

Report of the Independent Expert Panel

Accompanying the Commission report

Assessment of European Innovative Medicines Initiative 2

A Joint Technology Initiative Under Horizon 2020

23 December 2012

The views expressed in this report are the sole responsibility of the authors and do not necessarily reflect the views of the European Commission.

## **List of acronyms used in the document**

COM	European Commission
EFPIA	European Federation of Pharmaceutical Industries and Associations
EoI	Expression of Interest
EU	European Union
IMI	Innovative Medicines Initiative
IMI2	The proposed new IMI under the Horizon 2020
IP	Intellectual Property
IPR	Intellectual Property Rights
JTI	Joint Technology Initiative
JU	Joint Undertaking
PPP	Public Private Partnership
RDG	EFPIA Research Directors Group
SME	Small and Medium Seized Enterprise
SRA	Strategic Research Agenda

## Executive Summary - The Panel's Recommendations

### 1. **IMI is a success. It is working and should be continued with an enlarged scope.**

Whereas the funding activities of the current IMI will not be concluded until 2014 and the IMI JU project execution will run through December 2017, results generated to date provide evidence that:

- IMI-funded projects have already achieved and demonstrated scientific excellence,
- IMI-funded projects are effectively addressing key challenges and barriers in the field of biomedical research and development,
- IMI's operational implementation has significantly improved over the past years, although further improvements are still possible and desirable.

The Panel supports the creation of IMI2 which should build upon the lessons learned from the current IMI and have an extended scope in order to even more effectively address the societal challenges of health, demographic change and wellbeing.

### 2. **The new and broader IMI2 should encompass streamlined governance structure and flexible implementation, consistent with the concepts of trust, openness and transparency.**

In order to maximise the impact of the initiative and increase participation from various stakeholders, the Panel advocates for simplification of the administrative procedures, and stresses that IMI2 should rely on:

- simplifying financing and project management mechanisms,
- pushing decision-making down the organization - all the way to project team leaders and project managers, when appropriate,
- maintaining its current flexible (case specific) approach to managing IPR.

### 3. **The Strategic Research Agenda (SRA) should be developed in an inclusive manner but remain the responsibility of the Research Directors Group (RDG).**

The primary focus of the SRA should remain on addressing the bottlenecks in biomedical research and development in order to deliver new solutions to the health problems of Europe. Development of the SRA scope and priorities should be transparent and include a broad group of stakeholders. Extra efforts should be made to encourage SMEs and non-EFPIA organizations to contribute. Nonetheless, the RDG must maintain ownership of the SRA.

### 4. **IMI2 should further enhance its communications.**

Effective, pro-active communications are essential to assure that all stakeholders have a correct understanding of various aspects of the new PPP. This is especially true for any derogation from the general legal framework of Horizon 2020 or differences from other JUs. The IMI Office should establish a help-function for Project Team Leaders, Project Managers and PPP-Management to fully understand and use EC regulations appropriately, effectively addressing problems as they may arise.

External IMI communications should also be further enhanced. Based on a wider dissemination of the results and benefits of IMI-funded projects, the external communication policy should notably stress the European added value and the high-level societal and economic impact of the projects.

### 5. **IMI2 should pursue more active involvement of SMEs and non-EFPIA entities.**

IMI currently has a relatively good level of SME participation. However, IMI2 should go farther to increase their effective involvement by addressing the unique needs of SMEs. IMI should provide a forum where EFPIA members can give guidance to SMEs as to where they see unmet needs and where SMEs can alert EFPIA companies to new opportunities. This is especially important for new and converging technologies.

More active participation from non-EFPIA entities should also be pursued in the context of IMI2. With the expansion of IMI's scope, the IMI2 Board should seek to actively engage non-EFPIA companies of key importance in biomedical research and development enabling them to contribute in cash and/or in-kind to IMI2 projects.

## Introduction

An independent expert panel (hereon referred to as the Panel) was appointed in 2012 to assist the European Commission (EC) in conducting an impact assessment on launching a European Public-Private Partnership (PPP) in life science research – the Innovative Medicines Initiative 2 (IMI2). Established under Horizon 2020 with the aim to contribute to Europe 2020 objectives of smart, sustainable and inclusive growth and to tackle the societal challenges of health, demographic change and wellbeing, this PPP would be a successor programme to the Innovative Medicines Initiative (IMI).

Established in 2007 as a €2 billion Joint Undertaking (JU) between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), IMI is Europe's largest PPP in health research. It aims to speed up the development of better and safer medicines for patients. IMI funding activities will be concluded by 2014 and the IMI JU by 31 December 2017.

This report summarises the key recommendations formulated by the Panel.

### **1. IMI is a success. It is working and should be continued with an enlarged scope.**

The Panel concludes that, even though further improvements are still possible, results to date show that IMI is already a success. It has achieved and demonstrated scientific excellence and is effectively addressing key challenges and barriers in biomedical research and development. Worldwide, IMI is by far the most important PPP in the field of medicine and is starting to benefit many of the European stakeholders through innovative novel partnerships. IMI is an example of Europe taking the lead in creating an ecosystem where new innovative and unprecedented large-scale and ambitious partnerships are developed. The initiative should therefore be continued. The recommended way forward is to launch a successor programme with an extended scope - IMI2 - building upon the successes and lessons learned from the current IMI.

#### **1.1. IMI scientific excellence and positive impacts**

IMI is still a relatively recent initiative with its first call for proposals published in April 2008 and the latest 8<sup>th</sup> call in December 2012. As such, IMI projects are still at early stages with 14 out of the 37 current active IMI projects launched after January 1, 2011.

Nevertheless IMI-funded projects have already achieved a high level of scientific excellence. A bibliometric analysis of on-going projects shows that IMI projects' publication output has been constantly increasing since 2009 and has reached 214 publications by August 2012. Considering that typically more than 50% of the publication output of health research projects is published after the end of the project, IMI's publication output is expected to continue rising as IMI projects yield new results. More than 80% of IMI publications to date appeared in well-regarded journals ranked in the top-quartile in their respective fields, while the average citation impact for IMI-funded project research (1.34) was above the world (1) and European (1.14) citation average in similar fields. This is indicative of the scientific excellence of research conducted in IMI projects.

An analysis by the IMI JU Executive Office of the key barriers in biomedical research and development addressed by IMI projects further shows that IMI successfully contributes in shaping the necessary ecosystem around pharmaceutical companies to optimize the drug development process in Europe. IMI projects notably contribute to: better exploiting and

pooling of existing data from various sources for novel analyses; eliminating inefficient preclinical models and establishing robust validated models for drug development; more effective approaches to predict adverse drug effects and prevent late attrition, discussed at early stages with regulators; joint development and regulatory submission of key standards for drug development; identification of new drug targets; development of novel biomarkers; more efficient patient enrolment in clinical trials; faster and cheaper clinical trials.

Stakeholder feedback confirms this along with other achievements. A Stakeholder Workshop (hereon referred to as SME Workshop) with Small and Medium Sized Enterprises (SMEs) held in 2012 concluded that the IMI PPP allowed them to achieve results that would not be possible without such partnership. In a European Commission survey on IMI project participants' perspective of IMI (hereon referred to as the "COM survey of IMI participants") conducted in 2012, 55% of the respondents indicated that IMI funding has been critical to achieve 75% or more of the project objectives. Furthermore 35% of the survey respondents reported that IMI funding facilitated access to other funds - thereby illustrating the IMI leverage effect.

In addition, based on the COM survey of IMI participants it is estimated that about 1 500 jobs have already been created by IMI projects. While this is expected to increase throughout the life span of those projects, this already represents one job created for every €200 000 of public funding invested in IMI. In comparison, health research projects funded under the 6<sup>th</sup> and 7<sup>th</sup> EU Framework Programmes have resulted in 1 job created for every €400 000 of public funding invested.

These positive outcomes stem from the successful implementation of IMI as an innovative cooperation platform. An online public consultation carried out in 2012 by the European Commission on the need and specificities for a new PPP in life science research and the SME Workshop both stressed that IMI facilitated bringing different stakeholders together. Similarly, the bibliometric analysis showed that co-authorship among researchers from different sectors accounted for 40% of all co-authorship of IMI project publications. These findings highlight IMI's success in breaking down traditional barriers and facilitating large-scale collaboration among public and private partners.

### **1.2. Improvements in IMI operational implementation**

The success of the current initiative partly depends on a significant improvement of the operational implementation of IMI that has been achieved since the launch of the PPP in 2008. Around 65% of the respondents to the COM survey of IMI participants indicated that the administrative load related to IMI was similar or lower than in other EU-funded programmes. Delegates to the SME workshop acknowledged that IMI's administrative burden was lower compared to other international research initiatives in this field. In this context, 73% of the respondents to the COM survey of IMI participants confirmed that they were likely to reapply to IMI calls.

Nevertheless room for improvement in the implementation of the IMI programme still exists. IMI participants are still not fully satisfied with the administration of the grant by the IMI office and the time to grant (17% and 25% of the respondents, respectively). The participants of the SME Workshop raised concerns about the administrative and cost burdens associated with audits, which are difficult to bear for SMEs.

### 1.3. IMI2 - Continuation with an expanded scope

As a result of its success, with the funding activities of the IMI to be concluded by 2014, the Panel recommends establishing a successor programme – the IMI2. This new PPP should draw upon the successes and lessons learned from the current IMI. However, in accordance with the conclusions of the IMI public and stakeholders consultations, the Panel recommends expanding the scope of the new PPP and increasing its budget. This would ensure that IMI2 effectively covers changing research landscapes and new opportunities arising from convergence with medical sciences and emergence of new technologies.

The Panel recommends this option as the most effective way to address challenges in life science research and development. It will ensure the sustainability of the IMI achievements and generate a critical mass of results needed to contribute to overcoming societal challenges in health. It will continue to shape a collaborative ecosystem in life science research needed for optimising the drug discovery and development process in Europe.

This expanded scope should strengthen and empower the translational process in life science research by pooling together various expertise and resources. To monitor this impact, the current IMI Key Performance Indicators (KPI) should be complemented with a results-based set of indicators. These metrics could include among others: measures of transfer of know-how and experience in translational research; reliable disease model standardisation showing a reduction in cost and lower redundancy in pre-clinical work; lower use of animals in experiments due to introducing EMA endorsed, standardised in vitro methods; improved reproducibility in model biology; shared data sets and information on safety of molecules and placebo data from clinical trials; reduced cost of drug development and improved success rates in clinical trials.

## 2. The new and broader IMI2 should encompass streamlined governance structure and flexible implementation, consistent with the concepts of trust, openness and transparency.

In order to maximise the impact of the initiative and increase participation from various stakeholders, the Panel advocates for simplification of the administrative procedures and stresses that IMI2 should rely on: simplifying financing and project management mechanisms, pushing decision-making down the organization and maintaining its current flexible (case specific) approach to managing IPR.

### 2.1. Simplifying financing and project management

According to the stakeholders participating in IMI, the new PPP should rely on simplified administrative and financial arrangements. Various key stakeholder groups called for the implementation of simplified procedures maximising the impact and attractiveness of IMI2. A consensus on this issue was evident in the conclusions of the SMEs Workshop, in the EFPIA proposal for a biomedical research PPP under Horizon 2020 (hereon referred to as the EFPIA proposal) and in the online public consultations. Here the Panel provides examples of such simplified procedures:

- Establishing mechanisms for conditional extension of high-impact IMI funded projects and high potential projects initiated under IMI2, i.e. allowing for the expansion of scope, budget and timeline of successful projects.

- Introducing the possibility for IMI2 to finance more than one consortium in the same program, i.e. enabling several projects in parallel to compete in reaching a desired, specific milestone.
- Enabling mergers of consortia, i.e. empowering IMI2 evaluators to suggest, when appropriate, merging two entire consortia or parts of them (i.e. integrating the most competitive elements of a runner-up project into the winning proposal).

## **2.2. Pushing the decision-making down the organisation**

This simplification of IMI2 procedures should rely on streamlined governance structures. Building upon the structures put in place under the current IMI, such streamlining would result in avoiding unnecessary, complicated and time-consuming decision-making processes. In accordance with the stakeholder consultations and the EFPIA proposal, the Panel recommends decentralisation of the IMI2 operational decision-making processes. Based on the concept of trust, operational decision-making related to project management should be delegated to the appropriate operational level.

## **2.3. Maintain the IMI flexible Intellectual Property policy**

The Panel recommends maintaining the current IMI Intellectual Property (IP) policy in IMI2, recognising that the IMI IP policy shows remarkable flexibility in meeting the needs of all partners in IMI projects. The Panel acknowledges that some respondents to the online public consultation have expressed concerns about some aspects of the IP policy. Such comments from respondents who have not (yet) participated in IMI projects however reveal an important perception issue related to the IM IP policy, as no evidence of major specific problems was obtained from IMI project participants.

As highlighted in the conclusions of the SME Workshop, the need for simplification of IMI administrative arrangements has to be balanced with the complexity of large projects and the development of agreements suitable for all partners, including the IPR. The current IMI IP policy evolved after very extensive discussions among all relevant stakeholders, guided by significant legal expertise. The Panel is therefore of the opinion that reopening negotiations at this stage is unlikely to generate modifications better satisfying all interested parties in IMI2, while significantly delaying the launch of IMI2.

However the Panel expects the relevant experts within IMI2-organizational entity to keep the IPR Policy current with any unique issues associated with the SRA, such as policy guidance related to rights to foreground patient samples, patients records, changes in patent law and social-ethical issues which are likely to be increasingly important parts of new proposals.

## **3. The Strategic Research Agenda (SRA) should be developed in an inclusive manner but remain the responsibility of the EFPIA Research Directors Group (RDG).**

The primary focus of the SRA should remain on addressing the bottlenecks in biomedical research and development in order to deliver new solutions to the health problems of Europe. Development of the SRA scope and priorities should be transparent and include a broad group of stakeholders. Extra efforts should be made to encourage SMEs and non-EFPIA organizations to contribute.

### **3.1. Focus**

In accordance with the conclusions of the online public consultation and the EFPIA proposal, the Panel recommends that the primary focus of the SRA should remain on addressing the bottlenecks in biomedical research and development that hamper the delivery of new cost effective solutions to unmet medical needs of society. Societal challenges such as those derived from the evolution of the age structure of the EU population are key factors in the growing public health and economic burden of chronic diseases and other medical conditions. The development of innovative medicines remains essential for progress in the prevention and treatment of human diseases.

However, the biotechnology and pharmaceutical sectors are struggling to advance promising ideas and candidate products to the market to address these unmet medical needs. This situation stems from technical barriers such as the lack of a coherent and comprehensive molecular taxonomy of disease, inaccurate target validation, inefficient conduct of clinical trials, complex and outdated regulatory processes and requirements, poor predictive capacity of early stage safety models, etc. To maximise the impact of IMI2, its SRA should focus on those barriers and face the overall challenge of incorporating novel technologies in bringing innovative diagnostics and interventions to patients.

### **3.2. Stakeholder involvement**

Effectively addressing these bottlenecks and the expansion of the scope of IMI2 both require inclusion of additional stakeholders into the formulation of the SRA. In line with the conclusions of the SME Workshop and the online public consultation, the Panel recommends ensuring the involvement in this process of all relevant stakeholders in biomedical research and development ecosystem.

Pricing and reimbursement decisions are key factors driving the introduction of new medical interventions and treatments on the market. Therefore, along with other key stakeholders, the active participation of the private and public health insurance sectors, health technology assessment authorities, health economists, healthcare providers, and patient groups would be notably of key importance to ensure that the SRA effectively identifies and addresses the unmet medical needs of European citizens. This broad and active participation would benefit all stakeholders, as it would improve the knowledge within the ecosystem on the entire process of biomedical research and development leading to introduction of new products and services.

Within the scope of this increased stakeholder involvement, additional efforts should be made to encourage SMEs to participate in this process. Improved SME involvement in the development of the SRA would contribute to increasing SME participation in IMI2, as their priorities would be better aligned with the related Expression of Interest and individual calls.

### **3.3. RDG responsibility**

At the same time, the involvement of a boarder range of stakeholders should not result in a dilution of responsibilities and ownership over the SRA, as such dilution could jeopardise the effective implementation of IMI2. In this respect, the Panel recommends that the final ownership and responsibility for the SRA continues to lie with the RDG and that the IMI2

Board holds the RDG accountable for designing and implementing the SRA through the IMI2 organization.

With a greater number and more diverse set of stakeholders involved in IMI2, developing and refreshing the SRA will be more complex. Each IMI2-organizational entity (to be established in the governance structure) will have a role to play. This complexity makes it imperative for the roles and responsibilities of the various entities to be clear, open and transparent.

#### **4. IMI2 should further enhance its communications.**

Effective, pro-active communications are essential to assure that all stakeholders have a correct understanding of various aspects of the new PPP. This is especially true for any derogation from the general legal framework of Horizon 2020 or differences from other JUs. The IMI Office should establish a help-function for Project Team Leaders, Project Managers and PPP-Management to fully understand and use EU regulations appropriately, effectively addressing problems as they may arise.

External IMI communications should also be further enhanced. Based on a wider dissemination of the results and benefits of IMI-funded projects, the external communication policy should notably stress the European added value and the high-level societal and economic impact of the initiative.

##### **4.1. Improve the level of understanding on the functioning of the PPP**

A review of the stratified data of the COM survey of IMI participants demonstrates that the level of communication, targeted information, training and tangible support provided to participants are determinant factors for the effective participation of SMEs in IMI projects. Similarly, the conclusions of the COM survey of IMI participants show that stakeholders could benefit from further support to deal with the relative complexity of the financing and administrative arrangements. The Panel therefore recommends more effort to increase the level of stakeholder understanding of the IMI2 IPR, and any derogations from the Horizon 2020 general rules.

Based on the model of the current IMI IP helpdesk, an additional helpdesk function should be implemented to assist project team leaders, project managers and PPP-management in understanding and applying Horizon 2020 general rules and any derogation to address their needs.

##### **4.2. Implement a broader dissemination policy**

While the bibliometric analysis shows that most of the IMI dissemination is done through scientific journals, the Panel recommends that IMI2 communication policy ensures a wider and more pro-active dissemination of the results and benefits of IMI-funded projects. The COM survey of IMI participants also pinpoints the need and added value of extending communication policy beyond scientific publications and internal dissemination channels within project consortia. For instance, creation and implementation of a simple access mechanism to relevant IMI2 project results and the translation of IMI2 key communications in multiple languages would contribute to reaching out to a broader range of various interest groups and end users in all Member and Associated States.

#### **4.3. Better communicate on the high-level societal and economic impact**

The Panel also recommends that the enhanced communication policy targets the high-level societal and economic impact of IMI2 projects. It is essential to demonstrate the impact and added value of IMI2 for the society beyond scientific excellence. Such communication policy should notably rely on KPIs, with metrics other than typical scientific output and performance indicators, which enable monitoring the European added value of IMI2 and its contribution to addressing the unmet medical needs of European citizens.

#### **5. IMI2 should pursue more active involvement of SMEs and non-EFPIA entities.**

IMI currently has a relatively good level of SME participation. However IMI2 should go farther to increase their effective involvement by addressing the unique needs of SMEs. IMI should provide a forum where EFPIA members can give guidance to SMEs as to where they see unmet needs and where SMEs can alert EFPIA companies to new opportunities. This is especially important for new and converging technologies.

More active participation from non-EFPIA entities should also be pursued in the context of IMI2. With the expansion of IMI's scope, the IMI2 Board should seek to actively engage non-EFPIA companies of key importance in biomedical research and development enabling them to contribute in cash and/or in kind to IMI2 projects. This is especially so for companies with diagnostic expertise, both large and small, which are crucial for the identification of patients for the innovative new therapies.

##### **5.1. SMEs participation in IMI: state of play and added value**

In the last five IMI calls SMEs accounted for 14.8% of all participants while receiving 22.1% of the financial contribution. Such participation in this collaborative platform yields positive impact on European SME activities. It allows SMEs to focus their activities on areas identified by large pharmaceutical companies as of added value. This focus not only generates commercial opportunities for SMEs but also improves their contribution to the development of an ecosystem in life science research optimising drug development process in Europe.

Therefore, within the scope of IMI2, efforts (e.g., IMI's role as an "honest broker") that have proved effective to support SME participation should be maintained. Those efforts could also go farther to improve and make the most out of SME participation in such an initiative. This would be in line with the conclusions of the online public consultation with 76% of the respondents calling upon the new PPP in life science research to ensure better involvement of SMEs than in the current IMI.

##### **5.2. Possibilities for further improvements**

Improvement of SME participation could be achieved by addressing their unique needs. Such possibilities include reducing the time-to-fund SMEs, further reducing administrative burden, improving recruitment of low-visibility SMEs into consortia, enabling the inclusion of strong elements of competing consortia and considering funding a portfolio of smaller projects. Additional mechanisms could also support improved participation from SMEs such as funding competing projects working towards the same key milestone, providing a flexible reserve fund at the project level to rapidly engage SMEs to solve unexpected problems or overcome bottlenecks faced during project execution.

Furthermore, IMI2 could operate as a neutral forum where EFPIA members can give guidance to SMEs as to where they see unmet medical needs as well as commercial interest and where SMEs can alert EFPIA companies to new opportunities. This is especially important for new and emerging technologies.

### **5.3. Improved participation of non-EFPIA entities**

As it is suggested to expand the scope of the initiative and in line with the objective of shaping an effective ecosystem in life science research to optimise the drug development process in Europe, the Panel stresses the importance of involving entities and stakeholders who are not members of EFPIA. This improved participation of non-EFPIA entities in IMI2 would ensure that important stakeholders in biomedical research and development are involved and contribute to this collaborative effort. As such, the Panel recommends that the IMI2 Board engage with non-EFPIA entities and seek their active participation in this new PPP, including enabling them to contribute in-kind and/or financially to IMI2 activities and individual projects.

## Annex 1 – Composition of the independent expert panel

The panel was composed of five members chosen from different areas of expertise in biopharmaceutical and life science research to contribute and support the preparation of the Commission ex-ante impact assessment report accompanying the Commission proposal for the setting up of an innovative health research public-private partnership (IMI2 PPP) in innovative medicines between the European Union and partners from health-related industries.

The members of the panel were:

- Fred Gvillo, Chairperson. Currently manager of Eyrie, LLC, F. Gvillo has more than 30-years experience in various functions at biotech and pharmaceutical companies, including Johnson & Johnson, Genentech, and 6-years as Head of Corporate Research Administration and Planning at Schering AG, Berlin, Germany.
- Maria Aguirre, PhD, MBA, BioBasque Agency Manager. After an initial research career in UK, M. Aguirre has held different positions in biotechnological, pharmaceutical and consulting companies in France and Spain. In 2001, she led the design of the strategy for life sciences development in the Basque Country, for the Basque Government, and since 2003 she manages the BioBasque Agency, charged with the life sciences strategy implementation.
- Jonathan Knowles, PhD, Professor of Translational Medicine, Ecole Fédérale Polytechnique de Lausanne. J. Knowles also holds a distinguished professorship in personalised healthcare at the Finnish Institute for Molecular Medicine at the University of Helsinki and has been appointed as a visiting chair at the University of Oxford. J. Knowles has held several senior positions in academia and the pharmaceutical industry, including president of group research for the Roche Group, and board member and chair of the corporate governance committee at Genentech.
- Nabil Safrany, rapporteur. N. Safrany is consultant for the European Centre for Disease Prevention and Control and has experience in impact assessment, programme evaluation and monitoring, and programme management in the field of public health.
- Marcin Szumowski, PhD, MBA, business development manager, BioTechMed Cluster Mazovia. Following a successful research career in the United States of America, M. Szumowski has been involved in technology transfer and start-up companies since 2000 and has co-founded and managed three start-ups. He is currently responsible for developing a technology transfer platform for a consortium consisting of three universities and seven Polish Academy of Science Institutes, executing a €100Million Centre for Preclinical Research and Technology project.

## Annex 2 - Terms of Reference and proceedings of the independent expert panel

The task of the expert panel was to assist the Commission services in drafting the report “Assessment of European Public-Private Partnership in life science research”. This task involved the following work performed by the experts:

- Reading and analysing the reference and supporting documents;
- Interpreting the results and analysing the achievements of the Innovative Medicines Initiative Public-Private Partnership;
- Reviewing the conclusions of the stakeholder consultations, drawing conclusions, participating actively in the scheduled meetings.

The experts performed their task between 1 October and 31 December 2012. The table below lists the meetings held by the Panel during this period.

	Date	Place	Participants	Objective
1	26 Sept 2012	Commission Brussels, Belgium	F. Gvillo, M. Aguirre, N. Safrany, M. Szumowski, E. Nimmesgern (RTD) and A. Mialhe (RTD)	Introductory meeting, discussion of the objectives and scope of the IAR
2	10 Oct. 2012	European Commission Brussels, Belgium	F. Gvillo, M. Aguirre, J. Knowles, N. Safrany, M. Szumowski, E. Nimmesgern (RTD) and A. Mialhe (RTD)	Set the stage of the exercise and provide the experts with the necessary information.
3	5 Oct 2012	Teleconference	F. Gvillo, M. Aguirre, J. Knowles, M. Szumowski and E. Nimmesgern (RTD)	Take stock of the work performed and identify gaps in the evidence base for the impact assessment.
4	16 Oct. 2012	European Commission Brussels, Belgium	F. Gvillo, M. Aguirre, J. Knowles, N. Safrany, M. Szumowski, E. Nimmesgern (RTD) and R. Draghia-Akli (RTD)	Take stock of the work performed and identify gaps in the evidence base for the impact assessment.
5	15 Nov. 2012	European Commission Brussels, Belgium	F. Gvillo, M. Aguirre, J. Knowles, N. Safrany, M. Szumowski, E. Nimmesgern (RTD) and R. D’Amario (RTD)	Wrap up the exercise and prepare the drafting of the expert panel report.
6	13 Dec. 2012	Teleconference	F. Gvillo, M. Aguirre, J. Knowles, N. Safrany, M. Szumowski and E. Nimmesgern (RTD)	Review of the draft expert panel report.
7	19 Dec. 2012	Teleconference	F. Gvillo, M. Aguirre, N. Safrany, M. Szumowski and E. Nimmesgern (RTD)	Finalisation of the expert panel report.

The independent expert panel delivered its final report on 23 December 2012.

### Annex 3 - List of references reviewed by the Panel

In the implementation of its tasks, the Panel reviewed the following documents:

- EFPIA, Proposal for a biomedical research public private partnership under Horizon 2020, 18 June 2012
- European Commission, Impact Assessment of the Innovative Medicine Initiative, IMI, IMI project participants' perspective, October 2012
- European Commission, Results from the EC public consultation about plans for a PPP in life sciences research and innovation under Horizon 2020, November 2012
- European Commission, Roadmap – Public Private Partnership in Innovative Medicines between the EU and partners from health-related industries to be established under Horizon 2020, September 2012
- Executive Office of the President of the United States of America – President’s Council of Advisors on Science and Technology, Report to the President on propelling innovation in drug discovery, development and evaluation, September 2012
- IMI Executive Office, Bibliometric analysis of on-going projects: IMI – JU (prepared by Thomas Reuters on behalf of IMI Executive Office), October 2012
- IMI Executive Office, Clarification Note – IMI IP Policy
- IMI Executive Office, Guidance Note – IMI IP Policy, November 2010
- IMI Executive Office, IMI IP Policy, August 2007
- IMI Executive Office, Periodic report, section 3: summary of major achievements and key dissemination activities, KPI, 2012
- IMI Executive Office, Report of the Stakeholder workshop with SME and ME addressing PPP in innovative health research under Horizon 2020, 19 September 2012
- IMI Executive Office, The Innovative Medicines Initiative: building the case for PPP to foster healthcare progress, August 2012
- JTI Sherpa Group, Designing together the ‘ideal house’ for public-private partnerships in European research, January 2010
- M. Goldman *et al*, The Innovative Medicines Initiative: building the case for PPP to foster healthcare progress, Expert Reviews Pharmacoecon. Outcomes Res. 12 (5), 2012
- Numerous other issue specific scientific publications, conference presentations and materials and data available in the public domain.

In accordance with its Terms of References, the Panel commented on and contributed to the preparation and drafting of the following documents:

- European Commission, Assessment of European Public-Private Partnership in life science research
- European Commission, Impact Assessment of the Innovative Medicine Initiative, IMI, IMI project participants' perspective, October 2012
- European Commission, Results from the EC public consultation about plans for a PPP in life sciences research and innovation under Horizon 2020, November 2012