

Innovative Medicines Initiative (IMI) - 1st Call 2008: Independent Observers' Report

IMI - 1st Call 2008

Evaluation of stage 1, September 2008

Independent Observers' Report

Hans Lehmann

Former Head of National Contact Points Life Sciences, Germany
Former Member of the German Delegation to Life Sciences Programmes, FP 3 - 7

and

Professor Matti Sarvas

Professor emeritus, National Public Health Institute, Helsinki, and Chairman of The
Board of Gene Technology, Ministry of Social Affairs and Health, Finland

Table of Contents

1. Introduction

2. Summary of Major Observations and Recommendations

3. Independent Observers: Role and Approach Taken

3.1 Role of the Independent Observers

3.2 Approach taken to perform the task

4. Evaluation Process: Observations and Recommendations

4.1 General Design of the Evaluation Process

4.2 Selection and Briefing of Experts

4.3 Evaluation Criteria and Scoring

4.4 Remote Evaluation

4.5 Consensus Meetings and Ranking

4.6 Ethical Issues

4.7 Organisational Aspects of the Evaluation Procedure

5. Conclusions

Acknowledgements

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 Privat Partnership

1. Introduction

This is a report on the evaluation procedure of the first Call (stage 1) of the Innovative Medicines Initiative Joint Undertaking (IMI JU). The decision to set up such an initiative was made by the Council of the European Union in December 2007 (Council Regulation No 73/2008 of 20 December 2007).

At the moment IMI JU is managed under the responsibility of the European Commission in collaboration with EFPIA¹. 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 first Call ever (IMI_Call_2008_1) was published 30 April 2008² with a deadline for submission of Expressions of Interest (EOIs) 15 July 2008.

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”³ 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 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 improved⁴.

2. Summary of Major Observations and Recommendations

Both observers are impressed by the high level of expertise of the evaluation procedure. The general approach combining individual remote reviews of experts, with the consensus meetings of these experts in Brussels proved to be appropriate in order to provide a fair decision.

In particular the consensus discussions between experts and the two representatives of the EFPIA consortium (acting as experts) were the crucial measure in order to confirm or - where necessary - to establish a common understanding on which the individual EOIs then were judged. Experts from EFPIA contributed significantly to the procedure due to their knowledge of the content and background of the Call and thus being able to clarify in panel discussions the crucial elements of proposals in terms of project objectives and key deliverables in relation to the published Call.

¹ European Federation of Pharmaceutical Industries and Associations

² see http://www.imi.europa.eu/calls-01_en.html

³ see <http://cordis.europa.eu/lifescihealth/src/evaluation.htm>

⁴ Text from Annex 1 of the Contract of the Independent Observers

Innovative Medicines Initiative (IMI) - 1st Call 2008: Independent Observers' Report

All experts taking part in the evaluation acted on equal rights, i.e. they were bound to identical terms and conditions with respect to confidentiality and conflict of interest. As it turned out, with this particular peer review a balance has been made possible, where public and private interests could be taken into account in a transparent, constructive and fair way. Both scientific excellence and feasibility in terms of the goals of the Call were appropriately considered in the evaluation.

We strongly recommend to follow this setup for future stage 1 evaluation procedures.

There was only one slight point of irritation. In the Call documents it is clearly stated that only the most highly ranked EOI will be sent to the EFPIA Consortium in order to develop and submit a full project proposal to be submitted to stage 2 of the Call, although an (unspecified) number of EOIs had to be kept in reserve for the case of unanticipated eventualities. Now the first three EOIs in ranked order will be sent to the EFPIA Consortium (provided all three Applicant Consortia agree). This has been changed in August 2008. For the experts taking part in the evaluation this was news. There was quite some discussion why this has been done and how this should be interpreted, because as stated in the original Call, the negotiations have to start with the top ranked EOI. Whether this will facilitate the matching of consortia to full proposals to be submitted for stage 2 is questionable too. In any case both observers strongly recommend not to interpret or change any rule after publication of a Call, how valid the intention may have been, unless a clear mistake had to be corrected.

Apart from the remark just made, no deviations of the procedure as set out in the rules of the Call were observed and all phases of the evaluation sessions and the conduct of experts were fair and impeccable throughout the procedure.

3. Independent Observers: Role and Approach Taken

3.1 Role of the Independent Observers⁵

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.

⁵ Texts (in Times) from Annex 1 of the Contract of the Independent Observers

Innovative Medicines Initiative (IMI) - 1st Call 2008: Independent Observers' Report

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. After an oral briefing from IMI JU staff the day before the start of the first round of evaluations, the independent observers attended experts' briefing sessions and most of the consensus meetings, either together or individually.

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. Wherever requested the independent observers had access to all documents.

4. Observations and Recommendations

As already mentioned, the IMI JU is a new Public Private Partnership which in addition is in its setting up 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

The aim of the first Call stage 1 (IMI_Call_2008_1) is to identify Expressions of Interest (EOIs) of Applicant Consortia, to be more precise: one for each topic as published in the Call.

To each of the topics an EFPIA Consortium already exists; it is clearly specified in the Call text together with its role and the expected contribution from EFPIA companies.

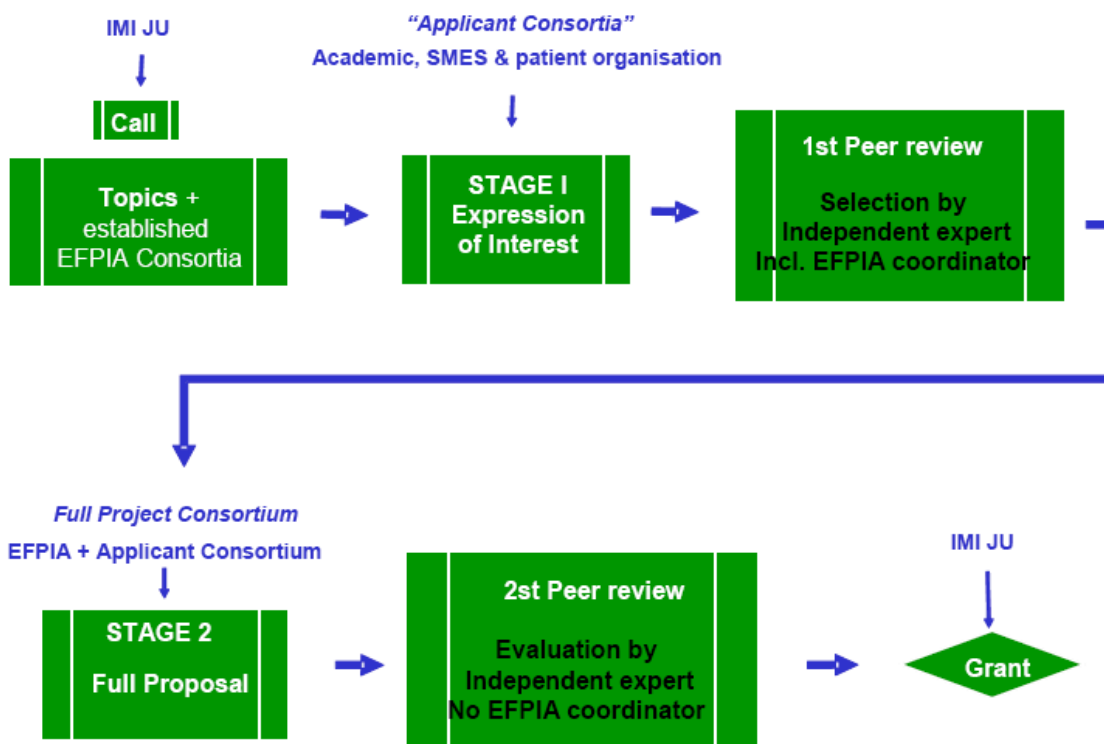
This is quite different as compared to the design and evaluation of customary FP Calls:

- in the FP a two-stage-evaluation is used in order to reduce the number of applications for a second step, where a detailed, full proposal with minor adjustments to the composition of the applying consortium has to be presented
- in the IMI_Call_2008_1 one top ranked EOI per topic has to be identified in order to match a pre-existing EFPIA Consortium, although all eligible EOIs (above threshold) are ranked. The EFPIA Coordinator has the task to merge the

top-ranked Applicant Consortium and the respective EFPIA Consortium and prepare a full proposal to apply for stage 2.

Having said this - on technical grounds - and as regards to IMI stage 1, one EOI per topic had to be specified in a peer review process. There are some differences, for example as regards to the selection of experts (see 3.2. in “Rules for submission, evaluation and selection of Expressions of Interest and proposals” and 4.2 this Report) and the evaluation criteria and scoring had to be adapted (see “Guide for Applicants” and “Evaluation Form” and 4.3 this Report), but as a whole the IMI stage 1 evaluation process clearly is based on the well known peer review processes as they are applied for example in the FPs.

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 observers suggest somewhat more thorough guidance in the following Calls due to the unique nature of IMI.



2

Figure 1⁶: 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 1 procedure ends with the "1st Peer review" above.

⁶ taken from IMI-GB-021v2-24042008-rules for submission.doc

Innovative Medicines Initiative (IMI) - 1st Call 2008: Independent Observers' Report

There was one major concern. In the Call documents it is clearly stated that only the most highly ranked EOI will be sent to the EFPIA Consortium in order to develop and submit a full project proposal to be submitted to stage 2 of the Call.

In the briefing of the evaluators as well as in the individual panel sessions this was slightly changed according to a "note de cadre August 2008". Now the first three EOIs in ranked order will be sent to the EFPIA Consortium (provided all three applicant consortia agree). This is not in contradiction with the original submission documents; indeed it is clearly stated, that the EFPIA Consortium has to start to prepare a Full Proposal with the ranked number 1 EOI and can only ask number 2 to step in, in case the preparation with number 1 is failing etc.

For the experts taking part in the discussions this was news and created some confusion. After clarification, this could be resolved finally, since a full ranked list of EOIs (above threshold) had to be established anyway. If the pure fact, that the EFPIA Consortia immediately get more detailed information on the first three as compared to the one topmost EOI will speed up the Full Proposal preparation should be carefully observed. These concerns have been shared by individual EFPIA coordinators.

Apart from this there have been concerns, as regards to the top ranked EOI and as decided by the panels, that this could be circumvented in the sense, that without convincing arguments and a clear cut demonstration of failure of negotiations, negotiations with the second or third ranked EOI could start early on.

Recommendations

From the point of view of the independent observers, to change rules in a running respectively already closed Call should definitely be avoided, unless clear mistakes had to be corrected. Small as they may be, like the clarifications in the "note de cadre August 2008", they are subject to questions and irritations and in any case consume precious time.

4.2 Selection and Briefing of experts

The evaluators have been selected by the IMI JU scientific officers (moderators) responsible for the different topics of the Call; the two representatives of the final consortium (coordinator and deputy) have been nominated by EFPIA. In order to manage the proper selection for the topics, the Expert Management Module (EMM) of the Commission was used, which is a large database where experts have - amongst other things - to indicate their particular expertise. This is a well established instrument, which facilitates the work of the moderators.

The selection was well done as turned out at the consensus meetings (see 4.5), which approximately 90% of the (remote) evaluators attended.

Briefing was provided in written form and a second time prior to the consensus

meetings in Brussels.

The selection of experts in this Call is unique (as compared to FP) due to the participation of EFPIA representatives and it is clearly related to IMI JU as a PPP and the construction of the Call, which is reflected in "4.1 General Design of the Evaluation Process". These evaluators faced the problem, that they participated as individuals, having signed declarations of confidentiality and conflict of interest with IMI JU and that they represented at the same time the respective EFPIA consortia, as outlined by the Call text. Legally this was no problem, since EFPIA members were not eligible as partner in an applicant approaches. It turned out, that this at first sight unusual construction altogether resulted in a balance, where public and private interests could be taken into account in a transparent, constructive and fair way. For more details see "4.5 Consensus Meetings and Ranking". Experts from EFPIA contributed significantly to the procedure due to their knowledge of the content and background of the Call and thus being able to clarify in panel discussions the crucial elements of proposals in terms of Project Objectives and Key Deliverables in relation to the published Call.

The presence and the good balance of both high level academic and industrial experts (including non-EFPIA industry experts) was of great advantage. Industrial experts could especially raise points of industrial importance, and thus both scientific excellence and the feasibility of projects in terms of the Call were thoroughly considered. Consensus between academic and industrial experts was achieved. The observers highly recommend to maintain this set up of members for future panels.

Recommendations

The selection of evaluators by IMI JU scientific officers and the nomination of two representatives of the EFPIA consortium should be followed in further stage 1 evaluation procedures - provided that these experts, as in the very first Call, take part on equal terms, i.e. all are bound to identical terms and conditions with respect to confidentiality and conflict of interest.

A close familiarity of EFPIA coordinators with the already existing EFPIA consortium turned out to be positive for the identification of the EOI best suited. It is therefore recommended to appoint EFPIA coordinators and deputies in due time, which was not always the case in this Call.

Further on it would be desirable, if the "rules for submission, evaluation and selection of EOI and proposals" could be clarified and amended in order to emphasize, that two EFPIA representatives take part in the evaluation - a fact which the Independent Observers appreciate as such.

Finally a solution should be considered on how to take advantage of the EMM in the future, once IMI JU will be independent and will have - as it is anticipated - no automatic access to this instrument.

4.3 Evaluation Criteria and Scoring

Evaluation Criteria

The evaluation criteria, threshold marks and scores including their explanation have been laid down in the evaluation form - stage 1, which was part of the Call documents⁷.

1. Scientific and/or technological excellence

- Quality of the approach
- Likelihood to meet the key listed objectives of the project
- Complementarities with the EFPIA Consortium
- Innovation, progress beyond the state-of-the-art and impact

2. Partnership case

- Quality and relevant experience of the individual participants
- Appropriateness of the allocation of role/input of each applicant

3. Quality of the Applicant Consortium as a whole

- Unique features, internal complementarity and balance of the consortium

4. Quality and soundness of the work plan, including budget

Score values and their definition

- 0 – fails to address the criterion under examination or cannot be judged due to missing or incomplete information.
- 1 – Very poor. The criterion is addressed in a cursory and unsatisfactory manner.
- 2 – Poor. There are serious inherent weaknesses in relation to the criterion in question.
- 3 – Fair. Broadly addresses the criterion, with significant weaknesses that need correction.
- 4 – Good. Addresses the criterion well, although certain improvements are possible.
- 5 – Excellent. Successfully addresses all relevant aspects of the criterion in question. Any shortcomings are minor.

Each of the subcriteria has to be scored, therefore in the respective main criteria the maximum scores are 20 (threshold 14), 10 (threshold 7), 5 and 5 respectively. Halve point scores are possible. This automatically gives the highest weight to the first criterium "Scientific and/or technological excellence".

In the course of consensus meetings it turned out, that this system with a manageable number of criteria and subcriteria and the full range of 0 to 5 points for each subcriterium is a good instrument to meet the needs of the evaluators; the score definitions were well accepted too.

There was only one concern: In a few cases time was needed in order to clarify, that the scientific and/or technological excellence (1st criterium) had to be seen in relation

⁷ IMI-GB-023v2-24042008-evaluation form stage 1

Innovative Medicines Initiative (IMI) - 1st Call 2008: Independent Observers' Report

to the topics addressed by the call, as explicated by the second and third subcriterion and in the text of the appropriate project description.

More often time was needed in order to find a consensus for the meaning of "innovation", the fourth subcriterion. The consent found was, that innovation in relation to the topics must have a strong translational feature and innovation in the sense of novelty as such was not considered sufficient.

In a few cases it was considered to combine the second and third criterion but without clear cut recommendations.

Recommendations

Evaluation criteria and scoring are mature and obviously have taken advantage from earlier Independent Observer Reports and recommendations in the theme "Health".

Our recommendation therefore is to retain them as they are and modify them only slightly with respect to two aspects.

- The adherence to the topics should be made clearer. Here we recommend to follow the evaluation forms of Collaborative projects in the theme "Health", which are more explicit. There the heading of the corresponding criterion reads "1. Scientific and/or technological excellence (relevant to the topics)", followed by a note as part of the form: "Note: when a proposal only partially addresses the topics, this condition will be reflected in the scoring of this criterion".
- In addition we recommend, to clarify the translational aspect of the fourth subcriterion "innovation"

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 Form to justify the 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

In the guidelines for the preparation of EOIs, a maximum number of 5 pages is indicated (two for the description of the innovative approach, one for the description of the complementarities of the consortium and two for the summary of the work plan). In addition for each participant one half page were accepted.

Innovative Medicines Initiative (IMI) - 1st Call 2008: Independent Observers' Report

It is clear, that full proposals for stage 2 will have to be more detailed. However, the decision for this stage 1 evaluation is far reaching: only one EOI will be chosen and only this single one will have to be matched with the EFPIA consortium. Thus the question was, whether the 5 pages were considered as sufficient as a basis for the decision. The answer is overall yes. The majority of those experts interviewed stated, that well written EOIs gave enough information in order to reach a decision. In some cases however it was mentioned more room especially for the work plan would have been appreciated.

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 as quite often marginal. The comments were often short and/or very general, and 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 per topic, in a few cases topics were combined for one consensus meeting. Due to the manageable number of EOIs per topic the final ranking was achieved in these consensus meetings too. In those cases where one panel discussed one topic evaluators had access to all EOIs of this particular topic.

The consensus meetings were co-moderated by IMI JU staff from Commission Services and EFPIA respectively EFPIA member companies. This will change, once IMI JU will be autonomous and will have employed its own staff.

The moderators introduced the topic and presented the individual scores of the remote evaluation in a clear and complete overview, where it became evident for the panel, who scored best and worst in each of the EOIs and each of the criteria. At the onset of the panel the rapporteurs were appointed for the drafting of the consensus

Innovative Medicines Initiative (IMI) - 1st Call 2008: Independent Observers' Report

reports and - as a rule - the moderators declared that they were willing to draft the evaluation summary report with the final ranking of the EOIs of the topic. All evaluators were asked to sign the consensus as well as the evaluation summary report before leaving premises. The observers paid special attention to the fact that the Consensus reports were prepared very carefully and amended with extensive and constructive suggestions for the applicants expected to file a proposal for the 2nd stage. These comments would be expected to be especially valuable to adjust the full proposal to match the skills, resources and goals of the Applicant Consortium with those of EFPIA Consortium.

Since approximately 90% of the evaluators were able to come to Brussels, everybody was well prepared. This and the relatively small number of approximately 8 to 10 evaluators per panel - together with well prepared moderators/comoderators from Commission services and EFPIA industry as well as the active participation of EFPIA coordinators and deputies gave an excellent basis for open and constructive discussions. The independent observers were impressed by the quality of the exchange of views; that arguments were listened to with open mind and the discussion ended in comprehensive conclusions of the panel.

In a few cases the panels discussed - prior to the final scoring - some aspects of the criteria respectively on how to apply the criteria correctly. Both observers had the impression that finally, after these preliminary discussions, the aim and the scope of the PPP and the particularities of the Call were well understood and the evaluation criteria well applied. In this process both, moderators as well as EFPIA coordinators were particularly helpful.

For the observers it is absolutely clear that remote evaluation alone never would have been sufficient to reach such well founded decisions.

Recommendations

The consensus meetings are of utmost importance in order to reach a fair, well-founded decision. Slightly different ways to handle the proceedings between individual moderators were observed, but in all cases a high level of scientific quality and impartiality was obvious. Provided that well experienced scientific officers are involved - as was the case in this Call - the independent observers recommend to accept such slightly differing personal approaches of the moderators; as a whole, the basic elements of the procedure as applied in this evaluation should be adhered to in forthcoming Calls.

4.6 Ethical issues

The evaluators were expected to indicate any ethical issues that may need further attention if the proposal is selected for 2nd stage. There was, however, very little guidance beyond referring to the Decision No. 1982/2006/EC. A number of evaluators obviously were not aware what kind of ethical issues they were expected to pay attention to. Clearly, more guidance should be provided in this respect for the evaluators of the 2nd stage, as well as information on the overall procedure of ethical evaluation of the proposals.

Recommendations

For the 2nd stage, when full proposals will have to be evaluated, an "ethical screening" of proposals should be introduced, comparable to procedures as applied in the FP7-Health programme in order to identify proposals which raise ethical issues and require a special ethical review

4.7 Organisational aspects of the evaluation exercise

With a view to earlier Independent Observers Reports in the theme "Health" it has to be stated, that the technical conditions in the Commission building "Covent Garden" obviously have been improved, they are fully satisfying now. 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.

The Independent Observers, who had the privilege to use the internet via "official" computers only would have preferred to have access to an easy to use guest account.

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.

It certainly was an advantage, that the number of EOIs as well as the number of persons involved have been relatively small (approximately 150 proposals and approximately 150 persons involved).

5. Conclusions

Whenever new, this was - as a whole - a well designed, mature evaluation procedure. Obviously the facilities as well as 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.