

IMI – 8th Call 2013

Evaluation of Stage 1

April 2013

**Independent Observers' Report**

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## **Abbreviations:**

EFPIA - European Federation of Pharmaceutical Industries and Associations

EoI - Expression of Interest

IMI - Innovative Medicines Initiative

## 1. Background

This is the report of the Independent Observers for Stage 1 of the 8<sup>th</sup> Call for proposals by the Innovation Medicines Initiative (IMI). The 8<sup>th</sup> Call was launched 17<sup>th</sup> December 2012. Submission of proposals were invited in response to three Call themes:

i) **Combatting Antibiotic Resistance: NewDrugs4BadBugs (ND4BB)**. The Call covered two topics: Topic 1C (Work Package 6 of Topic 1- Innovative Trial Design & Clinical Drug Development); Conduct of clinical studies supporting the development of MEDI4893, a monoclonal antibody targeting *Staphylococcus aureus* alpha toxin and

Topic 3. Discovery and Development of New Drugs Combatting Gram-Negative Infections

Both topics are part of a wider programme to combat antimicrobial resistance initiated by the IMI JU in May 2012 under the IMI's 6<sup>th</sup> Call.

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)

Topic B: Approaches to develop a new classification for neurodegenerative disorders with a focus on Alzheimer's disease (AD) and Parkinson's disease (PD).

A third topic under this theme addressing the taxonomy of chronic obstructive pulmonary disease (COPD) was not launched under this Call, the intention being to include it at a later date.

iii) **European Induced Pluripotent Stem Cell Bank**

The IMI JU through its electronic submission tool accepted Expressions of Interest (EoIs) in response to the Call up until a deadline for submission of 19 March 2013.

Submitted EoIs were then 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, were then brought together in the Crowne Plaza meeting rooms in Brussels from 9-12 April 2013 to finalise the Stage 1 evaluation process with a series of plenary, panel discussions and telecom hearings. The evaluations for each Call were spaced throughout the week of the 9-12 April with each taking between two and three days. General discussion on the merits of each application, initial rankings and cogent questions to ask each set of applicants, took place on the first of these days, with the collated questions being asked and the evaluations being finalised on, the second or third. This resulted in a consensus ranking of the submitted EoIs for each Call topic. The results of these evaluations will be communicated to the Applicant Consortia in May 2013, concluding Stage 1 of the 8<sup>th</sup> Call.

## 2. Overall observations

Stage 1 evaluations were in the view of both Observers, conducted professionally, fairly and with commitment from all participants, ensuring an impartial and thoughtful evaluation of all EoIs. The publishing and publicising of the call by the IMI team appears adequate in view of the number of EoIs received on each Topic. Each EoI appeared to attempt to adhere closely to the demands of the Call. As in previous Calls, the IMI Team organised the EoI submission and evaluation process with skill and finesse. Highly professional and well qualified professionals were contacted to conduct the evaluations, and take part in the onsite evaluation meetings.

Onsite briefings for Evaluators took place on the first day of each of the five groups of evaluators convening, with an overview of the process and the obligations of both the evaluators and the IMI Team as a whole, being set out clearly by Professor Michel Goldman, Executive Director of IMI. The on-site evaluation and review process was conducted in accordance with the plan set out at the start of the week, and all Panels for the five topics ran smoothly in line with the pre-defined Agenda. Meetings were moderated by IMI Scientific Officers.

In our opinion:

- There were no violations against the rules of the published evaluation guidelines.
- Independent experts were of a high quality and possessed expertise relevant for the evaluation of each topic.
- Evaluation of the proposals, panel discussions and questioning of the applicants, were fair and transparent.
- A consensus was reached by the independent experts on the scoring and ranking of all proposals.
- 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 improve the Stage 1 process for future Calls. These are described in detail in Section 4.

### **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 1 evaluation process and attended singly and jointly, all five days of the briefing and evaluation sessions, Panel discussions and tele-conferences held at the Crowne Plaza meeting rooms in Brussels 9-12 April

2013. We spoke individually with many of the evaluators, EFPIA representatives 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.

#### **4. Observations and recommendations**

The following sections record our observations on the Stage 1 evaluation process, collate comments we received from participants over the five days of the meeting and give some recommendations and suggestions for modifications we feel could further improve the process for future Calls. Designated as “Recommendations A, B, C...etc...” these observations and recommendations should be read against the background of the general comments given above under Section 2. Our overall opinion is that the evaluation process was carefully and fairly implemented, of excellent quality and conformed to International standards of peer review.

##### **4.1 The Call**

The length of time between launch, the 17<sup>th</sup> December 2012 and the deadline for the submission of Expressions of Interest (EoI) on the 19<sup>th</sup> March 2013 was in line with that of previous Calls. Given the diverse topics being considered under this Call, the workload upon the Executive Office in collaborating with the applicants convening the Experts / EFPIA representatives and arranging the five separate meetings within the same week, was considerable. As stated above, the arrangements and execution of the evaluations were expertly undertaken. There was though due to the Calls for EoIs taking place over the Christmas and New Year period perhaps unnecessary pressure upon the IMI-JU Team due to many of the Consortia not being in a position to focus on the needs of the Call until the second week of January. This may have effectively given many applicants and potential applicants, only just over 8 weeks to consider and write their EoIs.

**RECOMMENDATION A:** It is recommended that the IMI-JU consider not launching a Call(s) over an extended holiday period to allow a realistic length of time for applicants and potential applicants to consider their response and write their EoIs. A possibility exists that potential applicants may not have been in a position as of the 19<sup>th</sup> March to submit an application.

It was noted that under Topic B of Developing an Aetiology based Taxonomy of Human Disease - Approaches to develop a new classification for neurodegenerative disorders with a focus on Alzheimer’s disease (AD) and Parkinson’s disease (PD), some overlap may have occurred in the stated needs of this Call and the focus and objectives of the IMI’s European Medical Information Framework (EMIF).

The EMIF project aims are to:

“... develop a common information framework of patient-level data that will link up and facilitate access to diverse medical and research data sources...” ( <http://www.imi.europa.eu/listpdf/389> )

With a start date of October 2012 and extending over 5 years, Alzheimer’s Disease is together with other causes of dementia, one of the Framework’s two key research areas.

One of the expected key deliverables of Topic B is for development of “...standardised and harmonised databases and biobanks for data-mining from the whole bio-medical community.”

This topic, like EMIF, will extend over a 5 year period.

Given the considerable sums involved in both projects, consideration should be given to ensuring that no calls have objectives / key deliverables which may potentially give rise to competing interests for either the Commission / EFPIA Members or / and raise the issue of potentially funding similar areas of research twice.

**RECOMMENDATION B:** Summaries should be provided to the independent experts by the IMI JU of those Projects so far approved under the IMI process and include the Project's key objectives and deliverables. The summaries should also, where applicable, highlight areas where a project's objectives and deliverables potentially overlap with those of other IMI / Commission funded research and / or impending Calls.

**RECOMMENDATION C:** Prior to a Call being approved under the IMI process, the objectives / deliverables for that Call should be reviewed by a Panel independent of either the IMI-JU or EFPIA Members. The Panel should ensure that where a potential overlap in those objectives / deliverables exists, the overlap is minimal or justifiable based on different research outcomes or negligible / minimal additional cost.

## **4.2 Guidance to applicants**

Most applicant Consortia had, in the opinion of the evaluation panels attempted to adhere closely to the demands of the Call, though as in previous Calls, a small number of Consortia had submitted proposals that were only partially in scope.

## **4.3 Expert evaluation panels**

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

Panel members appeared 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 each of the Topic meetings.

The five scientific Expert Panel discussions consisted of:

- 1) Each panel member including the EFPIA representatives for each Topic being invited by the IMI Chairperson, to introduce themselves.
- 2) The EFPIA Coordinators and/or the Deputy Coordinators were provided with an opportunity at the beginning of each individual topic plenary session, to detail the requirements of the Topic and to describe how the EFPIA representatives had approached their own separate EoI evaluation, scoring and ranking process. The scores provided by the EFPIA Members did not contribute to the final consensus evaluation scoring which helped rank the EoIs.
- 3) A specific explanation on how the texts of the Calls were developed and the vision behind them was not provided. This allowed ground for free interpretation by the Evaluators or more frequently, for guided clarifications to be given by the EFPIA coordinators present at the Panel meetings. Though this is an asset in the proceedings, special care has to be taken that information given in this way, may not be perceived as being linked, to a preferred EoI proposal.

The concept of joint development with Industry and the role of the EFPIA representatives as

Evaluators in the 1<sup>st</sup> stage and the development of Full Applications during the 2<sup>nd</sup> stage were well understood by all Evaluators.

- 4) The Rapporteur responsible for the writing of the Consensus evaluation report and appointed prior to the meeting, was invited to briefly describe the key points of the EoI and any concerns and observations he / she had as to the proposal.
- 5) Other Panel members were then invited in turn to give their views on the EoI and if any issues might benefit from additional information from the Consortia members. The EFPIA representatives made active contributions to the discussions (see also point 3 for further comments).

A series of questions were collated and ranked separately for each Topic in order of importance. In some instances the set of questions were specifically prepared for each EoI, though in others the expert evaluators decided on a basic set of common questions for all EoIs with additional questions for individual EoIs.

- 6) Top ranked EoI Consortia were invited after they were sent the collated questions, to answer the questions in a pre-arranged telecom with the Panel, IMI moderator, Members of the IMI Executive Office and EFPIA representatives.
- 7) The independent experts then finalised their recommendations and the consensus evaluation report, based on the earlier discussion and answers provided by the Consortia Proposers.

All Experts brought considerable knowledge and understanding of the issues to the Panel evaluations. Nevertheless we would like to stress as it was done in the 7th IMI Call Observer's Report for Stage 1, that Evaluators from outside the EU may not have as good an understanding as EU-based Evaluators, of the EU "environment", how the public health systems work or the key stakeholders involved. Some additional education or background should be required for Evaluators from outside of Europe, and additional measures considered to ensure where relevant, the participation of Evaluators from a range of Global areas (for instance a greater participation from Asian countries). All reviewers took an active role in the preliminary discussions and the drafting of the collated questions prior to the hearings. The IMI moderator and wider on site Secretariat, gave considerable support to both the review Committee as a whole and the Rapporteur specifically.

One question that was, and has previously been raised in prior Calls, was the ability to invite applicants or groups from one EoI to join a second EoI positioned further up the rankings. This applicant may not have addressed the Call fully or failed to gain the support of the Evaluation Committee as a whole, but may still have an individual idea or attribute which would complement a lead Proposal. It is recognised that inviting an Applicant on this basis would currently be regarded as "cherry-picking". Given the need though to find solutions with limited resources and budget, the IMI is asked to consider if an approach to an applicant or group from a second EoI, might be possible if they were already ruled out of consideration for the Call on the basis of their own proposal.

This issue of "cherry-picking", was also considered by the Independent Observers of the 7<sup>th</sup> IMI Call. The Report mentions the practical problems that could arise if one specific key Organization has to be present / be invited into competing Consortia. The IMI JU is asked to consider the setting up of possible alternative scenarios for when such cases arise. Flexibility in including "non-traditional" or key participants where required, into a given Consortium may be necessary and important for the success of a given proposal.



**RECOMMENDATION D:** The IMI is asked to consider whether and how an applicant or group from a second EoI could be approached to join a lead consortium, if the applicant / group has been ruled out of the Call on the basis of their own proposal, but may offer a novel solution or attribute that could substantially enhance the lead EoI.

### 4.3.1 Hearings

The IMI JU rules state that a maximum of four of the top ranked proposals from the remote evaluation may be asked to take part in Hearings. Applicants were asked to answer specific and suitably detailed questions (maximum 5-7 questions per EoI) formulated by consensus from both the Independent Experts and EFPIA representative in each Panel.

Special care was taken in giving the same time allocation to each EoI for the hearing. The applicants received the questions the evening of the day before the Hearing, together with information on when they must be available for the Hearing itself.

The Hearing is a “question-answer” session: questions being read aloud by the IMI moderator (in order to maintain the anonymity of the Panel) with answers being given by the proponent(s). In several cases more than one person answered, depending on the question. Participants should be informed they will not receive any feedback from the Panel on their answers, and that they will have to judge that the information or clarification they provide, is sufficient.

Hearings have two advantages. They firstly provide information and obtain responses to comments raised by the Panel and secondly allow an opportunity to judge the “capacity” (leadership, flair) and personalities of the people leading the Proposal.

In spite of the full support that hearings have had from the Panels and from previous evaluations, the Observers would like to propose further actions for their improvement.

It was felt by some of the Evaluation Panels that an ability to share computer screens to allow better reference to figures and graphics would be a welcome additional support to aid discussion.

Also, it was noticed that during the discussion that followed the Hearings, that there were some discrepancies on what had been understood by some Evaluators, from the answer(s) given. In order to avoid / limit differing interpretations, a request is made to record the Hearings. This will enable the Panel a possibility of re-listening to what had been said by the proponent(s).

**RECOMMENDATION E:** The Executive Office is asked to consider whether use of technologies such as Microsoft’s “Live Meeting” would enhance the two-way discussion between the Evaluation Panels and EoI Proposers during Stage 1 Hearings. This would change the format of the meeting, and allow a more balanced and insightful two-way discussion.

**RECOMMENDATION F:** The Executive Office is asked to consider gaining permission from both parties to record the Hearings. This would allow a faithful account of the answers to be made available for the following Panel discussion.

**RECOMMENDATION G:** The Executive Office is asked to provide more information on the Hearing process itself to the proponents, (eg the fixed time, the Procedure, that the Hearing has an “exam-like” format, and that they cannot expect any interaction with the Panel). This information will allow for better preparation by the applicants.

## 4.4 Timelines

### 4.4.1 Timelines for evaluation of Expressions of Interest

The time allotted for remote evaluation of the EoIs, appeared adequate, though consideration should as stipulated above, be given to the timing of the Call to ensure all potential applicants are in a position to submit an EoI.

#### **4.5 Role of the EFPIA coordinators and deputy coordinators**

It was noted that EFPIA had fully engaged with the evaluation process and Panel discussions, with the Coordinator and Deputy Coordinators attending the meetings often being substantive stakeholders in the respective Call topic. It is important that the EFPIA representatives are of sufficient seniority and experience to be able to clearly articulate the rationale behind the Call (i.e. the question to be answered) as well as command the respect of the Expert Panel.

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

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

The moderating Scientific Officers were given considerable support by other Members of the IMI Executive office. A dedicated IT officer and two lawyers were available throughout the sessions. These arrangements must be mandatory for all Panels.

This difficult role was done with tact, professionalism and impartiality. Where needed, advice was given on process and compliance with regulations. No issues arose concerning the moderation or direction of the Evaluation Teams, which given the complexity and number of Topics, was a huge compliment to the skill of the individuals.

#### **4.7 Choice of Rapporteur**

The Rapporteur for each EoI was an Expert Evaluator chosen to present the EoI to the Evaluation Panel and then act as the primary scribe for the writing of the consensus evaluation Report for that EoI. This is an important role, with a direct impact on the discussions in the Panels and the feedback given to the applicant Consortia. The assignment of a Rapporteur also helps to streamline the process and brings focus to the Evaluator group.

Rapporteurs were, as in previous Calls pre-assigned prior to arriving in Brussels, in principle giving them time to prepare for this role.

#### **4.8 Remote Evaluation**

The expert evaluation panels had approximately two weeks to evaluate the EoIs remotely. This process worked well with the Evaluators providing full reports prior to the "face-to-face" meeting on the 9-12<sup>th</sup> April. When some of the Independent Evaluators were not able to be present at the evaluation sessions in Brussels, their comments were readily available to everyone and the Scientific Officer made ensured they were taken into account through the discussions. In the case of one Panel, a single Member from the USA participated remotely. The communication through a phone call was not optimal and since this Evaluator followed only day 2 of the discussion, it was not felt to be optimal, producing delays. It is noted though that this situation was unexpected and the IMI Team had little opportunity to prepare for this eventuality. In general, no problems were reported in the viewing of the EoIs, the supporting IMI Guidance or the subsequent uploading of the independent reviewer's reports.

#### **4.9 The Evaluation Tool**

The online submission and evaluation system, SOFIA functioned well during both the remote evaluation and the writing / uploading of the Consensus Reports.

#### **4.10 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:** It is recommended that the IMI-JU consider not launching a Call(s) over an extended holiday period to allow a realistic length of time for applicants and potential applicants to consider their response and write their EoIs. A possibility exists that potential applicants may not have been in a position as of the 19<sup>th</sup> March to submit an application.

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**RECOMMENDATION E:** The Executive office is asked to consider whether use of technologies such as Microsoft's "Live Meeting" would enhance the two-way discussion between the Evaluation Panels and EoI Proposers during Stage 1 Hearings. This would change the format of the meeting, and allow a more balanced and insightful two-way discussion.

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#### **5 Acknowledgements**

We were helped in our task by all participants in the Stage 1 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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