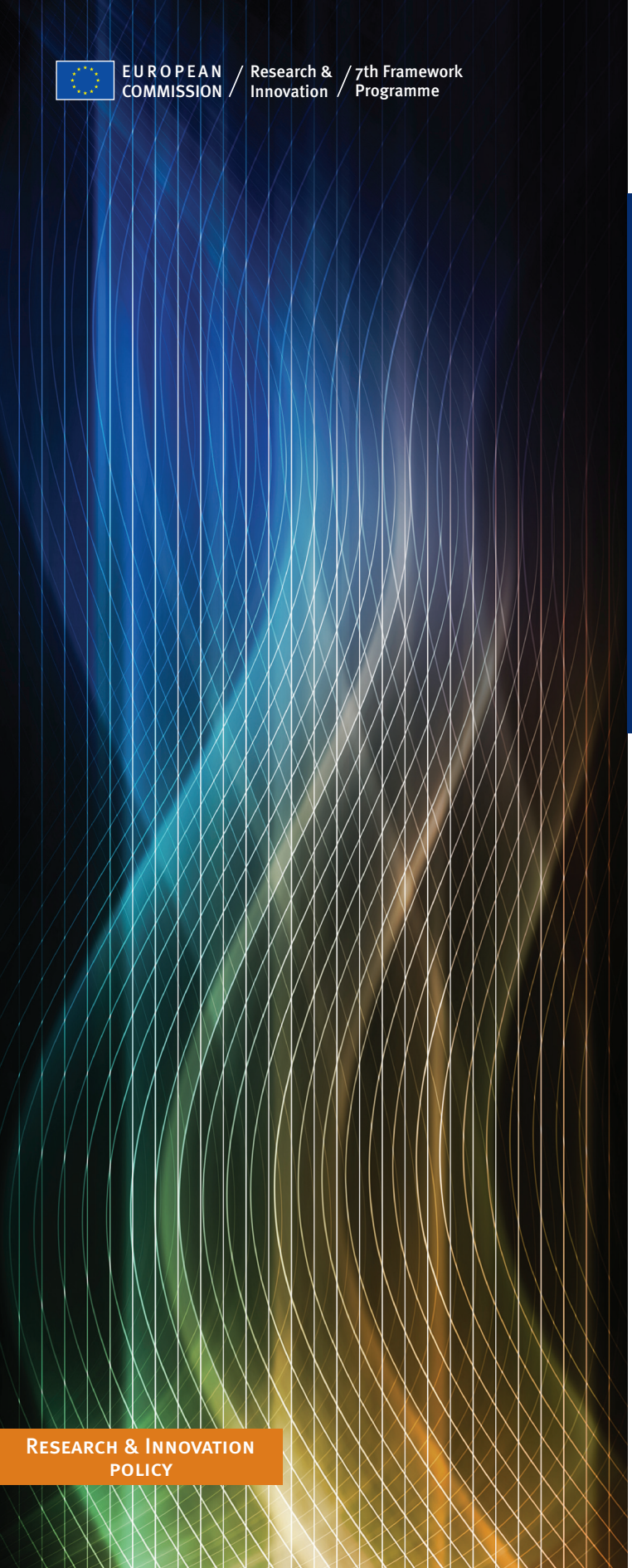


First Interim Evaluation of the Innovative Medicines Initiative Joint Undertaking

Panel report

EUROPEAN COMMISSION

Directorate-General for Research and Innovation
Directorate F – Health
Unit F.2 – Medical Research

E-mail: infodesk@imi.europa.eu

Contact: Elmar Nimmesgern

European Commission
Office CDMA 02/011
B-1049 Brussels

Tel. +32 2 29 55785
Fax +32 2 29 55385
E-mail: elmar.nimmesgern@ec.europa.eu

EUROPEAN COMMISSION

First Interim Evaluation of the Innovative Medicines Initiative Joint Undertaking

Panel Report

Fred Gvillo, Chair
Magdalene Rosenmöller, Rapporteur

Tom Andersen
Manfred Horvat
Ruth Keir
Bart Wijnberg

Directorate-General for Research and Innovation
Medical Research – Innovative Medicines Initiative

2011

EUROPE DIRECT is a service to help you find answers

to your questions about the European Union

Freephone number (*):

00 800 6 7 8 9 10 11

(*) Certain mobile telephone operators do not allow access to 00 800 numbers or these calls may be billed

Cataloguing data can be found at the end of this publication.

Luxembourg: Publications Office of the European Union, 2011

ISBN 978-92-79-20505-7
doi 10.2777/65341

Executive Summary

The overall result of the evaluation of the Innovative Medicines Initiative Joint Undertaking (IMI JU) performed by a Panel of independent experts is positive.

The IMI JU's objective is to address the bottlenecks currently limiting the efficiency, effectiveness and quality of the drug development activities needed to bring innovative medicines to the market. Through the IMI JU, Europe has succeeded in establishing a new business model between public and private sectors, which unites research strengths across European pharmaceutical industry, academia and small to medium enterprises (SMEs). The consortia formed carry out focussed research addressing problems of immediate relevance to industry and future public health. To have formed and embedded this new, applied, research environment is a significant achievement for Europe.

The IMI JU's development has been meaningfully enhanced by its engagement with the regulatory authorities and patients organisations. To have succeeded here is rare, and taken together with the scale of interest of research organisations, is a tremendous illustration of Europe's strengths in creating consensus and collaboration.

By facilitating enhanced cooperation between academic, SMEs, patients organisations, regulatory authorities and the pharmaceutical industry, the IMI JU enables mutual learning and the opportunity to build understanding of respective rationales and approaches, with benefits to all parties. This is powerful. Although at a relatively early stage, the dialogue now underway across the participating groups aligns well with the IMI JU's intent.

The scientific scope of the initiative is well targeted, embodied in the IMI Research Agenda, and the IMI JU has had the foresight to ensure that the Research Agenda is updated regularly. The first such review and update was on-going at the time of the Panel's review. The financial resources available to the IMI JU, totalling €2Bn, make this the largest public private partnership in health research in the world. Yet the research challenges to be addressed with this sum are significant. The Panel was satisfied that the funding is being distributed adequately to help reach the objectives set and also saw appropriate consideration being given to the scope and scale of future projects to best achieve impact from the finite research funding.

IMI constitutes a novel model for implementing the concept of "open innovation". No other European programme has enabled cross-company collaboration within the pharmaceutical sector on the scale that has been achieved with IMI. This step is very important in developing open innovation in the health sector as it has enabled an unprecedented pooling of industrial research assets allowing scientific challenges to be tackled in a manner that

could not be done otherwise. In many respects the IMI JU is an incubator for changing minds on how parties can work together across traditional boundaries and is therefore likely to have an important structuring effect in Europe, fully in line with the Innovation Union objectives.

Despite the great strides that have been made in fostering open innovation through IMI, the Panel heard evidence that the IMI framework is not satisfactory for all research actors, particularly where the funding reimbursement is considered not to be adequate or where sharing of intellectual property as contemplated within IMI JU is perceived to limit future business or research opportunities. These are important issues, not least because they have the potential to limit or tarnish the successes of the IMI JU.

The IMI JU is now at the stage of implementing its third annual research call. Its Executive Office is not yet fully staffed, but within this limitation is providing necessary support to the programme. Taking the learning from the programme to date, the Panel sees benefit in refining certain aspects of governance to maximise the alignment across the JU Governing Board, Scientific Committee, Executive Office and external advisory bodies.

In achieving its progress to date, the IMI JU has attracted positive interest from prominent organisations based outside of Europe. This augurs well for the IMI JU's prospects for developing into a major flagship in life sciences research worldwide. The assessment of the IMI JU by the Panel is summarised in a SWOT analysis, which details IMI strengths, weaknesses, opportunities and threats. On that basis, the Panel considers that the IMI JU has good prospects for reaching its objectives. It has the necessary tools at its disposal to work in an efficient way and appears to support high-quality research.

However, the Panel wishes to emphasise that following its start-up phase, the IMI JU should now work on its consolidation, a prerequisite condition for its sustainability.

Having identified many positive points, the Panel also identified certain weaknesses:

- Internal governance structures are not yet working optimally: e.g. pace of decision making, clarity on responsibilities for key actions, crispness in assignment of accountability for tasks;
- Proactive communication activities have been lacking, as exemplified by the diffuse and varied understanding various stakeholders have of the purpose of IMI;
- The advisory potential of several stakeholders, such the European Medicines Agency (EMA), is not exploited fully by the IMI JU;

- The lack of identified and used key performance indicators by the IMI JU risks making the output of the whole initiative diffuse.

The Panel therefore came up with seven recommendations summarised below. Each is associated with a precise set of actions detailed in the report:

Recommendation 1. Continuously improve stakeholder involvement in IMI-supported research projects

Engagement across stakeholders in IMI should be further developed. Project participation would be broadened if perceptions of imbalance in the incentives available for SMEs, universities and research organisations were addressed. This must be achieved without losing the engagement of EFPIA organisations. In this regard, issues related to negotiation of intellectual property, reimbursement of indirect costs, and industry in kind contribution must be quickly and adequately addressed. The IMI JU should envision cooperation with non-EU stakeholders.

Recommendation 2. Continuously ensure EFPIA and Commission commitment to IMI's success and sustainability

Continuous, adequate commitment of both the Commission and EFPIA to IMI is necessary to ensure IMI's success and sustainability. The consensus strategy driven by industry in the interest of public health is a unique strength of IMI. It requires industry to better develop its leadership responsibilities and to consolidate its commitment towards IMI. On the Commission side, lessons learnt for the "ideal house" of public private partnerships (see "Sherpa report") should serve the future of IMI and be crucial for other similar initiatives in the future.

Recommendation 3. Ensure excellence and exploit new ways to support IMI scientific objectives.

With the focus on good science to address drug development bottlenecks being the main priority of the IMI JU, the review of the IMI Research Agenda must have high priority and requires industry leadership in collaboration with other stakeholders. The IMI JU needs to consider new ways to better sustain the aims of the IMI Research Agenda.

Recommendation 4. Improve IMI communication

The understanding of IMI's purpose is still scattered and diffuse among various stakeholders, three years following the IMI JU legal set up. The underlying

concepts of "*pre-competitive research*" or "*open innovation*" have also shown a lack of clarity among stakeholders. These issues need to be addressed urgently.

Recommendation 5. Reinforce and streamline decision making and well-functioning processes

There is a need for clarification of the remits of all parties in the IMI structure, defining responsibilities and room for action and decision making. This is exemplified by the disparate views and opinions heard regarding which party is responsible for specific tasks relating to the first update of the IMI Research Agenda.

Recommendation 6. Ensure best use of IMI results and IMI sustainability

IMI should develop a sound long-term strategy towards knowledge management and learning processes in order to ensure best use of results and sustainability of the IMI concept.

Recommendation 7. Develop monitoring and evaluation processes

There is a need to develop sound monitoring and evaluation processes, to generate the indicators and evidence needed to strengthen IMI's capabilities for monitoring of projects and taking strategic decisions. The results should be measured regularly and accountability for results should be ensured.

Index

1. Introduction

1.1. Objectives of the first Interim Evaluation of the IMI JU

The present report is the result of the work of the Independent Expert Group (hereinafter referred to as the "Panel"), set up to assist the Commission to carry out the first interim evaluation of the Innovative Medicines Initiative Joint Undertaking (IMI JU). The evaluation performed by the Panel is based on the Terms of Reference[1], defined by the European Commission after consultation of the IMI JU. Its objective was to assess the IMI JU against three criteria: the *quality* and *efficiency* of the IMI JU and its *progress towards the objectives set*.

This Panel report provides for the Commission a brief summary of the achievements of the IMI JU, a detailed assessment based on the three criteria, and finally, conclusions and recommendations.

1.2. Methodology of the first Interim Evaluation of the IMI JU

The Panel was composed of six individuals whose areas of expertise encompass the whole landscape of the pharmaceutical drug development process, as well as policy and management and evaluation issues. A short biographical sketch of the experts is presented in Annex 1[2].

The methodology followed by the Panel is based on the Terms of Reference, providing a set of predefined questions under the evaluation criteria (cf. Annex 2). The evaluation took place in the autumn of 2010 with a combination of remote work, conference calls and three Panel meetings in Brussels. The Panel built its assessment on (i) documents and other published information (see Annex 3 for the list of documents, most of them available on the IMI website[3]) and (ii) interviews with a wide range of IMI stakeholders, including representatives of both founding members, IMI bodies, participants of ongoing IMI-supported research projects, and representatives of regulatory bodies, patients organisations and research associations (see the list in Annex 4).

After the performance evaluation, a SWOT analysis (strengths, weaknesses, opportunities and threats) was performed to review findings and to develop sound recommendations.

[1] Terms of Reference, Clean Sky, FCH and IMI Joint Undertakings, 1st Interim Evaluation, European Commission, Brussels: 2010. *Note that there is a common framework between the three JUs, in order to provide coherence.*

[2] The views expressed by the independent experts do not represent the view of the respective institutions.

[3] IMI Europe – www.imi.europa.eu

2. IMI JU– Background and Implementation

2.1. IMI JU Legal Basis

The IMI JU is a Public Private Partnership between the European Union, represented by the Commission (public partner), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) (private partner). The IMI JU was set up by the *Council Regulation for the implementation of the Joint Technology Initiative (JTI) on Innovative Medicines*[4] on the basis of Article 187 of the TFEU[5]. The IMI JU is established under European Law until 31 December 2017. It is a Union Body, which became autonomous on 16 November 2009, meaning that it has now the operational capacity to implement its own budget. Before the autonomy, the Commission was responsible for the management of the IMI JU[6].

2.2. IMI JU Objectives

The IMI JU objective is to remove bottlenecks and significantly improve the efficiency, effectiveness and quality of the drug development process, with the long-term aim that the European pharmaceutical sector produces safe, effective, innovative medicines more rapidly. It also aims at stimulating investment in the biopharmaceutical sector in Europe in order to leverage research capabilities in a sector where the EU traditionally enjoys a comparatively strong position.

IMI is jointly and equally supported by resources from the European Union and from EFPIA together with its member companies. The maximum Union contribution is €1,000 million, covering research activities and running costs, paid from the appropriation in the general budget of the European Union allocated to the "Health" theme of the specific programme "Cooperation" implementing the Seventh Framework Programme (FP7). EFPIA provides monetary contributions to the IMI JU running costs, in an amount equal to the respective contribution by the Union. The pharmaceutical company members of EFPIA jointly fund the IMI research activities through non-monetary contributions ("in-kind contribution") at least equal to the financial contribution of the Union. Universities, research organisations, patients organisations, and small and medium enterprises (SMEs) are eligible for IMI JU financial support, while the pharmaceutical company members of EFPIA are not, and participate with their own resources (in-kind contribution) in the research projects.

[4] Council Regulation No 73/2008 (OJ L30 of 04.02.2008, p.38-51)

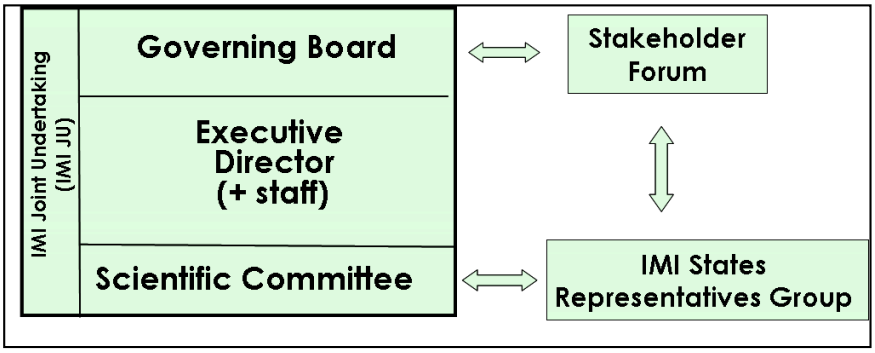
[5] TFEU: Treaty on the Functioning of the European Union; Article 187 (ex-Article 171 of the EC Treaty): The Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.

[6] Article 16 of the Council Regulation setting up the IMI JU

The IMI JU supports collaborative "*pre-competitive*" research projects, pooling resources from various stakeholders (industry, academia, SMEs, regulatory authorities, healthcare providers, patients organisations). The research projects flow from the framework of the IMI Research Agenda which is a multi-annual plan, derived from the Strategic Research Agenda, developed prior to the setting up of the IMI JU as an analysis of the bottlenecks affecting the development of safe innovative medicines. It focuses on four key research priorities: better prediction of *safety*, *efficacy* of new medicines, better *knowledge management*, and strengthened *education* and *training*. The yearly *IMI Annual Implementation Plans* define the yearly activities of the IMI JU. They include the annual scientific priorities, which are expected to be covered by specific topics published in open and competitive calls for proposals. The IMI Research Agenda is currently in a revision phase to ensure it accommodates relevant new learning that would influence the onward IMI JU research programme.

2.3. IMI JU Governance

The IMI JU is composed of three bodies (Governing Board, Scientific Committee, Executive Director) and is supported by two external advisory bodies (States Representatives Group, Stakeholders' Forum).



These bodies have been set up with the following functions:

Body	Function	Established
IMI JU Governing Board	Represents Commission and EFPIA. Overall responsibility for strategy and operations of the IMI JU	3 March 2008
IMI JU Executive Director	Legal representative and Chief Executive responsible for day-to-day management and activities. Total of 28 staff expected by 31 December 2010	Appointed 10 June 2008, took up duties 16 September 2009
IMI JU Scientific Committee	Advisory body (e.g. Research Agenda and Scientific Priorities)	21 November 2008
IMI States Representatives Group	Represents Member and Associated States. Advisory body (e.g. Research Agenda and Scientific Priorities) and interface between stakeholders and IMI JU	26 June 2008
IMI Stakeholders' Forum	Meeting open to all stakeholders	14-15 June 2010

In terms of governance documents, the IMI JU Governing Board also approved, amongst others: the IMI Research Agenda; the IMI Financial Rules; the IMI model Grant Agreement (including the IMI intellectual property policy); the IMI Internal Control Standards, the IMI Staff Policy Plans; the IMI Annual Implementation Plans 2008, 2009, 2010; the IMI Annual Activity Reports 2008 and 2009. The IMI JU is temporarily hosted at the Research Executive Agency (REA) in the Covent Garden building in Brussels together with the four other JTIs (ARTEMIS, ENIAC, Clean Sky and FCH).

2.4. Implementation of IMI JU Research Activities

Research activities are supported through research projects selected after open and competitive calls for proposals, including peer review evaluations. The IMI JU implemented a particular two-stage call process:

- in stage 1, applicant consortia (i.e. formed from academia, SMEs, patients organisations, regulatory), submit expressions of interest for joining a pre-established consortium of member companies of EFPIA (industry).

- in stage 2, the successful applicant consortium and the pre-established consortium of member companies of EFPIA (industry) are invited to develop and submit a full proposal.

Both stages 1 and 2 are peer reviewed by independent experts. The successful consortia conclude a Grant Agreement with the IMI JU and a Project Agreement between the participating parties of the project. The IMI JU is in charge of the follow up and monitoring of the projects, based on the provisions and modalities established in the Grant Agreement.

Between 2008 and 2010, the IMI JU has published three calls for proposals (for the call topics, see Annex 5). The first two calls for proposals have each attracted more than 1,000 legal entities from 20 different countries and more than 20 EFPIA pharmaceutical companies in each call. The two first calls have mobilised close to € 400 million nearly equally contributed by the IMI JU and EFPIA companies. The IMI JU is currently supporting 15 Grant Agreements (four in "*Safety*", seven in "*Efficacy*" and four in "*Education and Training*"), all resulting from the 1st Call for Proposals[7] (see Annex 6 for projects launched). Projects resulting from the 2nd Call for Proposals are currently under negotiation, with the Grant Agreements expected to be finalised and signed by Quarter 4 2010 or Quarter 1 2011 (see Annex 7 for call statistics).

The IMI 3rd Call for Proposals was launched on 22 October 2010.

2.5. IMI JU Communication

Communication of the IMI JU is facilitated by a well-designed web presence, a strong logo, and by events such as the Open Information Days held at the time of the publication of each call. The IMI JU has also organised several press events and has launched several press releases. It has presented its activities at national or international conferences.

[7] Call on IMI Page: www.imi.europa.eu/sites/default/files/uploads/documents/imi-1st-call-factsheets_en.pdf

3. Performance Assessment

This chapter will focus on what the IMI JU has achieved so far. As already stated in the Terms of Reference, this interim evaluation takes place at an early stage of the IMI JU, only three years after its legal set up and less than one year after it became an autonomous body, at a point in time when none of the research projects funded by the IMI JU has been completed and only a few projects have produced any outputs. Also, formal reporting and evaluation systems are not yet in place. Consequently, the Panel's assessment of effectiveness, efficiency and quality has utilised qualitative input in combination with quantitative information available in respect of the calls and their outcomes.

3.1. Is IMI Effective? – Progress towards objectives set

IMI's overall objective is to address bottlenecks in the development of safe and more effective innovative medicines by supporting research that is applicable to all pharmaceutical development organisations, in a manner that lifts overall European research performance. IMI builds on the European strengths and long-term experience in collaborative research which are core to the competitive advantage of Europe. The IMI JU is a public private partnership that is unique in scale and is already visible on the global stage.

Despite a somewhat cumbersome start-up process, IMI's progress in the short period of its existence has been remarkable. Setting up the IMI JU as a major European initiative in accordance with the TFEU and complex Community regulations is an achievement in itself, as is completing the parallel development of the legal and organisational framework and structures.

The IMI JU Office is now up and running as an autonomous organisation, taking on the duties assumed by the Commission during the start-up phase. Although its existence has been brief, most of the functions have been established. However, the office is overworked as the hiring process under the current staff regulations has been slower than desirable. Some functions remain to be developed or need to be improved: for example an IT system for monitoring performance indicators and for communication management is missing. A sound monitoring and evaluation system would allow basic key performance indicators to be tracked, as proposed in the IMI Impact Assessment [European Commission 2007] and this in turn would support IMI's sustainability.

The research projects from the first call are up and running, and working well. The projects related to the second call are in the negotiation phase, and the third call has been launched. The projects all address identified priorities of the

research agenda, and appear complementary to other FP7 life sciences activities, albeit with no defined process to ensure coordination.

IMI is expected to contribute to the development of a cross-sectoral life-sciences research community in Europe, thus contributing to the European Research Area and the Innovation Union. IMI has already succeeded in engaging a whole variety of stakeholders, and the resonance for those who are involved in projects is positive. By strengthening cooperation between academic research, SMEs and the pharmaceutical industry, IMI has an important "structuring" effect in Europe by providing a space for mutual learning and the opportunity to become familiar with the respective rationalities and approaches.

For the 1st call, 138 expressions of interest (EoI) were received for 18 topics (about 8 EoIs per topic) with 1294 participants from 36 countries. The 2nd call received 124 EoIs for 9 topics (averaging 14 EoIs per topic) with 1118 participants from 39 countries. Substantial interest has been shown in both IMI calls and it is not possible to conclude if the expressed interest could have been even higher or that interest has decreased from the first to the second call.

However, a set of open issues (intellectual property rules and the calculation of overheads) have clearly discouraged the participation of some potential participants from the SME, university and research and technology organisation sectors. The Panel is concerned that these issues have been left unresolved for too long and that communication with stakeholders has been less than optimal, causing unnecessary discord between IMI JU and relevant target groups. It appears that the issues are finally in the process of being resolved. Convincing evidence therefore has to be provided (e.g. 2nd clarification paper) that these issues have been sorted out satisfactorily. Targeted actions for "healing the wounds" would help to engage those disaffected parties who are currently sceptical of the value of participating in IMI projects.

In general, more could be done to raise awareness of IMI within the SME community in order to facilitate their participation. SME involvement in IMI is currently at a similar level to that seen in other FP7 programmes, but greater engagement could be fostered by reaching out to them more via the IMI JU Office or the IMI States Representative Group to improve SME awareness and understanding of the initiative and the opportunities it offers. A specific SME "helpdesk" within the IMI JU Office could also be a useful new facility. The returns on such a relatively modest "SME investment" are likely to be significant.

With increased impact from SME participation, the Panel would expect the IMI initiative to firmly underpin the sustainability of the Knowledge Economy in the EU. As one of the main initiatives focusing on a research-intensive segment,

IMI is of high importance in strengthening the competitiveness of the European Union.

Building on the interest and willingness of the regulatory authority EMA to engage with the programme would help maximise the potential effectiveness of IMI. Involvement of EMA is very positive and ensures that the qualification process and requirements are considered at an early stage (ideally, starting at the point of definition of call topics) raising the probability that the right studies and data will be provided from the projects.

All in all, the Panel is satisfied from the evidence available that the model on which IMI is based is effective and considers that IMI has the potential to develop into a global flagship for supporting industry-led practical research directed to improving the development of innovative medicines.

3.2. Is IMI Efficient?

In considering the efficient use of resources, two primary elements can be considered: governance structure and processes (including communication) and the use of funding (including dissemination and uptake of research outcomes).

The governance structure and processes have been implemented. However, the Panel notes that it is appropriate at this stage to clarify the remits and mandates of each element of the management structure and its members (the Board, the main partners – EPFIA, Commission – the IMI JU Executive Office and other stakeholders) to ensure that the processes of the IMI JU are as efficient as possible.

At Board level, the members should be empowered to make decisions directly, or where consultation with others is required, should utilise a mechanism that enables speedy closure of actions, decision making and related communication. Improved accountability for strategic actions by Board members is required to optimise efficiency, with concomitant clarity of ownership flowing to all relevant groups and individuals within the governance structure. This would, for example, reduce the administrative burden for the IMI JU Office, created by unresolved issues (such as the ones related to IP policy and overheads mentioned earlier) and remove ambiguity in responsibilities for items such as the update of the IMI Research Agenda.

Allowing the IMI JU Office to act more autonomously would also facilitate flexibility and speed of its action (e.g. with respect to staff recruitment, communication activities, implementation of monitoring and evaluation systems). Clarification of mandates would moreover aid smooth transition in the case of possible personnel changes within the main partners.

IMI appears to attract a lot of interest in the European research community, as demonstrated by the massive response to the calls. This is an achievement in

itself. IMI is also considered a very interesting initiative internationally. However, an enhanced communication strategy could draw-in additional potential applicants, such as patients organisations and particularly SMEs, where focused efforts could address their particular issues. It would also raise visibility with the public in general and further sensitise policy makers to the topic.

The Panel sees opportunities in making full use of all involved parties by exploiting the potential and preparedness to contribute of the States Representative Group and the Scientific Committee. Interaction with the two groups in respect of information sharing and timing of consultation seems to be less than optimal and consequently could be strengthened.

The IMI Research Agenda is industry-driven, and coordination between national programmes and FP7 is performed between the IMI JU, the European Commission and the States Representative Group. For the future development of IMI, increased emphasis on pro-active alignment would be beneficial, to identify and take advantage of related opportunities both up- and downstream from IMI at an early stage.

Due to the early stage of the research, it is difficult to comment objectively on the efficiency of the use of funding, but using the indicators from the "Quality" section (see below), this point does not give current cause for concern. The projects selected so far are all in accordance with the IMI Research Agenda but are mostly of a modest size. It would, therefore, be interesting to consider whether greater efficiency could be achieved through scale, potentially by implementing bigger projects of greater ambition while at the same time ensuring that resources are not diluted across too many participant parties. This concept was voiced by some stakeholders. In the Panel's opinion, this issue deserves further consideration based on appropriate ex-ante impact analyses, with the prerequisite that this should not jeopardise academic and SME participation.

Adapting the call procedures to accommodate a wider scope of the available scientific and industrial resources (for example, from non-SME/non-pharma organisations) could enhance efficiency. Similarly, mechanisms alternative to the current call process might provide a better approach for implementation of certain activities relating to education, training, knowledge capture and dissemination.

It is probably too early to judge knowledge management**,** as IMI is only exiting the start-up phase, but little evidence was found of active plans for the implementation of appropriate processes and infrastructure. These should allow for knowledge implementation and mutual learning, not only for the research outcomes but also for sharing of best practices developed in the different

projects (e.g. with respect to managing cross-border collaborative projects in a public private partnership setting such as IMI). Such learning will not only enhance the ongoing efficiency of IMI but will also be beneficial for similar undertakings in this and other fields in the future. Now would be an opportune moment to put these processes in place.

3.3. Is IMI of a High Quality?

At this interim point, before first results of the sponsored research emerge, the research quality can be assessed through leading indicators such as the massive response to the IMI calls; the outcomes of the scientifically rigorous evaluation and selection process and the positive reports from the Independent Observers of the evaluation exercise. These suggest high quality, as do the enthusiasm of the partners and the inherent potential of the projects' aims. However, for the future, it is of particular importance to establish objective indicators which assess and periodically monitor quality, linking shorter term outcome indicators to the longer term objectives of IMI, in order to maximise impact across research programmes. The quality of future calls will also be supported by rapid conclusion of the ongoing revision of the IMI Research Agenda. This should accommodate new learnings from pharma and preferably from other stakeholders, in particular the regulatory authority and the Scientific Committee. Further, it can be hypothesised that greater quality of research outcomes could be achieved with enhanced involvement of innovative SMEs in IMI projects.

Although IMI is still quite young, it seems to be already well placed to achieve flagship status, judging by the cross-Atlantic attention it attracts (for example, from the NIH and the FDA). It is important for the Board to consider if greater cooperation with global research capabilities (US and others) would further stimulate quality in the future.

4. SWOT – Analysis

To see the assessment in a wider, strategic context, the Panel preformed a SWOT analysis. A SWOT analysis is a strategic planning tool used to evaluate the Strengths, Weaknesses, Opportunities and Threats in a project or business venture, with the objective of identifying the internal and external factors that are favourable and unfavourable in order to achieve its objectives. It was used as a guidance to see how IMI could build on its strengths, address weaknesses, take advantage of opportunities and manage threats, and from this help to build conclusions and recommendations.

STRENGTHS	WEAKNESSES
• IMI has succeeded in creating a new and unique partnership between public and private sectors: industry led, with highly applied intent, based on EU core value of consensus building and collaboration; a remarkable achievement. • IMI's new business model enables access to otherwise hidden resources in the pharmaceutical area. • IMI's unique format has enabled broad engagement across the European life sciences sector, including academia, small and medium enterprises, regulators and patients organisations. The diversity of geographies of the involved institutions has also been strong. • Interest in project participation has been high, with calls being significantly oversubscribed. This is illustrated by the 8% success rate for applicants. • The quality of the projects developed from the calls has been high (as assessed by review bodies and participants) – both in terms of science and the institutions involved. • Implementing a legal and organisational framework and structure from scratch has been a significant task but is now fully operational. The hire of a permanent Executive Director in 2009 was a key event. The JU Executive Office is now handling calls effectively.	• Focus on developing key performance indicators has been limited to date. Little attention has been directed towards enabling an impact assessment of IMI (e.g. no pre/post EU life sciences environmental scan). • Internal governance structures are not yet working optimally: e.g. pace of decision making and action at Board and Executive Office level; clarity on responsibilities for key actions (e.g. update of Research Agenda) and crispness in assignment of accountability for tasks; no risk management procedures. The mandates of the Board, Executive Office, Scientific Committee and States Representatives Group should be reviewed to drive efficiency. • Executive Office's lack of autonomy is limiting efficiency. The slow pace of recruitment to bring staffing to the levels needed is one example. Greater creativity of thought could be brought to filling staffing gaps. • Proactive communication activities have been lacking, in volume, impact and content. Because of its importance communication has in the understanding of IMI in the broader stakeholder communities and IMI branding, this is a critical gap that must be filled. • To date, there has been limited engagement with, or communication to, policy makers. • The minimal involvement of some participants within individual consortia makes their impact questionable. Consideration should be given to balancing

- Support by the founding partners (IMI JU Board) is at an appropriately high level, as exemplified by the appointment of an EFPIA company CEO. This illustrates the high level of engagement with, and visibility of, IMI within the participating pharmaceutical companies.
- The more industrial perspective of IMI JU projects means it has the potential to complement other FP7 health research activities.
- IMI has the potential to change the way research is carried out globally, not just in Europe, as exemplified by the interest shown by external agencies, such as FDA and NIH.

the desire to broaden engagement across organisations with the scale required from each participant to deliver value.

OPPORTUNITIES

- IMI can be used to aid positioning of Europe as "pharmaceutical-sector friendly".
- IMI is one of few research models that has succeeded in building appropriate links with the regulators. The regulators are willing to be engaged further and IMI should harness this to maximise the impact of research outcomes.
- IMI has the opportunity to synergise its research programme with others supported at national level. The States Representatives Group could facilitate potential coordination with complementary national programmes. This could harness the additional scientific excellence seen in the quality consortia that could not been funded through IMI (the "great losers") to the greater benefit of the health sector. Other ways to drive complementarities would be to seek to harness structural funds available at national, EU level or with other institutions such as the EIB.
- Drawing on the learning of the initial calls, IMI now has the ability to elevate its impact by addressing bigger topics (in ambition, scale) also including a greater diversity of organisations e.g. the non-SME/non-pharmaceutical life sciences sector.

THREATS

- Delay in answering stakeholders' concerns related to some financial provisions, such as the reimbursement of indirect costs, may affect their participation to IMI projects.
- The general economic downturn places tension on all finance resources – IMI cannot consider itself to be immune from this and must continue to drive – and, importantly, demonstrate – value from the Founders' investments.
- Mergers and acquisitions continue to be a feature of the pharmaceutical industry landscape, and subsequent integration activities could divert attention of senior EFPIA staff, potentially displacing key scientists and affect IMI's "organisational memory". Continuous effort may be required by IMI to minimise impact on the resources (e.g. people, data) directed to IMI within the pharmaceutical companies.
- The pace of science change continues to accelerate, and IMI will need to ensure it can be sufficiently nimble to adapt to breaking science.
- Misgivings of some stakeholders due to various perceptions around the negotiation of intellectual property rights can jeopardise IMI's credibility.
- The IMI "brand" can be severely damaged by bad press. To counter this, IMI will need appropriate communication mechanisms which provide proactive good news flow,

- As ambitions develop to move into bigger projects, consideration will be required to ensure the IMI business model is robust for all groups.
- Building on the experience of successful initial projects, IMI has the opportunity to place itself in the context of other patient-centric topics, demonstrating how it fits into a holistic approach to patient issues.
- IMI has the potential to change the way research is carried out globally, not just in Europe. It has already drawn interest from FDA and NIH – it has the opportunity to build on these links and with others in different regions. Similarly, IMI now has the opportunity to consider how to pull in non-EU based pharmaceutical resources into the programme. Each of these activities would facilitate IMI positioning as a global flagship research programme.
- IMI could further broaden its reach by a deeper collaboration with the IMI States Representative Group to reach out to high quality scientists, particularly in the SME sector where IMI is less well known or understood.
- The rise in use of social networks provides a new route to disseminate information relating to IMI and its successes to all stakeholder groups.

and if needed rapidly address any negative press.

- If bigger projects are developed under IMI, consideration will be needed to ensure that the university/SME sectors will be able to participate without being swamped by big pharmaceutical companies in such "think big" projects.
- Limited resources are in place to ensure sustainability.

5. Conclusions and Recommendations

IMI has achieved a lot in a very short time. Building on its strengths, the basis for a robust public private partnership has been laid out. The following observations and recommendations are to guide IMI in the process from the 'set-up' to the consolidation phase, preparing for a sustainable future.

5.1. What is working well and should not be changed

The observations made support the Panel's conclusions that IMI is a unique new business model with a high potential to achieve applied, impactful, outcomes from the research programmes it supports. In particular:

- The formation of the IMI JU as a major European initiative is an achievement in itself. Creating an environment for new types of research projects while developing in parallel the legal, organisational framework is a remarkable feat.
- IMI is a great *model of public and private partnership* (1:1 funding), starting from and building on the European strength of "collaborative research".
- The scale achieved by IMI is also a *unique* major achievement: enabling multiple pharmaceutical players to work together and trans-nationally with a wide range of universities, research institutions, patients organisations and SMEs. Joining forces and overcoming research 'silos' enables complex issues to be addressed in a manner that could not be achieved by one party alone.
- The structured programme between academic research, SMEs, patients organisations and the pharmaceutical industry provides space for mutual learning and the opportunity to gain understanding of the respective approaches. As such, IMI is an incubator for changing mind sets and enriching the intellectual capacity of Europe.
- By coupling the *industry-driven* agenda with a well-developed call process, the research carried out under IMI is being seen to address real challenges in a high quality manner. The focus on innovative, outcomes-oriented research is an important characteristic of IMI and its consensus approach is an important strength.
- The involvement of the European Medicines Agency (EMA) is a special asset, ensuring that the qualification process and requirements are considered at an early stage.

- As a new model for "Open Innovation", IMI has attracted interest from various organisations around the world. This confirms the visibility of IMI JU on the global stage and its potential to develop as a flagship for collaborative research.
- IMI's progress to date shows it is also participating in the generation of a life sciences research community in Europe – thereby contributing to the creation of the European Research Area and the Innovation Union that will have an important "structuring" effect in Europe.

5.2. Recommendations for action: how to make IMI better.

The Panel formulated a series of recommendations for action from its observations. These will help IMI to build on its strengths, address weaknesses, minimise the impact of potential threats and turn them into opportunities. Also, they guide IMI in managing towards consolidation and a sustainable future. This will support IMI in turning all its opportunities into concrete achievements.

The actor(s) who should take responsibility for implementing the elements of each recommendation is highlighted in **bold**.

Recommendation 1. Continuously improve stakeholder involvement in IMI-supported research projects

Engagement across stakeholders in IMI should be further developed. Project participation would be broadened if perceptions of imbalance in the incentives available for SMEs, universities and research organisations were addressed. This must be achieved without losing the engagement of EFPIA organisations. In this regard, issues related to the negotiation of intellectual property rights, reimbursement of indirect costs, and industry in kind contribution must be quickly and adequately addressed. The IMI JU should envision cooperation with non-EU stakeholders.

In particular, the Panel recommends:

1.1. The participation of *SMEs* could be greatly improved by partnering with the SME umbrella organisations and other means of reaching them. A specific SME help-desk function should be set up to support SMEs in establishing new consortia and in finding ways to build mutual trust among SME, corporate industry and academia.

IMI Executive Director

1.2. *Universities, Research* O*rganisations and SMEs* have concerns with the implementation of the IMI Intellectual Property Policy. The IMI JU should implement a "mediator" function to address specific issues arising in negotiations of intellectual property issues and should collect best practices gained from experiences in the earlier calls for proposals. It is also necessary to adequately address the problem created by the current financial policy for the reimbursement of indirect costs as this may jeopardise academic participation in IMI.

IMI JU Board, IMI Executive Director

1.3. The *Pharmaceutical Industry (EFPIA companies)* is global and *EFPIA* has the concern that its non-EU resources cannot be adequately mobilised to support IMI research projects. IMI should reflect on how to best account for resources contributed by EFPIA from locations outside of Europe and also learn from other public private partnerships.

IMI JU Board

1.4. The participation of *Patients Organisations* could be further enhanced; building on the good experiences resulting from their involvement in current IMI supported projects. Those projects including patients organisations should share their experience with a larger population of patients organisations and ensure that, where appropriate, the patient perspective receives sufficient attention.

IMI Executive Director

Recommendation 2. Continuously ensure EFPIA and Commission commitment to IMI's success and sustainability

Continuous, adequate commitment of both the Commission and EFPIA to IMI is necessary to ensure IMI's success and sustainability. The consensus strategy driven by industry in the interest of public health is a unique strength of IMI. It requires industry to better develop its leadership responsibilities and to consolidate its commitment towards IMI. On the Commission side, lessons learnt for the "ideal house" of public private partnerships (see "Sherpa report") should serve the future of IMI and be crucial for other similar initiatives in the future.

In particular, the Panel recommends:

2.1. Make sure that *enough staff are dedicated in each Founding Member* to support the IMI JU in resolving operational issues.

EFPIA, European Commission

2.2. EFPIA must take a more vigorous leadership role, show strong commitment and ownership and realise its responsibilities in the successful implementation of the IMI Research Agenda.

EFPIA

2.3. The *European Commission would benefit from a more risk-tolerant and trust-based approach*, in line with the Conclusions of the Competitiveness Council of 3 December 2009. The bureaucracy necessary to run initiatives such as IMI must be appropriate to enable more rapid decision-making and action

European Commission

2.4. The *European Commission* should draw attention to the possibility of setting up public private partnerships as a "*special body"*. This should be considered in the course of the revision of the Financial Regulation.

European Commission

Recommendation 3. Continue to ensure excellence and exploit new ways to support IMI scientific objectives.

With the focus on good science to address drug development bottlenecks being the main priority of the IMI JU, the review of the IMI Research Agenda must have high priority and requires industry leadership in collaboration with other stakeholders. The IMI JU needs to consider new ways to better sustain the aims of the IMI Research Agenda.
In particular, the Panel recommends:

3.1. Further strengthening and deepening the consultation with the regulators, in particular with the European Medicines Agency, in updating the IMI Research Agenda, developing calls for proposals, and where appropriate in evaluating those proposals. Likewise, their regular contacts with ongoing IMI research projects should be encouraged.

IMI JU Executive Director

3.2. The potential of the *IMI JU Scientific Committee* and of the *IMI States Representatives Group*, and their preparedness to contribute should be exploited as far as possible for the benefit of IMI. Trust in IMI is growing and must be nurtured through more frequent and timely communication. This will favour better access to the different expertise available in existing national initiatives and facilitate the identification of best-in-class research organisations.

IMI JU Board

3.3. The scope and relevance of calls could be increased, where "*think big*" means addressing more ambitious projects with increased funding, compared to current project patterns, to ensure success and impact. Clustering related project ideas could also be an option. Bigger scale does not necessarily imply more participants, and should not jeopardise academic and SME participation.

IMI JU Board

3.4. *Reflect on the involvement of industries that converge* with traditional pharmaceuticals, such as electronics, imaging and medical devices.

IMI JU Board

Recommendation 4. Improve IMI communication

The understanding of IMI's purpose is still scattered and diffuse among various stakeholders, three years following the IMI JU legal set up. The underlying concepts of "*pre-competitive research*" or "*open innovation*" have also shown a lack of clarity among stakeholders. These issues need to be addressed urgently.

In particular, the Panel recommends:

4.1. Develop a *common corporate identity*, a shared understanding of IMI and of its purpose (IMI "brand").

IMI JU Board, IMI JU Executive Director

4.2. Develop more pro-active communication activities. This is particularly important to more effectively address stakeholders concerns, such as those outlined in Recommendation 1.

IMI JU Board, IMI JU Executive Director

4.3. Improve IMI visibility and the *communication of IMI goals to all stakeholders*, conveying the message that IMI is a new model of doing research and not merely a new source of funding.

IMI JU Board, IMI JU Executive Director

4.4. Develop a clear strategy on how best to *disseminate results*.

IMI JU Board, IMI JU Executive Director

Recommendation 5. Reinforce and streamline decision-making and well-functioning processes

There is a need for clarification of the remits of all parties in the IMI structure, defining responsibilities and room for action and decision making. This is exemplified by the disparate views and opinions heard regarding which party is responsible for specific tasks relating to the first update of the IMI Research Agenda.

In particular, the Panel recommends:

5.1. The *IMI JU Board* needs to take more ownership in focusing on strategic issues, and in clarifying the remits of each party. This is particularly important for the update of the IMI Research Agenda, where the role of the Scientific Committee should be kept in mind[8].

IMI JU Board

5.2. The IMI JU Board needs to be empowered to take quicker decisions, particularly in response to stakeholders concerns raised in Recommendation 1.

IMI JU Board

5.3. More *autonomy* should be given to the IMI JU Executive Office to deal with operational issues – based on trust and delegation, keeping the administrative burden to the minimum that is possible under the current regulatory framework.

European Commission, IMI JU Board

5.4. The *recruitment process* needs to be accelerated to ensure full functioning of the IMI JU Executive Office. Staffing issues need to be resolved quickly, and staff capacity set at an adequate level, particularly in view of upcoming calls. The current staff regulations are limiting in these respects.

IMI JU Board, IMI JU Executive Director

Recommendation 6. Ensure best use of IMI results and IMI sustainability

IMI should develop a sound long-term strategy towards knowledge management and learning processes in order to ensure best use of results and sustainability of the IMI concept.

In particular, the Panel recommends:

6.1. Establish *knowledge management processes* with a clear concept for sustainable knowledge capture, sharing and learning, especially in areas such as management of transborder collaborative projects.

IMI JU Board

6.2. Consider *how to realise value from excellent, but ultimately unfunded, proposals* submitted to IMI by networking and knowledge management.

IMI JU Board

[8] Article 7 of the IMI JU Statutes

6.3. Foster *knowledge sharing and learning* between the projects: share best practices in managing these projects/consortia, enable continuous improvement and realisation of synergies, and contribute to IMI's corporate memory.

IMI JU Board

6.4. In the mid- and long-term, the IMI JU should position itself as a flagship in the coordination of pharmaceutical research, and as a unique business model embracing the concept of 'open innovation'.

IMI JU Board

6.5. As a centre of excellence for pharmaceutical collaborative research, IMI serves as an incubator for building entrepreneurial capacity, supporting the development of start-ups by linking new businesses to a network of potential corporate partners. This can potentially lead to equity investments by corporate partners and business angels. Loan funding from sources such as the European Investment Bank is then possible. The IMI JU Board should consider how best to sustain this support for creating new businesses.

IMI JU Board

Recommendation 7. Develop Monitoring and Evaluation Processes

There is a need to develop sound *monitoring and evaluation processes* to generate the indicators and evidence needed to strengthen IMI's capabilities for monitoring of projects and taking strategic decisions. The results should be measured regularly and accountability for results should be ensured.

In particular, the Panel recommends:

7.1. Adopt *shared metrics for key performance indicators* building on those proposed in the IMI Impact Assessment [European Commission 2007], and complemented as needed.

IMI JU Executive Director

7.2. Develop *a tracking system* to provide better information and indicators to provide evidence to promote IMI and its success stories at the political and public level, showing the added values for different stakeholders.

IMI JU Executive Director

7.3. Regularly perform a SWOT analysis and prepare measures to ensure long-term sustainability

IMI JU Executive Director

Annexes

Annex 1 Composition of the Expert Evaluation Panel

Fred Gvillo	(*Chair*)	Eagle Eyrie Consulting (*Chair*)
Magdalene Rosenmöller	(*Rapporteur*)	IESE Business School
Tom Andersen		European Investment Bank
Manfred Horvat	*(JU Evaluator)*	Vienna University of Technology
Ruth Keir		Archea Ltd
Bart Wijnberg		formerly Ministry of Health, Welfare and Sport, Netherlands

Fred Gvillo (Chair) (US) specialises in optimising biotechnology R&D operations and integrations following a merger or acquisition. Fred's career has spanned a variety of roles at Schering AG, Codon, Genentech, and Johnson & Johnson.

Magdalene Rosenmöller (*Rapporteur*) (D), professor at IESE Business School, is involved in research and health policy issues at European and global level, and an expert in management of innovation in the health sector. She served as rapporteur for the Innovative Medicines Initiative (IMI) social and economic impact assessment in 2007.

Tom Andersen (DK) is Deputy Economic Advisor at the European Investment Bank specialised in assessing economic viability of R&D projects and project finance operations in the pharmaceutical and chemical sectors. Previously, Tom worked on acquisition and divestitures within an industrial conglomerate and for Novo Nordisk, an EU-based pharmaceutical company, evaluating and reporting on developments of its drug discovery and corporate development arm.

Manfred Horvat (A) Honorary professor for European and International Research and Technology Cooperation at Vienna University of Technology; senior advisor for ministries in Austria and other countries and expert for the European Commission and international organisations. In his past career, he was responsible for the operational implementation of the EU RTD Framework Programmes from 1993 to 2006. Currently, he is member of the evaluation panels for the Joint Undertakings Clean Sky, Innovative Medicine Initiative and also Fuel Cells and Hydrogen.

Ruth Keir (UK) is principal of a UK-based biobusiness consultancy Archea Ltd and a non-executive director of a life sciences SME, Cambridge Cognition. In her previous role, Ruth was head of the Strategic Alliances group within Pfizer's Worldwide Business Development department. In this capacity she led the UK/US-based team responsible for Pfizer Global Research and Development's preclinical-compound & technology licensing and research collaborations.

Bart Wijnberg (NL) - before his recent retirement Bart Wijnberg worked for the Dutch Ministry of Health, Welfare and Sport where he held responsibilities for the commissioning of the seminal WHO Report Priority Medicines for Europe and the World in view of FP7, and for the launching of the Dutch Public Private Partnership Top Institute Pharma (TI Pharma). He was a member of the "Member States, Candidate and Associated Countries Contact Group for IMI".

Annex 2 Predefined Evaluation Questions

General Criteria / questions for 1st interim evaluation of IMI JU

Effectiveness: Progress towards meeting the objectives set.	
Q1	Which progress has been achieved towards the objectives set in the Article 2 of the Council Regulation setting up the JU? In particular:
Q1.1	How do you evaluate the support provided so far by the IMI JU to pre-competitive pharmaceutical research and development in Europe?
Q1.2	Have the research topics published by the IMI JU in the two first calls for proposals sufficiently matched the priorities set out in the Research Agenda?
Q1.3	Have the research topics published by the IMI JU in the two first calls for proposals ensured complementarity (i.e. no overlap) with the "Health"-related activities performed so far in the Seventh Framework Programme?
Q1.4	To what extent has the IMI JU succeeded in networking/pooling various stakeholders between the public and private sectors and in combining private-sector investment and European public funding? Is the IMI JU being considered by stakeholders as an appropriate tool for increasing research investment in the European biopharmaceutical sector at long term?
Q1.5	Has the IMI JU contributed/promoted to the participation/involvement of Small and Medium sized Enterprises (SMEs) in its supported research activities?
Q2	What changes have occurred in the research and socio-economic context of this sector since the initiation of the programme and what are their likely effects? Are the objectives and timeline of the JU still in line with these challenges?
Efficiency: The extent to which the JU has been operated efficiently, whether there has been good communication of objectives and progress, and the ability to address problems as they arose.	
Q3	Are the governing structures set up by the IMI JU appropriate to operate efficiently? Do they allow an efficient implementation of the objectives set?
Q4	Are the activities of the JU carried out efficiently?
Q5	Do the activities of the JU constitute effective methods of achieving the objectives set?
Q6	Are levels of funding and other available resources adequate to reach the objectives set?
Q7	Are the JU's objectives and achievements adequately communicated to and understood by external stakeholders? Is the JU effective in terms of knowledge dissemination? Are the JU's activities sufficiently visible to the public?
Q8	How adaptable is the JU to changing research needs and policy priorities? How are external stakeholders from science, industry and policy involved in identifying these needs and shaping the priorities?

Quality: The extent to which the JU supports top-class RTD in the area.	
Q9	At this stage, which are the indications that the RTD activities supported by the JU are of high quality?
Q10	Does the IMI JU attract the best researchers and research organisations active in the field? How is the participation pattern in terms of stakeholders (academic, industrial, including SMEs, and research organisation sectors), geographical and gender balance? What has been done and could further be done to ensure that European best researchers are involved in projects supported by the JU?
Q11	Are the measures described in the Research Agenda, and are the topic descriptions in the Call for Proposal texts appropriate to ensure innovation?
Q12	Is the JU perceived as flagship for Public Private partnership-supported RTD in the world and what more could be done in this respect?

Annex 3 IMI-related Documents and Information Consulted

Most documents and additional information can be found on the IMI website: www.imi.europe.eu

- ***Council Decision*** – Council Regulation (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines (OJ L30 of 04.02.2008, p. 38-51) [Council of the European Union 2008].
- ***Opinion of the European Parliament*** on the Commission Proposal for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking, of 11 December 2007
- ***Opinion of the European Economic and Social Committee*** on the Commission Proposal for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking of 24 October 2007.
- ***Commission Proposal*** for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking, of 15 May 2007 [European Commission 2007]
- ***Impact Assessment*** - Commission Assessment of IMI's potential socio- economic impact [European Commission 2007]
- ***IMI Strategic Research Agenda***, 2006 [Innovative Medicines Initiative 2006]
- ***EFPIA Vision Document*** [EFPIA 2004]
- IMI JU documents (cf. www.imi.europa.eu)
    - IMI Financial Rules
    - IMI Staff Regulation Implementing Rules
    - IMI Research Agenda
    - IMI Annual Implementation Plan
    - IMI Staff Policy Plan
    - IMI Annual Activity Reports
    - IMI Model Grant Agreement
    - IMI Rules for Participation
    - IMI Rules for Submission, evaluation and selection of proposals
    - IMI Guide for Applicants
    - IMI Internal Control Standards
    - IMI Call Statistics
    - IMI Project description and webpages.
- ***JTI Sherpa Report***, January 2010 – Designing together the 'ideal house' house for public-private partnership in European Research [JTI Sherpa Group 2010]
- *First Interim Evaluation of the Artemis and ENIAC Joint Technology Initiatives*.[European Commission 2010]

Published Articles related to IMI

- The Drug Deadlock, Nature, 10 Nov 2010 - [Abbott 2010]
- Correspondence: Clarifying knowledge ownership in Europe's Medicines Initiative , Nature, 2010 [De Rijck et al. 2010]

- Universities shun Europe's Drug Initiative; Nature, 13 July 2010 2010 [Gilbert 2010]
- Joint Statement on the Innovative Medicines Initiatives by EARTO et al. [EARTO 2010]
- Letter on the Innovative Medicines Initiative by LERU [LERU 2010]
- Data-rich, Discovery Poor: Pharma Looks to "Pre-Competitive" Collaborations [Goldgaber 2010]
- Press release from NEWMEDS, 10th November 2010 [Kapur et al. 2010]

Annex 4 List of People Interviewed

- ***Brian Ager***, Executive Director of EFPIA and EFPIA Representative at the IMI JU Governing Board
- ***Nicola Bedlington***, Executive Director, European Patients' Forum
- ***Daan Crommelin***, Executive Director TIPharma (*in writing)*
- ***Ruxandra Draghia-Akli***, Director "Health", European Commission DG Research,
  Commission Representative & Deputy-Chair of the IMI JU Governing Board)
- ***Hans-Georg Eichler***, Senior Medical Officer, EMA
- ***Hüseyin Firat,*** Firalis (SME), Participant in project SAFE-T
- ***Michel Goldman***, Executive Director, IMI JU
- ***Chris Hull***, Secretary General EARTO
- ***Carlo Incerti***, Genzyme, EFPIA representative and Chair of the IMI JU Governing Board
- ***Stavros Malas***, Chair, IMI States Representative Group
- ***Nathalie Moll***, Secretary General, EuropaBio, together with Tom Saylor, Ludovic Lacaine and Thomas Bols.
- ***Christian Noe***, Chair IMI JU Scientific Committee
- ***David Roblin***, Pfizer, Chair of the EFPIA Research Directors Group and EFPIA Representative at the IMI JU Governing Board
- ***Elisabetta Vaudano*** and ***Maria Teresa de Magistris***
  IMI JU Executive Office, Scientific Managers
- ***Bernd Stowasser***, Sanofi – Aventis, Project Leader, project IMIDIA
- ***Thierry Troosters***, University of Leuven, (KUL), Managing entity of IMI beneficiaries in project PROactive

Annex 5 IMI JU Call Topics, 3 Calls (2008, 2009, 2010)

Topics 1st IMI Call (2008) launched on 30 April 2008 with 18 topics covering 3 of 4 pillars.

Pillar I: Improving the Predictivity of Safety Evaluation

1. Improve Predictivity of Immunogenicity
2. Non-genotoxic carcinogenesis
3. Expert systems for in silico toxicity prediction
4. Improved predictivity of non-clinical safety evaluation
5. Qualification of translational safety biomarkers
6. Strengthening the monitoring of the benefit/risk of medicines

Pillar II: Improving the Predictivity of Efficacy Evaluation

7. Islet cell research
8. Surrogate markers for vascular endpoints
9. Pain research
10. New tools for the development of novel therapies in psychiatric disorders
11. Neurodegenerative disorders
12. Understanding severe asthma
13. COPD patient recorded outcomes

Pillar IV: Education and Training

14. European Medicines Research Training Network
15. Safety sciences for medicines training programme
16. Pharmaceutical medicine training programme
17. Integrated medicines development training programme
18. Pharmacovigilance training programme

Topics 2nd IMI Call (2009) - launched on 27 November 2009 with 9 topics, covering 2 of 4 pillars

Oncology:

1. New tools for target validation to improve drug efficacy
2. Molecular biomarkers, accelerating cancer therapy development, refining patient care
3. Imaging biomarkers for anticancer drug development

Infectious diseases:

4. Identification and development of rapid point-of-care bacterial diagnostic tests to facilitate clinical trials and clinical practice

Inflammation:

5. Understanding aberrant adaptive immunity mechanisms in chronic immune-mediated diseases: rheumatoid arthritis, systemic lupus erythematosus and inflammatory bowel disease.
6. Translational research in rheumatoid arthritis and related diseases

Knowledge Management:

7. Drug/disease modelling: library & framework
8. Open pharmacological space
9. Electronic Health Records

Topics 3rd IMI Call (2010), launched on 22 October 2010 with 7 topics covering 3 of 4 pillars

1. Improving the early prediction of Drug Induced Liver Injury in Man
2. Immunogenicity: assessing clinical relevance, risk minimization of Antibodies to Biopharmaceuticals
3. Immunosafety of Vaccines – New Biomarkers Associated with adverse events (early inflammation, autoimmune diseases and allergy)
4. Improving the preclinical models and tools for Tuberculosis Medicines Research
5. Translational Endpoints in Autism
6. Development of personalized Medicine Approaches in Diabetes
7. Fostering patient awareness on pharmaceutical innovation

Annex 6 Information on IMI Projects launched under the first Call

IMI has successfully launched 15 projects. Research plans, the participants, the funding, the results and the benefits for patients

IMI projects under the first call (2008)

Acronym Pillar addressed	**Name**	**Coordinator / Managing entity IMI beneficiaries** Total Participants	**Start** **Length**	**Project Total Costs**	**Website**
SAFESCIMET Education / Training	European Modular Education & Training Programme in Safety Sciences For Medicines	**Hoffmann-La Roche / VU Univ Amsterdam** 15 Pharma 18 Univ / RO	1 Jan 10 60 months	6.653.588 Euros	www.safescimet.eu
EMTRAIN Education / Training	European Medicines Research Training Network	**AstraZeneca / Med Univ Wien** 16 Pharma 11 Univ / RO	1 Oct 10 84 months	7.722.663 Euros	www.emtrain.eu
PharmaTrain Education / Training	Pharmaceutical Medicine Training Programme	**EFCPM**[9] 15 Pharma 35 Univ / RO	1 May 09 60 months	6.653.588 Euros	www.pharmatrain.eu
EU2P Education / Training	European Programme in Pharmacovigilance and Pharmacoepidemiology	**Hoffmann-La Roche / Univ Bordeaux** 15 Pharma 9 Univ / RO	1 Sept 09 60 months	7.270.886 Euros	www.eu2p.org
IMIDIA Efficacy	Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes	**Sanofi-Aventis / Univ Lausanne** 8 Pharma 12 Univ/RO 1 SME	1 Feb 10 60 months	25.907.480 Euros	www.imidia.org

[9] EFCPM – European Federation of Course Providers in Pharmaceutical Medicines, University of Basel, acting as coordinator and managing entity of IMI beneficiaries.

SUMMIT Efficacy	Surrogate markers for Micro- and Macro-vascular hard endpoints for Innovative diabetes Tools	**Boehringer Ingelheim / Lund Univ** 4 Pharma 18 Univ / RO 1 SME	1 Nov 09 60 months	28.449.408 Euros	www.imi-summit.eu
EuroPain Efficacy	Understanding Chronic pain and improving its treatment	**AstraZeneca / Kings College London** 7 Pharma 12 Univ /RO 1 SME	1 Oct 09 60 months	18.232.458 Euros	
NEWMEDS Efficacy	Novel Methods leading to New Medications in Depression and Schizophrenia	**Lundbeck / Kings College London** 9 Pharma 7 Univ / RO 3 SMEs	1 Sept 09 60 months	24.015.436 Euros	www.newmeds-europe.com
Pharma-Cog Efficacy	Prediction of cognitive properties of new drug candidates for neurodegenerative diseases in early clinical development	**GSK / Univ Marseille** 11 Pharma 13 Univ / RI 5 SMEs	1 Jan 10 60 months	27.707.023 Euros	www.alzheimer-europe.org
U-Biopred Efficacy	Unbiased Biomarkers for the Prediction of Respiratory Disease Outcomes	**AMC Amsterdam** [10] 9 Pharma 26 Univ / RO 3 SMEs 1 other industry	1 Oct 09 60 months	20.685.241 Euros	www.ubiopred.eu
PROACTIVE Efficacy	Physical Activity as a Crucial Patient Reported Outcome in COPD	**Chiesi Farmaceutici / Univ Leuven** 8 Pharma 10 Univ / RO 1 SMEs	1 Sept 09 60 months	16.736.468 Euros	www.proactivecopd.com
MARCAR Safety	BioMARkers and molecular tumour classification for non-genotoxic CARcinogenesis	**Novartis / Univ Dundee** 5 Pharma 6 Univ /RO 1 SME	1 Jan 10 60 months	13.319.233 Euros	www.imi-marcar.eu

[10] AMC Amsterdam - acting as coordinator and managing entity of IMI beneficiaries

ETOX Safety	Integrating bioinformatics and chemo informatics approaches for the development of expert systems allowing the *in silico* prediction of toxicities	**Novartis / IMIM** 11 Pharma 8 Univ / RO 4 SMEs	1 Jan 10 60 months	12.974.267 Euros	www.etoxproject.eu
SAFE-T Safety	Safer and Faster Evidence Based Translation	**Novartis / Univ Tuebingen** 11 Pharma 5 Univ / RO 4 SMEs	15 Jun 09 60 months	35.871.055 Euros	www.imi-safe-t.eu
PROTECT Safety	Pharmacoepide miological Research on Outcomes of Therapeutics by a European Consortium	**EMA / Danish Medicines Agency** 12 Pharma 15 Univ / RO 2 SMEs	1 Jan 09 60 months	29.810.613 Euros	www.imi-protect.eu

Abbreviations used:

Pharma – Pharmaceutical Companies, Members of EFPIA
Univ / RO – Universities, Research Organisations, Public Bodies & Non-Profit
SME – Small and Medium Enterprises

Note that before the setting up of the IMI JU, the pilot project InnoMed (composed by the two projects *PredTox* and *AddNeuroMed*) has been supported under the Framework Programme 6. This project kicked off in October 2005 to run for 40 months and had a total budget of € 18 million to which the Commission contributes € 12 million. With its 16 large pharmaceutical companies cooperating with 14 universities and 8 SMEs it demonstrated that collaboration between several pharmaceutical companies and with the other stakeholders is not only feasible, but also productive.

Annex 7 Call Statistics

Overview of IMI Calls for Proposals I, II, III

	1st call for proposals	2nd call for proposals	3rd call for proposals
Publication Date	30 April 2008	27 November 2009	22 October 2010
Number of topics	18	9	7
Stage 1 Deadlin	15 July 2008	8 February 2010	18 January 2011
Expressions of Interest received	138	124	
Participants	1294	1118	
Stage 2 Deadlin	20 January 2009	28 June 2010	
Full Project Proposals received	18	9	
Grant Agreements signed	15	tbc	
Maximum IMI JU financial contribution (mil €)	110 (based on signed Grant Agreements)	80 (based on negotiation)	114 (based on call published)
Indicative in-kind contribution (mil €)	132 (based on signed Grant Agreements)	65 (based on negotiation)	matching (based on call published)

References

Abbott, A. (2010). "The Drug Deadlock." Nature 468: 158-9.

Council of the European Union (2008). Council Regulation No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiatives on Innovative Medicines. Official Journal 04.02.2008. Brussels.

De Rijck, K., et al. (2010). "Correspondence: Clarifying knowledge ownership in Europe's Medicines Initiative." Nature 466: 1040,1.

EARTO (2010). Joint Statement on the Innovative Medicines Initiative. Brussels, EARTO, EUA, Helmhortz, FlandersBio, BioDeutschland, VIB, Sweden BIO, BIO.be, Leibnitz, ASEBIO, KoWi.

EFPIA (2004). Creating Biomedical R&D Leadership for Europe to Benefit Patients and Society. Brussels, European Federation for Pharmaceutical Industries and Associations.

European Commission (2007). Accompanying Document to the Proposal for the Council decision on the setting up the Innovative Medicine Initiative Joint Undertaking. Analysis of the effects of a Joint Technology Initiative (JRI) in the area of Innovative Medicines. Impact Assessment. Commission Staff Working Document. Directorate, D. R. H. Brussels, European Commission.

European Commission (2007). Proposal for a Council Regulation setting up the Innovative Medicines Initiative Joint Undertaking (SEC 2007 568/569). Brussels, European Commission,.

European Commission (2010). First Interim Evaluation of the Artemis and ENIAC Joint Technology Initiatives. Brussels, European Commission.

Gilbert, N. (2010). "Universities shun Europe's Drug Initiative." Nature 466: 306/7.

Goldgaber, D. (2010). Data-rich, Discovery Poor: Pharma Looks to "Pre-Competitive" Collaborations, www.hypios.com Thinking.

Innovative Medicines Initiative (2006). The Innovative Medicines Initiative (IMI) Strategic Research Agenda. Creating Biomedical R&D Leadership for Europe to Benefit Patients and Society. Date of Preparation: 16 September 2006 (Version2.0). Brussels. , EFPIA.

JTI Sherpa Group (2010). Designing together the 'ideal house' for public-private partnerships in European research. Brussels, European Commission.

Kapur, S., et al. (2010). Press Release: International Collaboration Amasses Largest Database to Advance Drug Development in Depression and Schizophrenia, www.newmeds-europe.com/en/media/NEWMEDS_WP10_WP08_press_release.pdf

LERU (2010). LERU Letter on the Innovative Medicines Initiative (IMI), LERU - League of European Research Universities.

European Commission

First Interim Evaluation of the Innovative Medicines Initiative Joint Undertaking
Panel Report

Luxembourg: Publications Office of the European Union

2011 — 44 pp. — B5 - 17,6 x 25 cm

ISBN 978-92-79-20505-7
doi 10.2777/65341

How to obtain EU publications

Free publications:

- via EU Bookshop (http://bookshop.europa.eu);
- at the European Commission's representations or delegations. You can obtain their contact details on the Internet (http://ec.europa.eu) or by sending a fax to +352 2929-42758.

Publications for sale:

- via EU Bookshop (http://bookshop.europa.eu);

Priced subscriptions (e.g. annual series of the Official Journal of the European Union and reports of cases before the Court of Justice of the European Union):

- via one of the sales agents of the Publications Office of the European Union (http://publications.europa.eu/others/agents/index_en.htm).

KI-30-11-193-EN-N

The Innovative Medicines Initiative (IMI) is Europe's largest public-private partnership aiming to boost innovation in the health sector by supporting a more efficient discovery and development of better and safer medicines for patients.

IMI is a €2 billiion Joint Undertaking between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) in which EU funding is matched by 'in-kind' contributions from EFPIA.

This report is the first interim evaluation of this Joint Undertaking

Innovative Medicines Initiative

SEVENTH FRAMEWORK PROGRAMME

efpia
European Federation of Pharmaceutical Industries and Associations

Publications Office

ISBN 978-92-79-20505-7