

**Innovative Medicines Initiative  
(IMI) – 8<sup>th</sup> Call 2013**

**Evaluation of Stage 2  
August 2013**

**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 the Stage 2 of the 8<sup>th</sup> Call for proposals by the Innovative Medicines Initiative (IMI).

The 8<sup>th</sup> Call was launched 17<sup>th</sup> December 2012. Submission of proposals was invited in response to three Call themes: i) **Combatting Antibiotic Resistance: NewDrugs4BadBugs (ND4BB)**. The Call covered two topics: Topic 1. Clinical studies supporting the development of monoclonal antibodies targeting *Staphylococcus aureus* and Topic 2. Discovery and Development of New Drugs Combatting Gram-Negative Infections. ii) **Developing an Aetiology Based Taxonomy of Human Disease**: Topic A: Approaches to develop a new classification for systemic lupus erythematosus (SLE) and related connective tissue disorders and rheumatoid arthritis (RA) and Topic B: Approaches to develop a new classification for neurodegenerative disorders with a focus on Alzheimer's disease (AD) and Parkinson's disease (PD). iii) **European Induced Pluripotent Stem Cell Bank**. Expressions of Interest (EoIs) in response to the Call were accepted by the IMI website up until a deadline for submissions of 19<sup>th</sup> March 2013.

Submitted EoIs were remotely evaluated over a two week period prior to the 4<sup>th</sup> April 2013, both by independent experts and representatives of the companies within the planned EFPIA Consortium for the Call topic. The review period was extended by 24 hours from the 3<sup>rd</sup> to the 4<sup>th</sup> April due to the last minute replacement of experts who disclosed a conflict of interest after the EoI submission deadline. The independent experts, coordinators and deputy coordinators of the Call-generating EFPIA consortium, met in Brussels from 9-12 April 2013 to finalize the Stage 1 evaluation process. The results of these evaluations were communicated to the Applicant Consortia in May 2013. The consortia who gained the highest ranked evaluations under stage 1 were invited to join with matched EFPIA Member Companies to submit a Full Project Proposal (FPP) by the 26<sup>th</sup> July 2013 deadline.

Five FPPs were evaluated by independent experts, including ethics reviewers, first through remote evaluation between July 26<sup>th</sup> and August 23<sup>rd</sup> 2013 and then in separate panel discussions and hearings which took place in Brussels on August 27<sup>th</sup>, 28<sup>th</sup> and 29<sup>th</sup> 2013. In parallel with these discussions, independent ethics reviewers held separate discussions in adjacent meeting rooms. Both sets of experts were supported and moderated 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 five FPPs. These consensus reports were subsequently communicated to the applicant Consortia.

## 2. Overall observations

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 five FPPs. The IMI JU 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 the five FPPs discussed.

Clear briefings and intended objectives were provided to evaluators prior to the panel discussions and hearings with the applicant Consortia. The predefined Agendas for the three days of meetings were expertly respected.

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 previous Calls, included in this report are some observations and general recommendations we hope may help improve Stage 2 review process for future Calls. These are described in detailed 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 Crowne Plaza Hotel in Brussels on the 27<sup>th</sup>, 28<sup>th</sup> and 29<sup>th</sup> August 2013. They spoke individually with 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 three day meeting by the Executive Director, experts and moderators alike were encouraged to 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 three 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 1, 2, 3...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 and the overall process is of excellent quality and follows International peer review standards.

### **4.0 The Call**

Given the diverse topics being considered under this Call and the short time that was allocated to prepare the Call documents and the fact that several Calls have been launched by IMI in a short period of time, special attention should be provided to ensure that all documents are aligned with IMI standards and EFPIA expectations. Evaluators expressed concerns indicating that, in some cases, the Call documents did not fully reflect realistic expectations on the Topic.

**Recommendation 1:** The Independent observers suggest that the IMI and EFPIA engage an external consultant that could do a 'proof reading' of all documents related to The Call to ensure that all conditions are realistic and could be accomplished in the timelines defined by the team that prepared The Call. This exercise could take 2-3 days and in principle should not slow down the Call launching process.

#### **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 final rankings of the initial EoI under Stage 1 were communicated to the teams in May 2013 with the FPPs required to be provided to the IMI Secretariat by the 26<sup>th</sup> July 2013 deadline – a period of just over two months. Given the complexity of this Call, a formidable amount of work was completed in the time available.

All Five 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 details. In particular, comments were made regarding some FPPs that failed to fully address budget changes, the rationale of these changes and their alignment with the project goals.

**Recommendation 2:** Consideration should be given to ensuring that changes made in the budget during preparation of the FPP, in particular those from SME and EFPIA partners, should be aligned with the overall project goals, duration of the project and particular work packages. We recommend that the applicant consortia prepare a short document (1-2 pages) describing the budget changes made in the FPP with the explanation of consequences of these changes.

#### **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 three weeks 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 (27<sup>th</sup>, 28<sup>th</sup> and 29<sup>th</sup> of August). No major problems were reported in the viewing of the FPPs, supporting documentation or uploading of the reviewer’s reports.

The following recommendation is made in order to increase the contribution of the remote evaluation to the onsite work:

**Recommendation 3:** In order to facilitate the onsite preparation of the Hearings, the Independent Observers recommend that IMI Officers ask evaluators to provide 2-3 questions per FPP, as part of their remote evaluation document, so that these questions could be compiled and curated more effectively during the “face-to-face” meeting.

#### **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 to their non-availability or potential conflicts of interest,

some of the members for each of the Five FPPs had been replaced between the two review stages.

Evaluators were, at the time of the “face-to-face” meeting, familiar with the Five FPPs 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.

Issues of potential conflict of interest were taken seriously by the IMI staff, IMI lawyer and IMI Director, each evaluator of the panel was invited to declare and explain any potential conflict of interest situations. In fact, two evaluators had to withdraw from the evaluation at the start of the “face-to-face” meeting for one FPP. Consequently, their individual reports were not considered by the remaining evaluators in the adoption of the final recommendations and scores in the consensus evaluation report.

The Five 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 for each Topic in order of importance.
- 4) Consortia Members were invited to give a presentation on their proposal and then answer the collated questions in front of the panel. 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. A small set of questions were selected by the Ethical expert panel and transferred to the scientific panel by an IMI officer. Ethical experts could participate as observers during the Hearings. However, even if both panels were present in the same venue at the same time, there was no formal opportunity for them to meet and 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 moderator and wider onsite Secretariat gave considerable support to both the review Committee as a whole and the Rapporteur specifically.

With respect to the panel members and meetings:

**Recommendation 4:** Though it is recognized that declaration of Conflict of Interest is the responsibility of each of the evaluators, the Independent Observers consider that the IMI could help ensure that evaluators are well aware of potential conflict of interest that may arise during the FPP evaluations (and were not present at the EOI evaluation). In particular, it is recommended that IMI JU officials send to evaluators a document listing the EFPIA partners that are part of the newly created consortia and specifically ask evaluators to check for potential conflict of interest with these companies.

**Recommendation 5:** Though the importance of a detailed Ethical review is recognized, the non-scientific panel could benefit from a multidisciplinary set of experts (Legal, IP, Health Economists, Behavioural scientist, Animal welfare expert, etc.) that could also evaluate other aspects of the FPP such as the competitive advantage, socioeconomic impact, etc.

**Recommendation 6:** To increase the value of the non-scientific review, we recommend that both expert panels meet for a short period of time (30 minutes) before the hearings, and before questions are sent to the Consortia Members, in order to discuss potential issues of common concern or interest. The ethical and scientific aspects of the proposals should not be viewed as separate entities either by the panels or the Consortia Members.

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

**Recommendation 7:** Since all experts in the panel and IMI Officers have read the FPP and know the project in detail, we recommend that the Consortia presentation be very short (10 minutes maximum) and focus only on updates, new aspects and changes in the work packages or budget. With shorter presentations more time will be given to the discussion between Consortia Members and the expert panel.

**Recommendation 8:** Consideration should be given to allowing individuals that are participating in the Hearings by phone. Having the opportunity to call specific Consortia Members (e.g. ethical experts) following the reception of the questions prepared by the panel could increase the value of the discussions.

#### **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.

Some of the ethics reviewers voiced concern about the limit in the size of both the individual and the consensus report. This was however not the general opinion of the group of ethics reviewers.

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

## 4.5 Budgeting

Two of the FPP evaluated during the “face-to-face” meeting had budget changes that were discussed by the panel members. 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 reflected the cost of the proposed work.

**Recommendation 9:** Given the changes that were made in the budget between the EOI and the FPP, in particular those associated to the contribution of EFPIA Members, we recommend having an independent financial review of each of the projects.

## 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.

Care should be taken during the panel discussions and the hearings to ensure that all panels follow the same procedure to avoid inter-panel variability. Additional tact and moderation needs occasionally to be used if an individual within the review panel holds a particularly forceful or monopolized view.

## 4.7 Overall Conclusions and Comments

There were no apparent violations of the published guidelines and the evaluations, and discussions were fair and transparent leading to concrete recommendation to improve the projects and ensure results delivery.

The following recommendations are offered:

**Recommendation 1:** The Independent observers suggest that the IMI and EFPIA engage an external consultant that could do a ‘proof reading’ of all documents related to The Call to ensure that all conditions are realistic and could be accomplished in the timelines defined by the team that prepared The Call. This exercise could take 2-3 days and in principle should not slow down the Call launching process.

**Recommendation 2:** Consideration should be given to ensuring that changes made in the budget during preparation of the FPP, in particular those from SME and EFPIA partners, should be aligned with the overall project goals, duration of the project and particular work packages. We recommend that the teams prepare a short document (1-2 pages) describing the budget changes made in the FPP with the explanation of consequences of these changes.

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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.

