



Innovative Medicines Initiative

**INNOVATIVE MEDICINES INITIATIVE**

**JOINT UNDERTAKING**

**ANNUAL ACTIVITY REPORT**

**2010**

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## **I. FOREWORD**

The Innovative Medicines Initiative (IMI JU) was established in 2008 as a large scale public-private partnership between the European Union, represented by the European Commission, and the European Federation of Pharmaceutical Industries and Associations (EFPIA) with the mission to support the development of efficient and safe medicines for patients across Europe by removing research bottlenecks in the drug development process and by increasing investment in the biopharmaceutical sector in Europe.

This document presents the activities undertaken by IMI JU during 2010 to pursue this mission within the parameters of the administrative and financial autonomy granted on 16 November 2009.

In line with the major objectives outlined in the 2010 Annual Implementation Plan, the following were the most significant milestones and achievements accomplished during the year:

- The commencement of the first wave of IMI research projects from the First Call for Proposals, following the finalisation of the corresponding Grant Agreements
- The evaluation, selection, and negotiation of the second wave of research projects emanating from the Second Call proposals and which will result in the launch of new projects during Q1 2010
- The launch of the Third Call for Proposals
- The establishment of the Overheads Policy
- The publication of a Guidance Note on how to apply the Intellectual Property Policy
- The launch of a new website including a electronic partner search tool
- The setting-up of the Internal Audit function

In parallel, several actions were taken during the year in preparation for the key objectives set for 2011. These included:

- Amendments to the Grant Agreement model and the definition of IMI Financial Guidelines
- The revision of the IMI Research agenda and the definition of topics for future Calls
- The enhancement of communication activities on the basis of the first results achieved in research projects
- The organisation of the ex-post audit activities

Overall, the activities described in the 2010 Annual Report demonstrate that IMI JU has the capacity and capability to launch research projects based on the public-private partnership principles that underlie its mission. Building on these achievements, the major objectives of IMI JU for 2011 will include the enhancement of communication activities to further mobilise IMI stakeholders and the establishment of key performance indicators for both IMI projects and IMI JU.

## **II - IMPLEMENTING R&D and EDUCATION/TRAINING ACTIVITIES**

During 2010, IMI JU undertook several activities and initiatives to support prospective, pre-competitive pharmaceutical research and development.<sup>1</sup> These included the launch of open and competitive calls for project proposals, the completion of independent evaluations, the conclusion of Grant Agreements and Project Agreements, the revision of the Scientific Research Agenda and several events.

### **A – Support for the revision of the Scientific Research Agenda**

*The IMI Scientific Research Agenda (SRA) is the research strategic document of the IMI JU. It includes recommendations to address bottlenecks in drug development and a plan to guide their implementation. The version of the SRA released in 2008 continued to serve the basis for the IMI Research Activities.*

The SRA was conceived as a ‘living’ document to be periodically updated in order to reflect scientific advances and the evolution of needs of the pharmaceutical industry. In 2010, both Founding Members agreed that the SRA should be updated.

*The revision of the SRA was first addressed with the Scientific Committee in November 2009. The review process was initiated during Q1 2010 and is expected to be concluded in Q2 2011.*

For this purpose, the Scientific Committee produced a Status Report entitled "Trends, Challenges and Opportunities in Drug Research" with the aim of providing an overview of what the Committee considered as potential innovative research opportunities for the academia and SMEs.

On basis of this Status Report, the IMI Executive Office and the Scientific Committee organised a workshop on 1 and 2 June 2010 to solicit ideas and feedback from stakeholders, including industry, academia, regulatory authorities and patient organisations. During this workshop, a major recommendation from EFPIA participants was that IMI JU should consider launching a number of large initiative projects, focused on 'game-changing' ideas and areas where the maximum number of companies could join forces. Such ‘Think Big’ topics would cover proposals that can change the landscape in which pharmaceutical, academic and healthcare sectors operate.

The feedback and comments of the EFPIA Research Directors’ Group to the Scientific Committee Status Report were integrated by IMI JU Executive Office in a Draft Working Document that was presented to the Scientific Committee during the meeting of 1 and 2 December 2010.

The Draft Working Document was also sent for comments to the European Commission (EC) and to the States Representatives Group (SRG). Their feedback is expected during Q1 2011 and will be forwarded by the IMI Executive Office to the Scientific Committee for the compilation of the first draft of the revised Strategic Research Agenda by March 2011. The final revision of the Strategic Research Agenda will be completed during Q2 2011 after a final round of consultations and final approval by Founding members.

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<sup>1</sup> In this context ‘pre-competitive pharmaceutical research and development’ should be understood as research on the tools and methodologies used in the drug development process.

With respect to the Knowledge Management Pillar, the IMI JU Executive Office organised two Knowledge Management workshops on 16 May and 1 June 2010. These events focused particularly on the development of implementation plans and on the gathering of ideas and feedback on the knowledge management aspects of the projects and on specific knowledge management calls. The report produced by the IMI JU Executive Office on the workshops ("Results of the Knowledge Management Workshops 6 May and 1 June 2010") was used for the updating the SRA for the development of additional implementation plans for Translational Knowledge Management. Following feedback from the EFPIA Research Directors Group, it was also decided to develop a Knowledge Management workgroup to share best practices in Knowledge Management and to set up a Knowledge Management strategic workgroup to define 'game-changing' knowledge management initiatives.

## **B – Call-related activities**

*During 2010, the IMI Executive Office worked with the Founding Members to adapt the Calls process and take into account the operational needs and experience of the 1<sup>st</sup> Call. The IMI JU model Grant Agreement was also amended to reflect the entry into force of the Lisbon Treaty.*

In addition, it was necessary:

- to provide some clarifications and more guidance regarding the rules applicable to the Calls process and to the IMI Intellectual Property policy (refer to section C);
- to define a methodology for in kind contribution; and EFPIA companies financial reporting;
- to discuss the cost methodology for indirect costs following comments made by the States Representatives Group

In order to address these issues, actions were taken during 2010 that will lead, in 2011, to the:

- Modification of the IMI JU model Grant Agreement; and,
- Finalisation of IMI Financial Guidelines with retrospective application to the 1<sup>st</sup> Call projects.

### *- Implementation of 1<sup>st</sup> Call projects*

The 1<sup>st</sup> Call for Proposals was published on 30 April 2008 with 18 topics addressing the following three strategic pillars: Predictivity of Efficacy Evaluation, Predictivity of Safety Evaluation, Education and Training. The total budget for the 1<sup>st</sup> Call included a maximum financial contribution from the European Commission to the IMI JU of € 109 million and 'in kind' contributions estimated at € 132,6 million by the research based companies that are members of EFPIA<sup>2</sup>. These amounts do not include the applicants' contribution.

The negotiations with the participants of the fifteen projects selected for funding following the two-stage evaluation process were finalised during Q2 2009, and the signing of respective Grant Agreements was concluded in Q1 2010.

*During 2010, the IMI Executive Office also managed the pre-financing for the fifteen projects and followed-up on their implementation, including amendments to the Grant Agreements. In addition, the annual interim reports of the participants' consortia*

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<sup>2</sup> 'In kind' contributions refer to non-monetary contributions such as personnel, equipment, consumables, etc.

*describing the financial and scientific development of the projects have been or are being received within the established deadlines (see below).*



Moreover, in order to promote communication between the IMI JU Executive Office and the projects' consortia as well as facilitate interaction and potential communication within the same scientific area, the IMI JU Executive Office organised during 2010 the following series of meetings with the EFPIA projects coordinators, the managing entities of IMI JU funding and the projects managers:

AREA	PROJECTS	DATE
BRAIN DISORDERS	EUROPAIN, PharmaCog, NEWMEDS	6 <sup>th</sup> July 2010
DIABETES	IMIDIA, SUMMIT	7 <sup>th</sup> September 2010
SAFETY	SAFE-T, MARCAR, e-TOX, PROTECT	3rd May 2010
RESPIRATORY PROJECTS	PROactive, U-BIOPRED	8th December 2010
EDUCATION AND TRAINING	EMTRAIN, SafeScimet, PHARMATRAN, Eu2p could not participate	26th May 2010

During these meetings, the IMI Executive Office presented guidelines and offered advice on reporting and communications, amongst other matters. The Executive Office also acted as a facilitator by encouraging collaboration and communication between projects. All of these meetings were successful and well-received. They also provided further incentive for increased collaboration and knowledge sharing between projects. To varying extent, such collaboration has already started between for example Newmeds and PharmaCog. Additionally, two other projects (Imidia and Summit) are working on finding the best legal basis to allow sharing of methods, data and, possibly also, samples. A meeting organised by the IMI Executive Office has also allowed the Education and Training projects coordinators to identify common needs and to set up a strategic coordination board to tackle these issues together.

## *- Evaluation of 2<sup>nd</sup> Call for Proposals and Projects Negotiations*

The 2<sup>nd</sup> Call for Proposals was officially published on 27 November 2009 and consisted of nine topics based on the 2009 Scientific Priorities. The total budget for the second Call includes a maximum financial contribution from the EC to the IMI JU of € 76.8 million and 'in kind' contributions by the research based companies that are members of EFPIA estimated at € 65,8 million.

The Call process, managed by the IMI Executive Office, comprised of a two-stage process, based on the principles of peer-review, excellence, transparency, fairness and impartiality, confidentiality, efficiency, speed and ethical considerations. The process was also implemented in accordance with the "IMI Rules for submission, evaluation and selection of Expressions of Interests and proposals".

In addition, together with the independent experts, the co-ordinator and the deputy co-ordinator of the 'EFPIA consortium' associated to the topic participated in the evaluation panels except for final assessment and without voting rights.

The IMI Executive Office also invited three independent observers, Graham Johnson, Matti Sarvas and Adam Smith, to the two-stage evaluation process. The reports of the observers were published on IMI JU's website (<http://www.imi.europa.eu>). An Action Plan based on the Independent Observers' Report of the Evaluation of Stage Two was also published and the Executive Office is implementing these actions for the 3<sup>rd</sup> Call for Proposals.

In total, 124 Expressions of Interest involving 1,294 applicants from 27 different countries were received. These were evaluated against the following four criteria: Scientific and/or technological excellence; Partnership; Quality of the applicant consortium as a whole; and the Quality and soundness of the work plan, including the budget.

Following the Governing Board decision of 16 March 2010, the IMI Executive Office invited the first nine highest-ranked Expressions of Interest to prepare, together with the pre-established EFPIA consortium, a Full Project Proposal (FPP) by 28 June 2010.

For this purpose, meetings together with the Applicant Coordinator of the successful Expressions of Interest and the coordinator of the respective pre-established 'EFPIA consortium' were held in order to foster interaction between the partners as well as facilitate the formation of a 'Full Project consortium' and the preparation of a 'Full Project Proposal'. The IMI Executive Office participated in each of these meetings providing assistance and acting as a facilitator on scientific, administrative, financial and legal issues.

The evaluation of the nine received FPPs was conducted with independent external experts. During this stage of the evaluation, the EFPIA co-ordinator and deputy co-ordinator were excluded. In addition, an ethical review was carried out for each FPP.

All nine proposals were deemed eligible and passed the necessary threshold applicable to criteria 1. The Independent Experts found that the FPPs were a constructive development of the stage 1 application, addressed most of the questions raised during the review process and met the objectives of the call topic. They additionally agreed that

modifications may be required during the negotiation process. The Independent Experts also strongly recommended that the FPPs from topics 5 and 6 are merged.

Following the Governing Board decision of September 2010, negotiations with the eight projects selected for funding were concluded between September 2010 and November 2010.

*The Grant Agreements will be signed in Q1 2011, thereby allowing the research activities to kick-off by April 2011, at the latest.*

<b>Maximum IMI JU financial contribution (after negotiation)</b>	<b>EFPIA in-kind contribution (after negotiation)</b>	<b>Total projects' costs (after negotiation)</b>
<b>80.740.072</b>	<b>65.872.527</b>	<b>171.707.565</b>

*- Preparation and launching of 3<sup>rd</sup> Calls for Proposals*

*The finalisation of the Topics text for the 3<sup>rd</sup> Call was achieved during the summer of 2010, through active interaction between the EFPIA Topic writers and the IMI Executive Office. After a final round of consultation with EFPIA and the EC as well as a positive decision of the Governing Board, the IMI Executive Office launched the 3<sup>rd</sup> call for Proposals on 22 October 2010. Each topic is associated with a pre-established consortium of pharmaceutical companies that are members of EFPIA ('EFPIA Consortium').*

The 3<sup>rd</sup> Call includes seven topics addressing the three following strategic pillars:

1. Improving early prediction of Drug Induced Liver Injury (DILI) in man;
2. Immunogenicity: Assessing the Clinical Relevance and Risk Minimization of Antibodies to Biopharmaceuticals;
3. Immunosafety of vaccines – New biomarkers associated with adverse events;
4. Improving the preclinical models and tools for tuberculosis medicines;
5. Translational endpoints in autism;
6. Personalized Medicine in Diabetes treatment;
7. Fostering patient awareness on pharmaceutical innovation.

The 3<sup>rd</sup> Call Topics were presented during workshops at an IMI Info Day organised in Brussels on 22 October 2010.

Further communication on the Topics was achieved through a series of Webinars organised during November 2010.

## **C – Guidance for intellectual property management**

In November 2010, the Executive Office issued an IMI Intellectual Property Guidance Note for applicants and participants, following discussions of the Intellectual Property Working Group (IPWG). This group is composed of representatives from the Executive Office, the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Commission (EC) and the IMI States Representatives Group (SRG). The purpose of this Guidance Note was to clarify the IMI IP Policy, and in doing so to highlight the flexibility provided therein. The Guidance Note also explores ways on how to handle IP related issues and pitfalls that participants may encounter during the preparation, negotiation and completion phases of the Project Agreements.

The IPWG held three meetings in 2010 (during March, June and September). These events provided the necessary opportunities for the exchange of views on the IMI IP policy and for the coordination of targeted dialogue between interested parties. The experience gained from the negotiations of the project agreements of the 1<sup>st</sup> call was also taken into account.

*Following the Governing Board meeting of 14 December 2010, the IMI Executive Office set up a dedicated IP Helpdesk to assist with specific IP queries. The Helpdesk is accessible through IMI JU's website.*

## **III – MANAGEMENT OF EXECUTIVE OFFICE**

### **A – Staff implementation**

The recruitment of the second batch of staff members (Temporary Agents) of the IMI JU started in April 2010 and was mostly concluded during 2010. The recruitment included the engagement of staff to fill the posts of Internal Audit Manager, Scientific Manager, Communications and Events Manager, Financial Manager, IT Manager, Operations and Internal Control Manager and two Administrative Assistants.

During 2010, IMI JU also recruited six contractual agent positions. 3 of these are still in place.

The IMI JU employed 22 staff by the end of 2010.

<b>Staff</b>	<b>Status</b>	<b>Comments</b>
Internal Audit Manager	<b>DONE</b>	Took up his duties on 16 November 2010
Scientific Manager	<b>DONE</b>	Take up his duties on 16 January 2011
Communications and Events Manager	<b>DONE</b>	Take up his duties on 1 April 2011
Financial Manager	<b>DONE</b>	Take up his duties on March 2011
IT Manager	<b>DONE</b>	Took up duties on 16 June 2010
Operations and Internal Control Manager	<b>DONE</b>	Take up his duties on 1 January 2011
2 Administrative Assistant AST3	<b>DONE</b>	1 took up duties on 16 October 2010; 1 take up duties on 1 April 2011
Legal Officer CA GFIV	<b>DONE</b>	Took up duties on 16 March 2010. Contract ended 31 December 2010
2 Financial Assistants CA GFIII	<b>DONE</b>	1 took up duties on 16 July 2010 and resigned on 31 October 2010; 1 took up duties on 1 December 2010.
Assistant CA GFIII	<b>DONE</b>	Took up duties 1 July 2010
2 Secretaries CA GFII	<b>DONE</b>	1 took up duties on 16 January 2010 and resigned on 15 October 2010; 1 took up duties on 1 December 2010

The Staff Policy Plan 2010-2012 was adopted by the IMI JU Governing Board on 20 March 2009. It includes the Staff Establishment Plan which is annexed to the 2009 Annual Implementation Plan (AIP). In addition, the Staff Policy Plan (SPP) proposes a staffing structure and identifies the staff needs for IMI JU.

Seven vacancy notices, as foreseen in the Staff Establishment Plan for 2010, were published in April 2010, with a deadline for applications set for June and July 2010. Key staff has already taken up their positions and recruitment of the remaining posts is in its final stages.

An in depth review of IMI JU's organisational structure and management system was carried out, with the support of an external consultant, between October and December 2010. The purpose of this exercise was to define the "target organisation" towards which IMI JU should evolve during 2011 and to determine better ways of how to respond to the needs and expectations of stakeholders.

## **B – Administrative/ legal matters**

During 2010 IMI JU developed and enhanced its systems and processes, paying particular attention to the simplification of procedures and taking into account the specific needs and size of IMI JU.

In parallel, the European Commission commissioned an interim review according to Article 11 (2) of the Council Regulation setting up the IMI JU. The review focused on the quality, efficiency, and contribution of the IMI JU towards the achievement of set objectives.

This evaluation, carried out with the assistance of independent experts, was concluded in December 2010. The conclusions of the interim review will be addressed and followed up during 2011.

*- Internal audit*

In November 2010, the IMI JU established its own internal audit capability to provide independent, objective assurance and internal advisory services on the suitability, efficiency and effectiveness of the organization's risk management, control and governance processes, taking into account the size and the scope of the JU. During Q1 2011, the Mission Charter of the Internal Audit Service of the European Commission and IMI JU's Internal Audit Capability will be submitted to the Governing Board for discussion and approval. By Q3 2011, the first multi-annual strategic IAC plan and annual IAC work plan (for 2012) will be developed.

The European Court of Auditors visited IMI JU in January, April and November 2010 as part of the audit of the accounts of financial years 2009 and 2010. In the Court's published opinion, the 2009 annual accounts of the IMI JU presented fairly, in all material respects, its financial position as of 31 December 2009 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its Financial Regulation. In addition, in the Court's opinion, the transactions underlying the annual accounts of the IMI Joint Undertaking for the financial year ended 31 December 2009 were, in all material respects, legal and regular. Further visits are planned by the Court in 2011 for the audit of the 2010 accounts.

*- Management of Internal control systems*

This part of the AAR provides key information on the functioning and effectiveness of IMI's internal control system and risk management framework.

These systems are monitored by the Executive Office on a continuous basis through a number of reporting requirements and supervisory controls. Furthermore, each operational unit is periodically required to assess and report on its compliance with the internal control requirements, as part of IMI's annual risk assessment exercise and when requested by the Executive Director.

During 2010, the Executive Office has progressively developed and put in place systems and procedures in line with the internal control standards highlighted in the Action Plan of the Readiness Assessment Report that was prepared prior to the achievement of IMI JU's autonomy on 16 November 2009. The implementation of this Action Plan was also regularly monitored by the Executive Office with progress being tracked through three subsequent updates of the Action Plan in December 2009, April 2010 and September 2010.

In the 2010 Annual Implementation Plan the following two priority areas were identified in connection with the internal control framework. These were related to:

- ICS 3: "Recruitment, staff allocation and flexibility". The Staff Establishment Plan 2010 foresaw the recruitment of fourteen Temporary Agents and three Contract Agents in order to have the capacity to fully implement IMI JU objectives. This

required considerable effort due to the limited time and resources available within the human resource function to achieve this target. By the end of the year, twelve recruitment procedures were completed, one procedure was on-going and four new calls for recruitment were planned for 2011. Moreover, careful attention was given to ensure that the established rules for recruitment were complied with.

- ICS 8: "Documentation of procedures". IMI has adopted and systematically improve its own internal financial and IT procedures that comply with applicable provisions, document process management and guarantees data protection and segregation of duties.

There are a number of actors in processing payments: the initiating agent creates the transaction, then the file passes to the verifying agent who carries out the ex-ante verification, and then the authorising officer validates the expenditure, and instructs the accounting officer to make the payment. Payments are created in a financial information system (ABAC.) Here are the steps to follow: the first stage consists in entering details of the invoice into the system; the second stage is the payment request, which is created and validated by the financial initiating agent; the third stage involves the creation, still in ABAC of a payment order comprising preferably just one (or several) payment requests. The payment order must pass through the various stages of the workflow: after being validated by the AOS, it proceeds to central level (R/3) where the payment is processed by the accounting officer; and the final stage is the payment run or physical payment which is made via the SWIFT system.

The Executive Office has specifically focused, throughout the year, on establishment and harmonisation of existing rules and documentation linked to both internal and where appropriate FP7 procedures and arrangements. These related to: (i) the procedures for the evaluation and selection of proposals, (ii) the management of negotiations and grant agreements, as well as (iii) the alignment of business processes with IT applications and controls. In 2010, significant work was also conducted on developing the Financial Guidelines applicable to beneficiaries of IMI JU's funding and to EFPIA companies (with particular attention being given to the "in-kind" contributions). This work was completed by the end of 2010 and presented for discussion to the Governing Board on 14 December 2010. The new Guidelines will be implemented in 2011 following approval by a written procedure.

In addition, between September and November 2010, IMI JU conducted its first annual Risk Assessment exercise. The evaluation on IMI's management of key corporate risks suggests that, given that this was the first full year of activity for IMI, the progress made in the development and establishment of key internal control systems and procedures has been satisfactory and in line with expectations.

During 2011, IMI JU will continue to build on these early positive results by further consolidating its internal control framework, enhancing its internal structures and procedures at all levels of management, and by introducing, where necessary, additional control mechanisms and risk management activities.

Overall, during its first full year of operation, the Executive Office initiated the process which should lead to robust internal control systems and procedures that are in line with the internal control standards. The progress made towards the achievement of this objective was also been systematically monitored and reviewed through regular

management meetings, periodic updates of the Action Plan and through the completion of IMI's annual risk assessment in November 2010. Decreasing unnecessary administrative burden is taken into account in the internal control implementation.

Further attention will be given during 2011 to the strengthening of specific internal control measures, including the development of enhanced procedures related to ICS 5 (Objectives and performance indicators), ICS 7 (Operational Structure), ICS 8 (Processes and procedures) and ICS 15 (Assessment of the Internal Control). These priorities are outlined in the table below,

*Internal control standards: priorities for 2010 and 2011*

Internal Control Standard	Priority AIP	
	2010	2011
1. Mission		
2. Ethical and organisational values		
3. Staff allocation and flexibility	✓	
4. Staff evaluation and development		
5. Objectives and performance indicators		✓
6. Risk management process		✓
7. Operational structure		✓
8. Processes and procedures	✓	✓
9. Management supervision		
10. Business continuity		
11. Document management		
12. Information and communication		✓
13. Accounting and financial reporting		
14. Evaluation of activities		
15. Assessment of internal control systems		✓
16. Internal Audit Capability		

The implementation and improvement of internal control standards is a continuous process. According to the international practice each year IMI assesses its internal organisation and defines a plan to strengthen and improve its Internal Control Framework.

#### *- Procurement & Grants*

The IMI JU adopted in 2010 the “IMI Guidelines for low-value procurement procedures”. These Guidelines will facilitate IMI JU's compliance with the General Guide for Public Procurement of the European Commission and reflects the Public Procurement threshold levels set in IMI JU's financial rules for Procurement Procedures.

During 2010, IMI JU had two high value Procurement Procedures leading to Framework contracts published in the Official Journal: one for the *IT Infrastructure* and another for *Ex-Post Audits*. These procedures were launched jointly with other Joint Undertakings.

In addition, the IMI JU launched low value procurement procedures for the development of IMI JU's website, for the organisation of communication events held during the year, and for the purchase of office furniture in the new premises (White Atrium).

In 2010 the "Kallas procedure" for the new office location was also concluded. This procedure was launched with the other Joint Undertakings and in close collaboration with European Commission Services. The outcome of the housing procedure was agreed by the Governing Boards after consultation with the Budgetary Authority.

*- Ex-Post audit strategy*

In December 2010, the Governing Board approved IMI JU's ex-post audit strategy. The strategy also foresees audits of in-kind contributions within the projects funded by IMI JU. The first ex-post audits will be undertaken by the end of 2011.

*- Data protection and access to documents*

The IMI JU follows the principle of transparency during the conduct of its activities and with regard to access to its documents. This policy applies to all stakeholders and interested parties.

During 2010 the IMI JU has established contacts with the European Data Protection Supervisor and participated to two meetings of the network of the Data Protection Officers of the European Institutions and agencies. In addition, the implementation of an inventory and a notification system is being implemented in coordination with the other Joint Undertakings. It should be established by Q2-Q3 2011.

## **C – Office**

*- The Kallas Procedure*

On 17 January 2011 the staff of IMI JU moved to a new office in the White Atrium building in central Brussels (Place Louise), following the finalisation of this so called "Kallas Procedure". The new office is based on an "activity based floor planning" (partly open landscape).

This Kallas procedure was a long process that required the intensive involvement of the Joint Undertaking in the collaboration with European Commission, other Joint Undertakings (JUs), the Office for Infrastructure and Logistics in Brussels (OIB), the owner of the building and the architects. The following milestones were achieved during the two-year procedure:

- The finalisation of the first stage on 26 October 2009 and the selection of three potential buildings (out of 27 proposals) to enter the second stage of the negotiations. The first stage was fully driven by the EC and involved the participation of JUs. An EFPIA representative also attended as an observer.
- The negotiation stage two with the three shortlisted candidates was concluded by 27 April 2010. The nominated evaluation committee, comprising of representatives from both the European Commission and the JUs met all candidates in multiple negotiation meetings and during site visits. A full technical analysis of each building was done together with specialists from OIB.

- The negotiations with the selected candidate (BEOS, White Atrium) were finalised on 27 July 2010. The proposed contract was submitted for the approval of the Governing Boards of the JUs. The JUs' Governing Boards decisions were taken during the period July-August 2010.
- In September 2010, the JU's submitted the dossier to the Budgetary Authority (that is, the Council and the Parliament) for their opinion. Different arrangements were made for the presentation of the dossier by the JUs: for the Council, IMI and FCH presented the dossier while for the Parliamentary hearing, ENIAC and Artemis were present. At both hearings the members of the budgetary committee asked questions directly to the JU Directors. The Budgetary Authority had no objections to the JUs proposals.
- The contract with the owner of the White Atrium Building (BEOS Louise) was signed by the JU Directors on 17 December 2010.

## **D – IT**

During 2010, the IMI JU focused mainly on the setting up of the new IT infrastructure for the new IMI building and on the consolidation of the information systems for the management of the Calls for Proposals.

The IMI Executive Office developed the specifications and launched an open procedure jointly with the other four Joint Undertakings for implementing a Joint Technology Initiative for setting up a new standardised infrastructure in the new building.

In 2010, a new website was also created and redesigned. It will be fully operational during 2011.

The principal IT tasks undertaken during 2010 included the following:

- *The setting up of the IT Infrastructure:* Acquisition (through an open tendering procedure) and the setting up the new IT Infrastructure in the new building; while minimising duplication costs due to the move to a permanent office;
- *The development of the Web Site:* The construction of a redesigned IMI web site;
- *The take over of the IMI submission tool:* The Executive Director accepted the donation of the IMI submission Tool owned by EFPIA and developed jointly by the two Founding Members. Preparation of the deed is on-going and will be concluded in 2011;
- *The evolution of the IMI submission tool:* Maintenance of the tool involved not only routine maintenance and incident management tasks but also the implementation of functionality to increase its coverage.
- *Reporting:* Provided the European Commission with data for its reporting to the European Council and the European Parliament.

## **E – Financial operations**

The IMI JU had two main activities in the pertinent period:

- the running activities, including administrative tasks, communication activities, as well as support for operational activities such as evaluation procedures (Title 1 & 2); and,
- the operational activities, which cover the support given to the research activities (Title 3).

Summary of the budgetary execution for the financial year 2010

<b>BUDGET and EXECUTION SUMMARY YEAR 2010</b>							
<b>Running costs</b>							
	<b>BUDGET</b>	<b>CONSUMED</b>		<b>AVAILABLE</b>	<b>PAYMENT AVAILABLE</b>	<b>PAYMENT EXECUTION</b>	
Staff costs (Title 1)	4.131.408	1.966.887	48%	2.164.521	2.212.055	<b>1.919.353</b>	46%
Administrative costs (title 2)	4.374.432	2.182.455	50%	2.191.977	3.409.971	<b>897.242</b>	21%
Admin. costs following obligations taken in 2009 carried-over (C8) and paid in 2010				n/a	n/a	<b>329.812</b>	
Summary	<b>8.505.840</b>	<b>4.149.342</b>	49%	<b>4.356.498</b>	<b>5.622.026</b>	<b>3.146.407</b>	37%
<b>Operational (Calls and Projects)</b>							
	<b>BUDGET</b>	<b>CONSUMED</b>		<b>AVAILABLE</b>	<b>PAYMENT AVAILABLE</b>	<b>PAYMENT EXECUTION</b>	
Research activities C1	98.644.744	0		98.644.744	-	20.504.000	100%
Research commitment C2	n/a	2.096.872		-	-	-	
Research payments C2	n/a	n/a		n/a	63.905.162	14.738.038	
					<b>Paid Grants</b>	<b>35.242.038</b>	
					<b>Paid Total</b>	<b>38.389.668</b>	
<b>REVENUE RECEIVED</b>							
EC	24.908.840						
EFPIA	2.126.460						

During 2010, the IMI JU handled 800 financial files for payments, for provisional and individual commitments, for recovery orders and for the management of appropriations.

In 2010, the IMI JU in relation to the 1<sup>st</sup> Call for Proposals, paid 15 pre-financings to the grant beneficiaries of a total amount of 34.704.183€, and executed 1 interim payment to the project PHARMA TRAIN of an amount of 534.382€.

IMI JU Commitment and Payment Appropriations Execution in 2010

<b>Budgetary Annual Account – Commitment appropriations Execution IMI JU 2010*</b>			<b>Budgetary Annual Account – Payment appropriations Execution IMI JU 2010*</b>		
<b>Title 1 Staff Expenditures</b>	<b>2009</b>	<b>2010</b>	<b>Title 1 Staff Expenditures</b>	<b>2009</b>	<b>2010</b>

11. Salaries a& allowances	278.934	1.871.677	11. Salaries a& allowances	278.934	1.868.177
12. Expenditures to Staff recruitment	20.212	17.196	12. Expenditures to Staff recruitment	9.434	15.196
13. Mission expenses	803	56.260	13. Mission expenses	803	35.227
14. Socio-medical infrastructure and other interventions	0	20.000	14. Socio-medical infrastructure and other interventions	0	0
17. Receptions and Events	0	1.754	17. Receptions and Events	0	754
<b>Title 2 Infrastructure and operating expenditures</b>			<b>Title 2 Infrastructure and operating expenditures</b>		
20. Rental of buildings and associated costs	140.900	504.715	20. Rental of buildings and associated costs	0	112.281
21. Information and communication technology	25.603	561.963	21. Information and communication technology	27.619	42.134
22. Movable property and associated costs	25.000	6.917	22. Movable property and associated costs	0	1.957
23. Current administrative expenditure	470	84.733	23. Current administrative expenditure	470	5.883
24. Postage and telecommunication	0	53.818	24. Postage and telecommunication	0	422
25. Expenditures on formal and other meeting	90.000	54.536	25. Expenditures on formal and other meeting	0	45.951
26. Running costs in connection with operational activities	252.677	108.036	26. Running costs in connection with operational activities	71.596	97.192
27. Information and publishing	29.281	306.126	27. Information and publishing	29.281	246.786
28. Studies	0	30.000	28. Studies	0	24.000
29. Experts contracts and meeting	316.048	471.611	29. Experts contracts and meeting	377.841	320.638
Sub-total title 1 & 2	1.179.928	4.149.342	Sub-total title 1 & 2	795.979	2.816.595
<b>Title 3 Operating expenditures</b>			<b>Title 3 Operating expenditures</b>		
30. Implementing the research agenda of the IMI JU	78.643.200	0	30. Implementing the research agenda of the IMI JU	0	20.504.000
Carried over commitment appropriation following Art 10 of IMI's Financial Rules (C2)	78.643.200	2.096.872	Carried over commitment appropriation following Art 10 of IMI's Financial Rules (C2)	0	14.738.038
<b>TOTAL EXPENDITURE</b>	<b>79.823.128</b>	<b>6.246.214</b>	<b>TOTAL EXPENDITURE</b>	<b>795.979</b>	<b>38.059.856</b>

\*The amounts includes EFTA contributions 2.52%

### IMI JU general budget status

Running costs	2008	2009	2010	2011	2012
Legislative Financial Statement	2.300.000	3.200.000	8.505.840	9.026.000	10.748.000
Cumul LFS (A)	2.300.000	5.500.000	14.005.840	23.031.840	33.779.840
<b>COMMITMENT APPROPRIATION</b>	<b>1.924.970</b>	<b>3.276.800</b>	<b>8.505.840</b>	<b>9.026.000</b>	<b>10.748.000</b>
Committed	1.519.602	1.179.928	4.149.341	0	0
Cumul committed (B)	1.519.602	2.699.530	6.848.871	0	0
Cumul difference to LFS (A-B)	780.398	2.800.470	7.156.969		
Carry over C2 commitment amount		2.096.872	2.178.249		
Carry over committed amount		1.179.828	1.282.993		
<b>PAYMENT APPROPRIATION</b>	<b>501.711</b>	<b>3.276.800</b>	<b>8.505.840</b>	<b>9.026.000</b>	<b>10.748.000</b>
Payments	343.948	795.979	3.146.407	0	0
Cumul payments ©	343.948	1.139.927	4.286.334		
RAL running costs (B-C)	1.175.654	2.136.873	4.219.506		
Carry over C2 commitment amount		2.096.872	2.178.249		
Carry over committed amount		1.179.828	1.282.993		

Operational costs	2008	2009	2010	2011	2012
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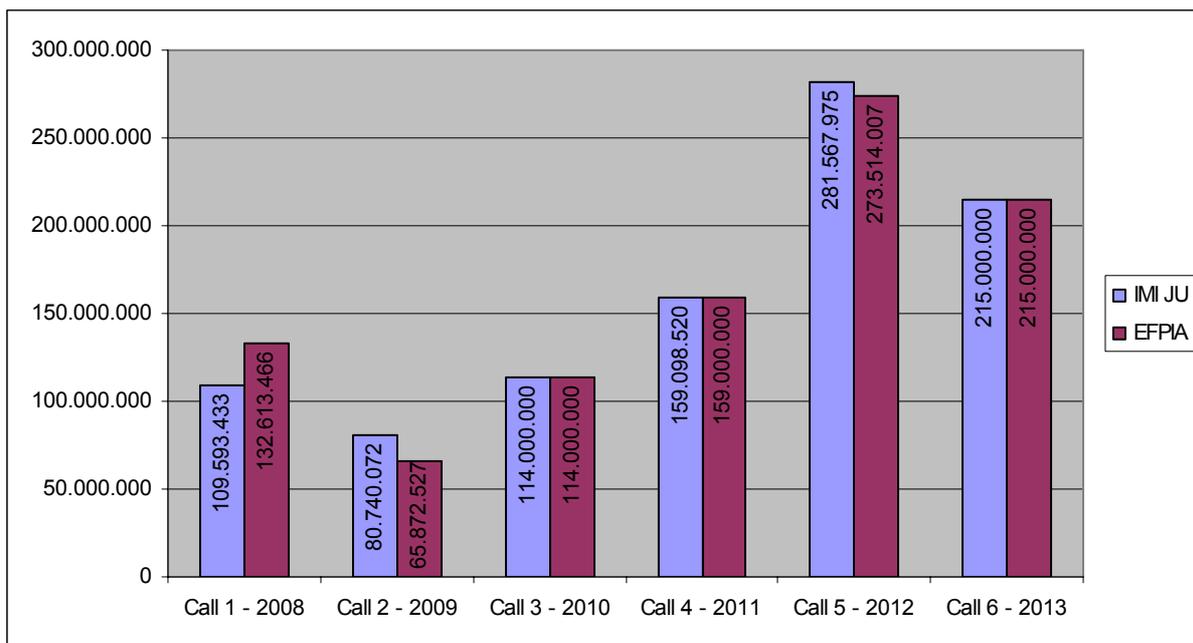
<b>Legislative Financial Statement</b>	122.700.000	78.643.200	98.644.744	159.098.520	301.304.340
Cumul LFS (A)	122.700.000	204.275.730	302.920.474	462.018.994	763.323.334
<b>COMMITMENT APPROPRIATION</b>	<b>125.632.530</b>	<b>78.643.200</b>	<b>98.644.744</b>	<b>159.098.520</b>	0
Committed	125.632.530	78.643.200	2.096.872	0	0
Cumul committed (B)	125.632.530	204.275.730	191.084.518		
Cumul difference to LFS (A-B)	-2.932.530	0	98.644.744		
Carry over C2 commitment amount			114.683.841		
Carry over commitment amount			191.084.518		
<b>PAYMENT APPROPRIATION</b>	<b>0</b>	<b>78.643.200</b>	<b>20.504.400</b>	<b>15.378.000</b>	<b>113.500.000</b>
Payments	0	0	20.504.400	0	0
Cumul payments ©	0	0	35.242.037		
Cary over C2 payment	0	78.643.200	64.506.664		
Carry over payment amount					

The Provisional Annual Accounts for 2010 including the report on budgetary and financial management for the same year with the balance sheet will be submitted to the IMI JU Governing Board together with this Annual Activity Report.

## 1. Call amount status

► **history of all closed calls (in blue) and forecast for the future calls (blank) in the prospective of IMI JU/EFPIA 50/50 contribution)**

	Proposal Call Identifier						
Data	Call 1 - 2008	Call 2 - 2009	Call 3 - 2010	Call 4 - 2011	Call 5 - 2012	Call 6 - 2013	Grand Total
Nbr projects	15	8	7				30
IMI JU	109.593.433	80.740.072	114.000.000	159.098.520	281.567.975	215.000.000	960.000.000
EFPIA	132.613.466	65.872.527	114.000.000	159.000.000	273.514.007	215.000.000	960.000.000
Total Call	242.206.899	146.612.599	228.000.000	318.098.520	555.081.982	430.000.000	1.920.000.000



## 2. Time to Grant

► Call 1 (even though most of the work has been done still by EC before autonomy, all grant signature occurred in 2010)

Project ID	Project Acronym	Project Duration	Project signature date	Proposal Call Identifier	Call1 Stage 2 closure date	Gov. Board Approval1	Gov. Board Approval2	Time to grant
115001	MARCAR	60	03/03/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	407
115002	e-TOX	60	21/01/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	366
115003	SAFE-T	60	03/03/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	407
115004	PROTECT	60	11/02/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	387
115005	IMIDIA	60	09/02/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	385
115006	SUMMIT	60	15/03/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	419
115007	EUROPAIN	60	14/01/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	359
115008	NEWMEDS	60	11/02/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	387
115009	PHARMA-COG	60	21/01/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	366
115010	U-BIOPRED	60	23/06/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	519
115011	PROactive	60	15/03/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	419
115012	SafeSciMET	60	11/02/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	387
115013	Pharma Train	60	11/02/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	387
115014	EU2P	60	11/02/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	387
115015	EMTRAIN	84	11/02/2010	Call 1 - 2008	20/01/2009	20/03/2009	15/12/2009	387
					<b>average</b>			<b>398</b>
					<b>median</b>			<b>387</b>

- Call publication: 27 November 2009
- Deadline Stage 1: 8 Feb 2010
- Evaluation Stage 1: 11-26 Feb 2010
- Launch Stage 2: 23/03/2010
- Deadline Stage 2: 28/06/2010

- Evaluation Stage 2:
- Negotiation Stage 2:

1-16/07/2010  
August-November  
2010

	EFPIA	Non EFPIA		
		Academia	SMEs	Others
Participants in Call 2 Projects	21			
Participation in Call 2 Projects	65	70	23	35
<b>Total participation</b>	<b>65</b>	<b>128</b>		
				<b>193</b>

Topic	Project ID	Project Acronym	IMI contribution	EFPIA in kind contribution	
5-6	1	115188	PREDECT	8.100.509	7.066.607
	2	115234	OncoTrack	16.050.282	9.726.557
	3	115151	Quic-CONCEPT	7.000.000	8.053.206
	4	115142	RAPP-ID	6.828.438	5.848.470
	5	115143	BTCURE	16.137.872	14.172.302
	6	115156	DD-MoRe	9.615.058	9.820.120
	7	115191	Open-PHACTS	9.988.867	4.142.649
	8	115189	EHR4CR	7.019.046	7.042.616
	9				
	Total		<b>80.740.072</b>	<b>65.872.527</b>	

Project ID	Project Acronym	Period Nr	Project start date	Period length	Period start date	Period end date	Period IMI JU Budgeted contribution	Period EFPIA estimated in kind contribution	Proposal Call Identifier	Date receipts deliverable	Payment 2010	Forecasting payment 2011
115013	Pharma Train	1	01/05/2009	12	01/05/2009	30/04/2010	1,053,090	1,200,000	Call 1 - 2008	23/07/2010	534,382	
115003	SAFE-T	1	15/06/2009	12	15/06/2009	14/06/2010	2,147,430	1,500,000	Call 1 - 2008	29/11/2010		507,646
115014	EU2P	1	01/09/2009	12	01/09/2009	31/08/2010	843,067	1,200,000	Call 1 - 2008	05/11/2010		748,801
115008	NEWMEDS	1	01/09/2009	12	01/09/2009	31/08/2010	1,872,226	2,000,000	Call 1 - 2008	04/11/2010		1,398,664
115011	PRoactive	1	01/09/2009	12	01/09/2009	31/08/2010	1,250,110	1,000,000	Call 1 - 2008	03/12/2010		923,849
115004	PROTECT	1	01/09/2009	12	01/09/2009	31/08/2010	2,425,218	1,500,000	Call 1 - 2008	03/11/2010		1,142,465
115015	EMTRAIN	1	01/10/2009	12	01/10/2009	30/09/2010	985,258	1,000,000	Call 1 - 2008	06/12/2010		255,881
115007	EUROPAIN	1	01/10/2009	12	01/10/2009	30/09/2010	1,355,460	1,300,000	Call 1 - 2008	09/12/2010		845,979
115010	U-BIOPRED	1	01/10/2009	12	01/10/2009	30/09/2010	1,983,844	1,400,000	Call 1 - 2008	07/12/2010		500,731
115006	SUMMIT	1	01/11/2009	12	01/11/2009	31/10/2010	4,000,000	2,000,000	Call 1 - 2008	18/01/2011		1,481,016
115002	e-TOX	1	01/01/2010	12	01/01/2010	31/12/2010	1,062,452	1,500,000	Call 1 - 2008			850,000
115001	IMARCAR	1	01/01/2010	12	01/01/2010	31/12/2010	1,340,675	1,400,000	Call 1 - 2008			1,000,000
115009	PHARMA-COG	1	01/01/2010	12	01/01/2010	31/12/2010	3,210,448	2,000,000	Call 1 - 2008			2,000,000
115012	SafeSciMET	1	01/01/2010	12	01/01/2010	31/12/2010	556,150	1,000,000	Call 1 - 2008			450,000
							<b>24,085,428</b>	<b>20,000,000</b>				<b>12,105,033</b>

2010	
IMI Prefinancing payments	34.704.184
IMI Intermediate payments	534.382
IMI total payments	35.238.566
EFPIA Accepted in kind contribution	0

#### IV – RELATIONS WITH GOVERNANCE BODIES

## **A – Support to Governing Board**

*The Governing Board is the governance body which has the overall responsibility for the operations of the IMI JU and oversees the implementation of its activities.*

In 2010 the IMI JU Executive Office continued to support the activities of the Governing Board in accordance with the established rules.

The Governing Board met three times during 2010 that is in March, July and December 2010. The main activities of the Governing Board during 2010 are summarised in the table presented on Section IV.

## **B – Support to Scientific Committee**

*The Scientific Committee as an advisory body to the Governing Board of the IMI JU conducts its activities in close liaison and with the support of the IMI JU Executive Office.*

The Scientific Committee met twice during 2010, namely in June and December. During the year, the Scientific Committee provided advice on the revision of the IMI Scientific Research Agenda A workshop was also organised by the IMI Executive Office for this purpose. The event included the participation of the EFPIA Research Directors Group, the European Commission Health Directorate and high level independent experts. (refer to page 4 of the revised SRA) The revision of the IMI Scientific Research Agenda was launched in 2010 as a major mission and will be concluded by Q2 2011.

In addition, the Scientific Committee has advised on IMI topics of the 3<sup>rd</sup> Call for Proposals and is working on the scientific priorities proposed by EFPIA for the 4th Call for proposals.

<b>Key activities in 2010 – timetable</b>	
Advice on 2011 Scientific Priorities	Q4
Advice on review of the IMI Research Agenda	Q3- Q4

## **C – Member States Representative Group**

*The IMI States Representatives Group (SRG), as advisory body, provides the IMI JU with opinion on the Scientific Priorities, on the update of the Research Agenda, and on the changes to the call and the evaluation process and intellectual property rules. The SRG, as the interface between the IMI JU and stakeholders in the Member States and Associated Countries, shall inform the IMI JU on relevant activities ongoing at national level and ensure dissemination of information related to the Calls for stakeholders within their own countries.*

The meetings of the IMI SRG were held on 29 April and 21 October 2010. The following table lists the key activities of the SRG during the year.

<b>Key activities in 2010 - timetable</b>
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Advice on 2011 Scientific Priorities, including the synergies with the Framework Programme	Q4
Ensure and facilitate the dissemination of information related to the second and third Call for proposals	Q1 & Q4
Involvement in the IMI IP working group assessing the IMI IP policy in terms of needs of clarifications and adjustments	Q1 to Q3
Information on the outcome of the evaluation process	
Opinion on the update of the Research Agenda	From Q4
Advise on the activities of the IMI Joint Undertaking	Q2 & Q4

In addition, some States organised an IMI Info Day (e.g. Latvia, Israel and Spain) in which the IMI Executive Office participated.

### **D – Stakeholder Forum**

*The Stakeholder Forum<sup>3</sup> shall be a meeting open to all stakeholders in which they shall be informed on the activities of the IMI JU.*

During 2010, the first Stakeholder Forum was held in Brussels on 14 and 15 June. The meeting gathered around 200 stakeholders from across a broad range of organisations including representation from patients and research bodies. The distribution across Europe included all of the Member States represented in IMI projects and some additional States Representatives.

### **V – COMMUNICATION ACTIVITIES**

The IMI communication activities in 2010 were centred on continuing to build on the good relations already well-established with its stakeholders. This was achieved in a number of focused communication actions which firstly delivered two successful major IMI-run and IMI mission-centred events held in Brussels during the year, namely the Stakeholder Forum and the Open Info Day. Additionally, there were many representations of IMI's mission made to a diverse and wide audience by members of the Executive Office at a variety of other conferences, symposia and specialist gatherings during the year. This representation was at meetings which were selected as important opportunities, as reflected in the IMI communications 2010 strategy, to promote its corporate image and raise awareness and visibility of IMI activities (please see list below).

Other communication activities were equally focused on the importance of developing the other channels through which the IMI Executive Office depends to transmit its on-going IMI message and to manage the interaction between IMI JU and its audience, namely through electronic communication means as well as more traditional dissemination channels such as press and media coverage. The IMI website was redesigned and relaunched. The IMI website plays a key role in the delivery of several of IMI JU's mission deliverables –

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<sup>3</sup> Article 9 of the IMI JU Statutes

transparency, accessibility to information, participation and interaction with its stakeholders and partners and provides one of the main interfaces between the IMI Executive Office and its audience. The on-going maintenance and development of the website included additional user-friendly features to reflect user feedback and both on-going 'business' and communication needs. This is a dynamic process which will continue to be updated to reflect the needs of IMI stakeholders and expansion of the role of the website is a high priority for 2011.

Traditional media and press communication methods continued also to be exploited through the issues of several Press Releases and articles/features which were conducted by members of the IMI Executive Office as well as through the active IMI Projects. External relations with the Press/Media continue to be conducted with a view to developing solid positive links for the dissemination of IMI's message to a variety of press/media outlets.

Additionally a Partner Search e-tool was designed internally and launched through the IMI website in response to a need to facilitate the process for potential applicants to find suitable partners with whom to form applicant consortia in the IMI Calls. The platform allows potential partners to sharing their relevant skills and knowledge in relation to the project Calls so that there is an easily-accessible pool of interested and available resource within the IMI database. The response was very positive with over 100 interested parties registering via the tool within the first week on-line.

Due to 'below optimal' staffing levels within the Communications and External Relations Team some activities such as the Drugs Safety Event which was planned for November 2010 have been postponed until communications staffing resources are sufficient.

The main IMI communication events in 2010 were the following:

<b>Event</b>	<b>Main objectives &amp; goals</b>	<b>Main target audiences</b>	<b>Format</b>
<b>Stakeholder Forum 2010 (14-15 June)</b>	<ul style="list-style-type: none"> <li>Promote IMI, and the Calls</li> <li>Raise awareness for IMI, and Open Innovation,</li> <li>Discuss the IMI Research Agenda,</li> <li>Create networking opportunities.</li> </ul>	<ul style="list-style-type: none"> <li>All interested stakeholders,</li> <li>Including patient organisations,</li> <li>Decision makers</li> <li>Press, as a proxy to general public.</li> </ul>	<ul style="list-style-type: none"> <li>Plenary keynote presentations,</li> <li>Parallel workshops on progress of 1<sup>st</sup> Call projects,</li> <li>Press conference,</li> <li>Second day dedicated to IMI Research Agenda.</li> </ul>
<b>Open Information Day 2010 (22/10/2010)</b>	<ul style="list-style-type: none"> <li>Attract research consortia and experts to the 3rd Call,</li> <li>Promote IMI.</li> </ul>	<ul style="list-style-type: none"> <li>Potential applicants.</li> <li>Promote and facilitate public-private collaboration</li> </ul>	<ul style="list-style-type: none"> <li>Building on the format of 2009.</li> </ul>
<b>IMI Thematic Day (combined with Open Info Day): (22/10/2010)</b>	<ul style="list-style-type: none"> <li>Raise awareness for strategic needs and opportunities in a specific area of disease/research,</li> <li>Promote IMI, and the Calls</li> <li>Raise awareness,</li> <li>Attract interest in IMI projects.</li> </ul>	<ul style="list-style-type: none"> <li>Scientific experts,</li> <li>Regulators, decision makers,</li> <li>Industry representatives,</li> <li>Patient organizations,</li> <li>Press as a proxy to the general public.</li> </ul>	<ul style="list-style-type: none"> <li>Plenary sessions,</li> <li>Dedicated workshops in specialised fields,</li> <li>Press conference.</li> </ul>

In addition to these IMI events, members of the IMI JU Executive Office have represented IMI and its mission at over 40 other events ranging from industry-focused EFPIA member conferences and meetings to a number of international events and IMI Open Info Days. IMI's

presence in these events has had a highly positive impact and has generated considerable support for IMI's mission and objectives. It has also helped to build many bridges across traditional boundaries within the pharmaceutical industry and has laid a foundation for strong positive relationships with stakeholders, participating EFPIA member companies, academia and SMEs.

During 2010, IMI was present during the following events:

Type of Event:	Where held:	Main Audience:	Objectives:
IMI InfoDays	France, Paris Spain, Madrid Portugal, Lisbon Israel, Tel Aviv Latvia	General Interest in IMI activities and Calls	To inform and raise awareness to IMIs mission and objectives. Public relations with IMI's potential users. To create press and media communication opportunities
EFPIA Members/Industry Meetings	Germany, Berlin Switzerland, Basel Switzerland, Zurich Switzerland, Geneva	EFPIA Members	To present IMI activities, achievements. To discuss and exchange ideas and experiences with participants in IMIs on-going projects. To provide access for EFPIA members' input into the future of IMI.
IMI IP Policy Workshops	Germany, Bonn UK France, Paris	General Interest in IMI IP Policy	To inform and educate on IMI IP Policy. To allow interaction and discussion on experiences of IP policy.
IMI Call Launch	Nice, France Antwerp, Belgium	Project participants, EFPIA coordinators	To assemble 'winning' academic and EFPIA partners to discuss making full project proposal and IP Policy
Knowledge Management Workshops	Italy, Ispra	General Interest	Joint Research Centre initiative to have interactive discussion on knowledge transfer and priorities for the Innovation Union
Open Innovation Workshops	Belgium, LLN Belgium, Brussels UK, Cambridge	Open Innovation Practitioners in Europe	To share best practise, recent experiences, perspectives and to explain how IMI implements open innovation
Conferences	Germany, Aachen Germany, Berlin UK, London Canada, Montreal Finland, Helsinki Italy, Turin Denmark, Copenhagen Switzerland, Zurich Netherlands, Lunteren US, Philadelphia	General Interest	To raise awareness to IMI's mission, activities and achievements to date. To interact with the largest possible audience/stakeholders/participants to ensure transparency and flow of information about IMI reaches widest audience. To permit media and press interest.
Networking Activities	USA, New York Belgium, Brussels	US PPP Dutch PPP	To discuss shared lessons learned and to benefit from other PPP experiences. To develop KPIs for PPP activities
Ongoing IMI Projects	France, Bordeaux	Education & Training Projects (1 <sup>st</sup> Call) and general student audience	To interact with project coordinators and managing entities for ongoing E&T projects. To build stronger relationships with these project leaders. To give projects an opportunity to show their progress and ideas and to discuss communication strategies

## **VI - OVERVIEW OF MAIN RESULTS ON 2010**

This final section presents the main results achieved in 2010 by reference to the objectives (“output indicators”) listed in the AIP 2010.

Annual Accounts and Balance-sheet 2009 <i>Included on the Annual Activity Report 2009. Decision by the Governing Board on March 2010</i>	Achieved in Q1
2 <sup>nd</sup> batch of Staff Implementing Rules <i>Decision by the Governing Board on February 2010 implementing the procedure for the appraisal of the Executive Director</i>	Q1
Scientific priorities 2010 <i>Included on the Annual Implementation Plan 2010. Decision by the Governing Board on March 2010</i>	Q1
First call for proposals: sign Grant Agreements of the research projects <i>Decision by the Governing Board on December 2009</i>	Q1
Second call for proposals: List of selected proposals at Stage 1 <i>Decision by the Governing Board on March 2010</i>	Q1
Amendment to the Grant Agreement <i>Decision by the Governing Board on March 2010</i>	Q1
Annual Implementation Plan 2011 <i>To be approved by the Governing Board on March 2011</i>	Q1
Staff Policy Plan (update) <i>Decision by the Governing Board on March 2011</i>	Q1
Annual Budget Proposal 2011-2012 <i>To be approved by the Governing Board on March 2011</i>	Q1
Methodology to evaluate in-kind contribution <i>Pending further amendment to the Grant agreement</i>	Ongoing
Financial Guidelines <i>Pending further amendment to the Grant agreement</i>	Ongoing
Ensure active communication about IMI in Europe through press event <i>Please see the communication section</i>	Q1- Q4
Revision of the Research Agenda <i>To be approved by the Governing Board on Q2-Q3 2011</i>	Ongoing

Second call for proposals: List of selected proposals at Stage 2 <i>Decision by the Governing Board on September 2010</i>	Q3
Stakeholders Forum <i>Held on 14-15 June 2010 in Brussels</i>	Q3
Third Call for proposals: Publication of the Call <i>Decision by the Governing Board on November 2010</i>	Q4
Third call for proposals: Call documents <i>Decision by the Governing Board on October 2010</i>	Q3-Q4
Revision of intellectual property policy based upon the experience gained during the preparation of the Grant Agreements following the 2008 Call for proposals <i>Preparation and publication of a IMI IP clarification note on November 2010</i>	Q4
Recruitment of Second batch of Temporary Agents <i>The recruitment procedure was launched in April 2010. Most of the recruitments were concluded in 2010. Recruitment of remaining positions to be concluded on Q1 2011</i>	Q2-Q4
Definition of Results Indicators (mid term) and the High level impact measures (long term) to monitor the performance of IMI JU as a whole and of individual projects <i>Two workshops were organised jointly with Ti-Pharma to come up with indicators to measure the value created by Public Private Partnerships</i>	Ongoing to be finalized in 2011
Set-up and implement a long-term office solution <i>Moving was completed on 17 January 2011</i>	Q1
Second call for proposals: List of selected proposals after negotiation <i>Decision by the Governing Board on December 2010</i>	Q4
Ex-post audits <i>Decision by the Governing Board on December 2010</i>	From Q4

**Key performance indicators** have been designed for the research related services of the European Union institutions and bodies<sup>4</sup> to support analysis and to provide reasonable assurance of the IMI JU operations. However, the indicators assessing the performance of IMI JU operational activities related to research projects were as yet unavailable since these can

<sup>4</sup> Please see Budgweg [http://www.cc.cec/budg/man/icrm/doc/ic/reporting/aar/instructions/guidances/doc\\_091030\\_keyindicators-research\\_en.pdf](http://www.cc.cec/budg/man/icrm/doc/ic/reporting/aar/instructions/guidances/doc_091030_keyindicators-research_en.pdf) on "key indicators supporting reasonable assurance for the research family – direct centralised management").

only be compiled once all the information from the first annual reports of each project have been received. Most of these reports will be received during 2011.

In parallel, in order to prepare the methodology to assess the global performance of IMI JU as a Public Private Partnership, the Executive Office organised jointly with Ti-Pharma, a Public Private Partnership operating in the Netherlands, two workshops to come up with indicators to measure the value created by Public Private Partnerships. These workshops included the participation and active contribution of various stakeholders. The outcomes of the workshops will be documented in a paper to be published in 2011. On this basis key performance indicators will be established.

## **VII – ANNEX**

*Declaration by the Executive Director on Reasonable Assurance*