick to highest scientific standards and criteria for excellence in their evaluation.

In all cases there was clear guidance by the moderators as regards to the rigorous nature of the peer review and the handling of adjustments as conditions imposed on the negotiations of successful proposals.

Recommendations

Due to the novelty and uniqueness of the evaluation procedure IMI JU stage 2 it is recommended, to be redundant by explicitly stating again and in written form the essentials of the stage 2 evaluation prior to inviting the evaluators to the consensus meetings

4.3 Evaluation Criteria and Scoring

Evaluation Criteria

The evaluation criteria including their explanation have been laid in the "evaluation form - stage 2" as part of the Call documents⁹. These documents were available to the evaluators before the consensus meeting.

1. Scientific and/or technological excellence

- Soundness and quality of approach to meet the objectives of the call topic
- Application of creative and cutting edge methodologies (or for the Education & Training topics, establishment of creative and up-to-date training programs)
- Uniqueness of the approach (no duplication of existing initiative)
- Where applicable, any ethical issues appropriately addressed

2. Excellence of the project implementation plan

- Adequate and appropriate representation of all relevant stakeholders within the consortium.
- Adequate documentation of the project plan with efficient timelines and well utilised resources. Includes justification of timelines and resource allocation (e.g. for research, management, training or other activities).
- Resource allocation (by value) by the EFPIA project participants should at least equal the funding requested by the participants eligible for funding by the

⁹ IMI-GB-045v4-22102008-EvaluationFormStage2

IMI JU (if not, the unequal resource allocation is adequately justified).

- Adequate documentation and appropriateness of the management structure and procedures. Management plan capable of building a cohesive and efficient team within the consortium

3. Consistency with Call Topic and stage 1

- Scope of Full Project Proposal is consistent with the Call Topic published in May 2008.
- Full Project Proposal contains core objectives and plans that do not substantially deviate in scope from the Expression of Interest selected at Stage 1, except to fulfil recommendations from the Stage 1 peer review.
- The composition of the applicant consortium does not substantially deviate from that described in the Expression of Interest selected at Stage 1, except where adequately justified or to fulfil recommendations from the Stage 1 peer review.

Score values

- Acceptable (excellent)
- Acceptable (subject to specified adjustments) - applicable to criteria 1 and 2 only
- Not acceptable

4. Potential impact of project results

Likelihood of IMI key benefits (i.e. new multidisciplinary development tools, new development paradigms) to be achieved following dissemination / publication of research results. For the Education & Training topics, likelihood of pan-European access to high-quality training for biomedical R&D, and likelihood of graduates, career scientists, and scientific stakeholders being better educated and trained in innovative pharmaceutical science.

Score values for category 4 only

- High impact
- Medium impact
- Low impact

Recommendations

The impact of this scoring system became evident in the course of the Consensus Meetings(see 4.5), where the motives for this recommendation are outlined.

In order to facilitate the task for the evaluators in the future - without changing the whole Call procedure - we recommend to change the scoring system for stage 2. The excellent scoring system of stage 1 should be adapted to the needs of stage 2 in order to implement a **finer grading**. The **decision on funding or no funding then should be made in a final step** on the basis of scoring either at the end of each of the consensus meetings or in an additional, final panel meeting, where all topics are discussed together. Such a procedure could promote more structured discussion in panels and finer grading when justifying the decision.

4.4 Remote Evaluation System

Having witnessed evaluation procedures prior to FP5, the remote individual evaluation system is a relief, in particular together with the well working IT tool, with remote access to EOIs as appointed to each of the evaluators.

Whenever there are some critical points to be mentioned, the advantages are obvious:

- evaluators arrive well prepared; admitted, that in a number of cases sufficient reasoning was not given in the Individual Evaluation Forms filed by evaluators to justify their scores (too short, too unspecific, respectively often no comments were provided), but evaluators arrived in Brussels well prepared for more in depth discussions in consensus meetings (see 4.5)
- the system is easy to use, both for IMI JU and the evaluators

Some evaluators were not able to participate in the consensus meeting, but they had filed the Individual Evaluation Form remotely. The independent observers considered the contribution of these reports quite often marginal. The comments were often short and/or very general. Most importantly they could not be related with the in depth discussion and argumentation in the panel. However, remote evaluation nevertheless could serve significantly the evaluation, if special expertise is required, and an expert is unable to attend the consensus meeting, and he or she is well guided for preparing precise and detailed comments.

Some experts faced difficulties to evaluate the match between funding requested and work to be done, especially because the detailed contribution of the EFPIA consortium was not yet known, only a survey of financial contribution was given. Careful attention should be paid in the second stage both to prepare a realistic budget, and the budgeted as a significant evaluation criterium.

Recommendations

The remote evaluation system as an element of individual evaluation (together with the consensus meetings, see next point) is an instrument which has proven its value. It prepares the ground for qualified discussions and facilitates the handling of the proposals. It should be maintained.

4.5 Consensus Meetings

The remote, individual evaluation was the basis of consensus meetings, where the evaluators were assembled in Brussels in a Commission Building dedicated to this task (Covent Garden, Place Rogier). In general there was one consensus meeting (panel) per topic, in a few cases topics were combined for one consensus panel.

The consensus meetings were moderated by IMI JU staff from Commission Services and EFPIA respectively EFPIA member companies.

The moderators introduced the topic and the individual scores of the remote

evaluation were presented in a clear and complete overview. The scoring system for stage 2 as such (see 4.3) was well defined and understood and as it turned out, "not acceptable" was assigned by some of the evaluators in a (whenever small) number for proposals.

In those cases, where there was doubt with regard to the highest possible quality of the proposal, the immediate question of the evaluators was, why only one full proposal had been put forward for evaluation; this of course was easily explained:

On formal grounds, this was the design of the Call and it was published in a clear-cut way. In essence of the content, there was one pre-existing EFPIA consortium, referred to in the work programme, to be merged with the highest ranked applicant consortium of the first stage. To ask the same EFPIA consortium to present two full proposals for any single topic would have been a useless effort, because one of them would have failed for sure.

Where necessary, this has been clarified by the moderators. It immediately became clear then, that the identification and formulation of recommendations or adjustments were the main task to concentrate on, because very few proposals were found unacceptable. And this again was foreseen in the evaluation forms of stage 2 (see ref. 9). Panels took a big effort and resulted in average to request a large number of adjustments and clarifications. The remaining point then was, how to assure, that the adjustments were seriously taken into account as conditions, imposed on the negotiations of positively evaluated proposals.

Thanks to the consensus meetings these concerns could be unfolded, discussed and resolved and the rules were finally accepted. However, it turned out, that this was a **heavy burden for the evaluators**, because if the proposal was judged not acceptable even in one of the three categories ("scientific and/or technological excellence", "project implementation" and "consistency with the Call topic and stage 1") immediately would mean failure of the proposal with the immediate consequence of no financial support for an important topic of the work programme for some time. The evaluators by themselves felt heavy pressure on the panels to consider and to judge whether a seemingly weak proposal might be saved with adjustment, and which number of adjustments would be feasible. The evaluators finally were able to reach a decision in 16 of the 18 topics. 14 proposals have been recommended for funding, two proposals have been rated as "not acceptable" and in two cases - up to now - it was not possible to reach a decision (see addendum as part of this report).

Because they had to read, assess and evaluate only one full proposal in their respective topics, the evaluators had ample time. As compared to "standard procedures", where the workload is much heavier, the evaluators had the opportunity to go deep into details of the proposals. This certainly is one of the reasons for the partially extensive adjustments. In some cases the reason was the concern of the evaluators that the description of the work could have been more detailed, although they found good potential in the proposal. Consequently many clarifications were requested to fill gaps.

Obviously the consensus meetings are of utmost importance. Having followed the discussions, we can say, that the rules of procedures as regards to the role of

moderators have been followed - however, in some cases efforts had been necessary in order to achieve this. For example, it had to be made clear, that it is the aim of the evaluators to achieve a consensus and not to convince a moderator; instead of this it is the role of the moderator to support them to reach such a consensus and to ensure with all patience, that the rules of the Call are followed. The independent Observers fully appreciate that this was a difficult task and that finally - as regards to consensus - the problems were resolved successfully in 16 of the 18 topics in the course of the consensus meetings themselves.

In summary, it definitely was a peer review, but it was a particularly demanding one.

Recommendations

With one exception all successful proposals have been accepted with **adjustments**, some of them far reaching. It became clear, that the evaluators would have felt much more confident if there would have been a well defined follow-up system set up and the evaluators would have been aware of the follow-up procedure. The large number of adjustments often requested also emphasize the need and benefits of a thorough follow up by experts, in addition to the mid-term review already set up. We strongly recommend to **implement a follow up** and to take advantage of the expertise of the evaluators, which have tracked the proposals in the course of the two stage evaluation. When asked, many of them affirmed to be ready to participate in such follow-ups.

With respect to the novelty of the evaluation procedure, it is further on recommended to support the moderators by some kind of preparatory training.

Consideration

As outlined, a number of evaluators would have preferred to have a choice - in each of the topics - between "competing" proposals. At present only one full proposals per topic is invited to apply for stage 2 with the serious consequence, that in the case of rejection an important research area will not be funded for a while - at least. This could be avoided by accepting two full proposals for stage 2. If one of these full proposals would fail, at least half of the money allocated to the topic could be spent as anticipated. If both full proposals would be successful the respective topic would be covered completely.

We are fully aware, that the whole consideration will live or fail whether there is a reasonable way to split a topic without taking the risk to loose the spirit of IMI JU.

4.6 Ethical issues

For stage 2 each of the evaluation panels was extended by two evaluators with ethical expertise. The evaluation of ethical issues was integral part of the panel discussions and clearly asked for by the moderators during the course of the meetings. The input of the ethical experts was valuable and where appropriately taken into consideration for the formulation of Adjustments. However, in some cases

the evaluators were of the opinion, that the description of the work could have been more detailed; therefore a follow-up, where considered necessary, could be helpful.

Recommendations

In extension to a follow-up, as recommended in 4.5, the inclusion of ethical follow-ups should be considered.

4.7 Organisational aspects of the evaluation exercise

As already stated in the previous report of the Independent Observers, the technical conditions in the Commission building "Covent Garden" are fully satisfying. There have been no complaints with respect to access to IT equipment. Private laptops were accepted and a wireless internet access was provided too, which could be used in the building.

But what is much more important, the procedural aspects of the whole evaluation exercise have been handled perfectly by the IMI JU staff. The scientific officers as well as the administrative staff provided excellent support of the experts as well as of the independent observers.

5. Conclusions

Whenever new, this was - as a whole - a well designed, mature evaluation procedure. Obviously the broad experience of the scientific officers have been used in a positive way. We observed well skilled moderators, which were able to conduct a fair, transparent process, broadly accepted by those, who finally had to take a decision. We are convinced, that this is the right way to do the job and we hope, that IMI JU, once well established, will follow these lines and will be able to use the facilities in Covent Garden in the future too.

We would of course appreciate if some of our few suggestions, as outlined in this report, could be taken into account in the future.

Acknowledgements

The Independent Observers gratefully acknowledge that their role was fully supported and seen as helpful by the evaluators and the staff. The Independent Observers would like to sincerely thank the staff members and the expert evaluators for their assistance and cooperation.

Addendum

In two cases it was not possible to reach consensus (see page 12) in stage 2. For such a case the "Rules for submission, evaluation and selection of Expressions of Interest and Proposals" state:

"If during the consensus discussion it is found to be impossible to bring all the experts to a common point of view, the IMI JU may ask up to three additional experts to examine the expression of interest or full project proposal" (page 11 of the "Rules").

According to this, the evaluators for these topics were convened again in May 2009, together with three additional experts. Thanks to this foresight in the "Rules" this time it was possible to reach consensus in an extensive and fair discussion. One of the full proposals was ranked as acceptable with adjustments, one as not acceptable.