

**Innovative Medicines Initiative  
(IMI) – 6<sup>th</sup> Call 2012**

**Evaluation of Stage 2  
October 2012**

**Independent Observers' Report**

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### **Abbreviations:**

- EFPIA - European Federation of Pharmaceutical Industries and Associations,  
EoI - Expression of Interest  
FPP - Full Project Proposal  
IMI - Innovative Medicines Initiative

## **1. Background**

This is the report of the independent observers for Stage 2 of the 6<sup>th</sup> Call for proposals by the Innovative Medicines Initiative (IMI).

The 6<sup>th</sup> Call was launched on 24<sup>th</sup> May 2012 with a submission of proposals invited in response to the Call theme: Combating Antibiotic Resistance: NewDrugs4BadBugs (ND4BB) – the combating and treatment of infectious diseases being a key research priority of the IMI programme. The Call covers two aligned topics: Topic 1 (divided into 2 subtopics 1A-1B). Innovative Trial Design & Clinical Drug Development, and Topic 2. Learning from success and failure & Getting Drugs into Bad Bugs. Expressions of Interest (EoIs) in response to the Call were accepted by the IMI website up until a deadline for submissions of 9<sup>th</sup> July 2012.

The Expressions of Interest (EoIs) submitted by applicant consortia were evaluated remotely in Stage 1 between the 10<sup>th</sup> and 23<sup>rd</sup> July 2012 by both independent experts appointed by the IMI JU and representatives of Companies within the intended EFPIA consortia for this Call. Following a “face to face” discussion and evaluation of the EoIs between the 25<sup>th</sup> – 27<sup>th</sup> July 2012 in Brussels, the Consortia who gained the highest ranked evaluations under Stage 1 (subtopics 1A, 1B and topic 2) were invited to join with matched EFPIA Member Companies to submit Full Project Proposals (FPPs)– one Consortium for each of the two Topics. Both invited Consortia submitted FPPs by the 10<sup>th</sup> October 2012 deadline.

The two FPPs were evaluated by independent experts including ethics reviewers, first through remote evaluation between the 15<sup>th</sup> and 24<sup>th</sup> October 2012 and then in separate panel discussions and hearings which took place in Brussels on the 29<sup>th</sup> and 30<sup>th</sup> October 2012. Discussions for Topic 1 took place on the 29<sup>th</sup> and those for Topic 2 on the 30<sup>th</sup>. In parallel with these discussions, independent ethics expert reviewers held separate discussions on the two Topics in adjacent meeting rooms. Both sets of experts were supported and the meetings chaired by Members of the IMI JU Secretariat.

The Stage 2 evaluation process ended with the generation of consensus evaluation reports and ethics review reports for each of the two FPPs. These consensus reports were subsequently communicated to the applicant Consortia.

## **2. Overall observations**

As with Stage 1, the Stage 2 evaluations were conducted professionally, fairly and in accordance with the established IMI procedures and regulations. All participants were impartial and thoughtful in their evaluations of the two FPPs. As in the Stage 1 evaluations, the IMI JU again performed an outstanding job in organizing the FPP submissions and evaluation process against tight timelines. All expert evaluators were well qualified professionals with a thorough knowledge and understanding of the issues involved in either antimicrobial resistance and / or the ethical problems posed by research in this area. All remote evaluations were comprehensive in their discussion and conclusions.

A welcome modification to the review of previous calls was the inclusion of the remote ethical evaluation of the FPPs. A recommendation from the 4<sup>th</sup> Call, the addition of this remote evaluation allowed a greater length of time for a considered view on ethical issues.

Clear briefings and intended objectives were provided to evaluators prior to the face-to face discussions and hearings with the applicant Consortia. The pre-defined Agendas for the two days of meetings were expertly adhered to, the meeting for the Ethics Committee finishing prior to its allotted time.

In our opinion:

- There were no violations against the rules of the published evaluation guidelines.
- Expert and ethical evaluators were of a high quality and possessed the relevant expertise to allow them to form an informed consensus on the merits of the proposed FPPs.
- Evaluation of the proposals and the “face to face” discussions were fair and transparent.
- All Expert reviewers contributed to the hearings with the applicant Consortia.
- Hearings were generally well conducted.
- The Final Consensus Evaluation Reports represent the consensus opinions of the panels.

As with Stage 1, we have some recommendations for modifications that we hope may improve the Stage 2 process for future Calls.

These principally concern the integration of the views of the Ethics Panels in the wider expert discussion and hearings with the Consortia, and whether a further step in the evaluation process should be considered after Stage 2 where additional clarification and undertakings from the applicant are deemed appropriate. These are described in Section 4 of this report.

### **3. Role and approach of the independent observers**

#### **3.1 Role of the independent observers**

As stated in the IMI’s Rules for submission, evaluation and selection of Expressions of Interest and Full Project Proposals 3.4, the role of the independent observers is as follows:

“The role of observers is to give independent advice to the IMI JU on the conduct and fairness of all phases of the evaluation sessions, on ways in which the experts apply the evaluation criteria, and on ways in which the procedures could be improved. As such, they shall verify that the procedures set out or referred to in these Rules are adhered to, and report their findings and recommendations to the IMI JU. They are also encouraged to enter into informal

discussions with the IMI JU staff involved in the evaluation sessions and to suggest to the IMI JU any possible improvements that could be put into practice immediately. However, in the framework of their work, they should not express views on the expressions of interest and full project proposals under evaluation or the experts' opinions on the proposals.”

### **3.2 Working method of the independent observers**

The two independent observers had access to all written and on-line information supporting the Stage 2 evaluation process and attended the evaluation sessions, panel discussions and hearings held at the Renaissance, Brussels Hotel on the 29<sup>th</sup> and 30<sup>th</sup> October 2012. They spoke individually with several of the attending expert evaluators and IMI employees. These included the Scientific Officers who acted as moderators, the supporting Secretariat, IMI lawyers, the IT support specialist and Professor Michel Goldman, the Executive Director of the IMI.

Formally introduced to the experts at the beginning of the two day meeting by the Executive Director, experts and moderators alike were encouraged to and did speak freely with both observers. Experts, if they wished were able to talk confidentially with the independent observers or alternatively leave anonymous comments only for the observers' review.

## **4. Observations and recommendations**

The following sections record our observations on the Stage 2 evaluation process, collate comments received over the two days of the meeting from participants, and give some recommendations and suggestions we feel could further improve the process for future Calls. Designated as “Recommendation A, B, C...etc”, these observations and recommendations should be read against the background of the general comments expressed above in Section 2. Our overall opinion is that the evaluation process has been well, carefully and fairly implemented throughout and the overall process is of excellent quality and follows International standards of peer review.

### **4.1 Preparation of the Full Project Proposals (FPPs)**

As has been commented on in previous Calls, the preparation of the individual FPPs following the choice of the top-ranked EoIs during the Stage 1 evaluation is both demanding and time consuming. In the case of this Call, the timeline for initial coordination between the EFPIA and academic collaborators and generation of the FPP was relatively short. The final rankings of the initial EoI under Stage 1 were completed on the 27<sup>th</sup> July 2012 with the FPPs required to be provided to the IMI Secretariat by the 10<sup>th</sup> October 2012 – a period of just over two months. Given the complexity of this Call, a formidable amount of work was completed in the time available.

Both FPPs were well constructed, with sound rationales provided for each of the Work Packages and details of the Consortia supporting them. The evaluators did however remark that there appeared to be some lack of clarity around both general Governance and Financial issues relating to the two topics. Comment was also

made that the FPPs failed to fully address contingency issues if timelines / objectives for the Work Packages were not met. Though it is recognized that the Call had specific timelines given to it from its outset, both Topics might have benefited from a slightly longer period of initial discussion and deliberation prior to the submission of their respective FPPs.

**Recommendation A:** Consideration should be given to ensuring that the timeline for preparation of the FPP following the ranking of Expressions of Interest after Stage 1, should be commensurate with the work required for initial coordination of the academic / SME and EFPIA partners. A minimum period should perhaps be stipulated, especially over the summer months when a number of parties may be away.

#### **4.2 Remote Evaluation Stage**

As in previous Calls, following generation of the FPPs, the expert evaluators including those reviewing ethical aspects of the projects, had approximately 10 days in which to evaluate them remotely. This process worked well with all evaluators providing full reports prior to the “face-to face” meeting on the 29<sup>th</sup> October. No problems were reported in the viewing of the FPPs, supporting documentation or uploading of the reviewer’s reports.

#### **4.3 Scientific and Ethical expert evaluation panels**

Experts in the evaluation panels were selected and invited by IMI JU officials as described in “Rules for submission, evaluation and selection of Expression of Interest and Full Proposals, 3.2”. All experts fulfilled the required criteria.

Many of the evaluation panel members had previously reviewed and attended the Stage 1 evaluations. Due of their non-availability or potential conflicts of interest, between two and four of the members for each of the two Topics had been replaced between the two review stages.

Evaluators were at the time of the “face-to-face” meeting, familiar with the two Call Topics and the considerations and comments of the Panel following Stage 1. Panel members were aware of the nature and goals of the evaluation process, their responsibilities, the choices available to them and the consequences of their decisions and recommendations. These were reiterated by the IMI’s Executive Director prior to the start of the Topic meetings.

The two scientific expert panel discussions consisted of:

- 1) Each panel member being invited by the IMI Chairperson, to introduce themselves.
- 2) The rapporteur responsible for the writing of the Consensus evaluation report and appointed prior to the meeting, being invited to briefly describe the key points of the FPP and any concerns and observations he / she had about the proposal.
- 3) Other Panel members were then invited in turn to give their views on the proposal and what issues might benefit from additional information from the

Consortia members. A series of questions were collated and ranked separately for each Topic in order of importance.

- 4) Consortia Members were invited to give a brief presentation on their proposal and then answer the collated questions in front of the panel, IMI Chairperson and Members of the IMI Secretariat. This was conducted both in person and by teleconference.
- 5) The expert evaluators then finalized their recommendations and the consensus evaluation report, based on the earlier discussion and the answers provided by the Consortia Members.

Ethical expert panel discussions were similar to those of the scientific review teams and ran in parallel with them, but no opportunity existed for a hearing with the Consortia Members. As such, no questions were drafted to help clarify specific aspects of the proposals. In addition, though both sets of experts, scientific and ethical, were present in the same venue at the same time, there was no formal opportunity for them to discuss the proposals or raise potential issues of common concern or interest.

All experts brought considerable knowledge and understanding of the issues to the panel evaluations. All reviewers took an active role in the preliminary discussions and the drafting of the questions prior to the two hearings. The IMI Chairperson and wider on site Secretariat gave considerable support to both the review Committee as a whole and the Rapporteur specifically.

With respect to the hearings with the Consortia Members, the following recommendations are made:-

**Recommendation B:-** Though it is recognized that face-to face time is limited, it is recommended that the Consortia Members be given a greater length of time to prepare for the questions posed by the review panel. This would allow for more thought to be given to the questions and hopefully produce both fuller and more insightful answers. Where multiple Topics are reviewed, one solution might be to collate questions to Topics on one or more days and ask Consortia Members to attend a hearing on a second day, giving them either the proceeding morning or afternoon to prepare.

**Recommendation C:** It is important that the Chairperson ensures all questions are answered fully and hearing timelines kept to. If questions remain unanswered at the end of the hearing they should be carried over and a written response requested. Consideration should be given to requesting that all questions posed by the review panel receive formal written responses. This is important both for clarity and to ensure that any concerns are fully addressed prior to an agreement between the IMI and Consortia.

With respect to the ethics expert panel discussions:-

**Recommendation D:-** Given the welcome presence of both scientific and ethical review experts at the same venue, it is recommended that time is set aside to allow the ethical reviewers to present any concerns to their scientific colleagues and for the scientific reviewers to ask any ethics based questions they may have.

**Recommendation E:-** Consideration should be given to allowing the ethical review panel to draft questions for the Consortia Members and ask these either at a separate hearing or preferably at a joint hearing with the scientific review panel. The ethical and scientific aspects of the proposals should not be viewed as separate entities either by the panels or the Consortia Members.

#### **4.4 Consensus Evaluation Reports and decision-making on the proposals**

All review panels took considerable time and care in writing the final consensus evaluation reports. Led by the Rapporteur, appointed by the IMI JU prior to the meeting, the reports were written either following the hearings with the Consortia Members, or in the case of the Ethics reports, following a thorough discussion of the proposal.

The reports accurately reflect the views and comments of the panel as a whole.

The panels did however consider that a number of questions remained incompletely resolved at the end of the hearing sessions. Proposal decisions made under IMI should be based on the collation and appraisal of all information required by the review panels.

**Recommendation F:** Consideration should be given to delaying a “ go / no go” decision on a proposal until all questions requested by the review panels prior to the formal hearings have been formally addressed in writing by the Consortium (Recommendation C) and reviewed by a majority of Members on the original Hearing Committee.

#### **4.5 Budgeting**

Given the complexity of the proposals, it was difficult for expert reviewers to be sure that the proposed budgets for individual Work Packages and the proposal as a whole, adequately reflect the cost of the proposed work. The nature of EFPIA Members’ “benefit in kind” to match payments by the Commission, are not always clear in the proposals.

#### **Recommendation G:**

Given the importance of the financial and “in-kind” contributions made by both the EFPIA Members and the European Commission, consideration should be given to an independent review of the financial viability of the individual Work Packages and the Call’s overall funding, prior to the “face to face” meeting. Any comments made under this review would not need to be binding on the evaluation group’s decision to accept the proposal, but would help to guide them as to the project’s viability.

#### **4.6 Moderation of the Expert Evaluation Panels**

The expert evaluation panels were chaired and moderated by The IMI’s Scientific Officers.



This difficult role was done with tact, professionalism and impartiality. Where needed, advice was given on process and compliance with regulations.

As mentioned above, care should be taken in the hearings that all questions requested by the Panels are answered as fully as possible and timings adhered to, especially on the part of the presenting Consortia. Additional tact and moderation needs occasionally to be used if an individual within the review panel holds a particularly forceful view.

#### **4.7 Interim Review**

As in previous calls, members of the review committees requested clarity on when and against what criteria and milestones, interim reviews of the proposals would take place.

**Recommendation H:** As referred to in the 4<sup>th</sup> Call, the coordinators of the FPPs should be required to generate a series of (4-5) 'High Level' Deliverables, relating to the objectives in the Call Topic. These should form a basis against which the project's progress will be reviewed at the time of the interim review.

#### **4.8 Overall Conclusions and Comments**

There were no apparent violations of the published guidelines and the evaluations, and discussions were fair and transparent.

The following recommendations though are offered:-

**Recommendation A:** Consideration should be given to ensuring that the timeline for preparation of the FPP following the ranking of Expressions of Interest after Stage 1, should be commensurate with the work required for initial coordination of the academic / SME and EFPIA partners. A minimum period should perhaps be stipulated, especially over the summer months when a number of parties may be away.

**Recommendation B:** Though it is recognized that face-to face time is limited, it is recommended that the Consortia Members be given a greater length of time to prepare for the questions posed by the review panel. This would allow for more thought to be given to both the questions and hopefully produce both fuller and more insightful answers. Where multiple Topics are reviewed, one solution might be to collate questions to Topics on one or more days and ask Consortia Members to attend a hearing on a second day, giving them either the proceeding morning or afternoon to prepare.

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## **5. Acknowledgements**

We were helped in our task by all participants in the Stage 2 consensus meetings.

Our thanks to the independent experts and consortia members for being amenable to being ‘observed’ and for the conversations that helped formulate this report. We would like to particularly thank the IMI staff for their help and hospitality before, during and after our stay in Brussels for the consensus evaluation meetings.

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