



Innovative Medicines Initiative

ANNUAL IMPLEMENTATION PLAN

2011

Innovative Medicines Initiative Joint Undertaking

TABLE OF CONTENTS

I – FOREWORD

II - IMPLEMENTING R&D and EDUCATION/TRAINING ACTIVITIES

A – Support to the revision of the Scientific Research Agenda

B – Call-related activities

- Monitoring of ongoing (1st Call) projects

- Implementation of 2nd Call projects

- Evaluation of 3rd Call for Proposals

- Preparation of future Calls for Proposals

C – Knowledge Management

D – Guidance for intellectual property management

E – Performance Indicators

III – MANAGEMENT OF EXECUTIVE OFFICE

A – Staff implementation

B – Administrative/ legal matters

- Internal audit

- Internal control & Risk assessment

- Procurement & Grants

C – IT

D – Financial operations

IV – RELATIONS WITH GOVERNANCE BODIES

A – Support to Governing Board

B – Support to Scientific Committee

C – Member States Representative Group

D – Stakeholder Forum

V – RELATIONS WITH EXTERNAL INSTITUTIONS

VI – COMMUNICATION ACTIVITIES

VII - OVERVIEW OF MAIN MILESTONES AND TIMELINES FOR 2011

VIII– ANNEXES

I – Annual scientific priorities 2011

II – Staff Establishment Plan 2011

III – Annual Budget Plan 2011 and preliminary draft Budget Plan 2012

I. FOREWORD

The Innovative Medicines Initiative Joint Undertaking (IMI JU) was established in 2008 as a unique public private partnership between the European Union, represented by the European Commission (EC) 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 to be conducted by the IMI JU Executive Office throughout 2011 in pursuit of this mission.

The year 2011 will be of special importance for the future of IMI JU as the revision of the Scientific Research Agenda (SRA) will shape the IMI Projects to be launched by 2013. The Executive Office will play a pivotal role in this process by coordinating and supporting the stages leading to the definition of the topics for the future IMI Calls for Proposals. Considerable attention will also be given towards attracting and obtaining the necessary input from the scientific community.

Other key milestones to be achieved by the Executive Office during 2011 include the analysis of the scientific and financial reports from ongoing projects, the commencement of the Second Call projects, the evaluation of the proposals submitted in response to the Third Call, and the launch of the 4th Call. Critical assistance and guidance on IP policy issues and on the management of Intellectual Property (IP) within the projects will be continued. Special attention will also be given to communication activities. Initiatives will be taken to further strengthened and reshaped with priority being given to the dissemination of information on the first achievements of IMI among key stakeholders, using a more proactive and target-oriented approach. The level of awareness of IMI JU will be raised. IMI's uniqueness and what it can offer to the medical and scientific community will also be highlighted.

With regard to the internal operation of the Executive Office, the year 2011 will be marked by the office relocation and the setting up of a new organization structure that will enable the Executive Office to be in a stronger position to achieve its mission.

Overall, the implementation of the activities described in this Plan should make 2011 a turning point in the lifetime of IMI with enhanced focus being given to the “core business”, that is the promotion of scientific advances and innovation in the pharmaceutical sector across Europe through the expansion of IMI's funding portfolio.

II - IMPLEMENTING IMI JU CORE ACTIVITIES AND MISSIONS

A – Support to the revision of IMI Scientific Research Agenda

The IMI SRA includes recommendations to address bottlenecks in drug development and a plan to guide their implementation. The recommendations included in the current version of the SRA released in March 2008 represent the outcome of an extensive consultation between Europe's key stakeholders in the biomedical sector. The SRA was conceived as a 'living' document to be updated in response to scientific advances and the evolution of the needs of industry.

Both Founding Members have agreed that the SRA should be updated and revised ahead of the launch of the 4th Call for Proposals (although the topics of the 4th Call will still be derived from the original SRA). There is an urgent need to revisit research bottlenecks and update pre-competitive research bottlenecks that will secure EFPIA commitments before 31 December 2013.

The process of revising and updating the SRA revision process was initiated in 2010 with the following steps and measures:

- With the aim of updating the SRA, the Scientific Committee produced a Status Report providing an overview of what the Committee viewed as potentially new and exciting research opportunities for the academic/SME world.
- After the completion of the Status Report, the Executive Office and the Scientific Committee organised a workshop to solicit ideas and feedback from stakeholders including industry, academia, regulatory authorities and patient organisations.
- The Founding Members have also provided feedback and will be further consulted prior to the finalisation of the SRA.
- Open consultation on the revision process has been and will continue to be encouraged via the IMI website.

These activities and the Scientific Committee meeting held on 1 and 2 December 2010 also enabled the Executive Office to define an agenda for the finalisation of the revision process of the SRA by 30 April 2011.

B – Call-related activities

- Monitoring of ongoing projects (1st Call for Proposals)

Fifteen projects originated from the 1st Call for Proposals launched in 2008. These projects are jointly funded through a financial contribution from the EC to IMI JU and a matching in-kind contribution by the research-based companies that are members of EFPIA.

The key objectives for 2011 are to follow up on the implementation of projects from a scientific, financial and administrative point of view and to implement amendments following modifications to the model Grant Agreement. In this regard, currently the methodologies for the calculation of indirect costs and of in-kind contribution of EFPIA companies are being defined and developed. Attention is also being given to the needs of the projects in order to

better reflect the unique mission and objectives of IMI JU. Specific amendments to guidelines and templates tailored to the requirements of IMI will be developed by the Executive Office in the course of 2011.

The Executive Office is also planning for interim project reviews to take place from Q3 2011. In addition, the first ex-post financial and scientific audits will be carried out by the end of 2011. Finally, concrete feedback from the implementation of the projects will allow the Executive Office to ensure the appropriate follow up of the discussions regarding IP-related matters.

- Implementation of 2nd Call projects

The Second Call for Proposals, launched on 27 November 2009, included eight topics addressing the following two strategic pillars: Predictivity of Efficacy Evaluation, and, Knowledge Management.

The key objectives for 2011 are to sign the Grant Agreements of the selected and successfully negotiated full project proposals and to follow up on their scientific, financial and administrative implementation.

The signature of Grant Agreements will be concluded in Q1 2011 (subject to the completion of the Project Agreements) and this will lead to the implementation of pre-financing arrangements.

Following the report of the independent observers who monitored the evaluation process, an IMI Action Plan was developed to address the highlighted issues. The Action Plan has been recently uploaded on the IMI JU website and it is foreseen that these action will be implemented in future IMI Calls for Proposals.

- Evaluation of 3rd Call Proposals

The Executive Office launched the Third Call for Proposals on 22 October 2010. It includes seven topics addressing the three following strategic pillars: Predictivity of Efficacy Evaluation, Predictivity of Safety Evaluation, Education and Training. Each topic is associated with a pre-established consortium of pharmaceutical companies that are members of EFPIA ('EFPIA Consortium').

The key objectives for 2011 are to evaluate, select and negotiate the research projects originating from the Third Call for Proposals. The signature of the grant agreements and payment of pre-financings are expected to be concluded by Q1 2012.

A two-stage Call and evaluation process, as used in previous Calls, will be followed and it is envisaged that the process is finalised, together with negotiations, in 2011.

The total budget for the Third Call for Proposals included a maximum financial contribution from the EC to the IMI JU of € 114 million and a matching in-kind contribution by the research based companies that are members of EFPIA.

- Preparation of future Calls for Proposals

The future Calls for Proposals (5th and additional Calls) will be based on the Scientific Priorities developed from the revised Scientific Research Agenda.

The key objectives for 2011 in relation with the calls for proposal will be to support the process of defining the Call topics for the 4th Call for proposals based on the Scientific Priorities 2011 as described in Annex I; to launch the 4th Call for Proposals (expected to be launched by Q2 2011) and to prepare the relevant Call documents (i.e. Call topics, Rules for Participation, Rules for Submission, Evaluation and Selection of Expressions of Interest and Full Project Proposals, Guide for applicants) for adoption by the Governing Board.

For the 4th Call and subsequent Calls, the Executive Office will propose, in due course, to EFPIA and the EC the adoption and implementation of a more streamlined process for future Call topics in line with the Scientific Priorities that will be defined through the revised SRA. Also, in the preparation of the Call topics, special attention will be given to getting the necessary input from opinion leaders in the academic community.

C – Knowledge Management

In 2010, the Executive Office issued the "Knowledge Management Report" as a result of two workshops held to investigate the Knowledge Management (KM) needs of a public-private partnership. The report proposes the setting up a KM service delivery group with the assistance of external experts to support the Executive Office in the implementation of a KM service infrastructure¹. The objective is to work closely with the project coordinators in order to explore their KM strategies and needs. Accordingly, the Executive Office will organise, in 2011, a KM workgroup with the aim of gathering and effectively sharing information from ongoing projects and future IMI projects in the following areas:

- (i) Metadata and quality of data;
- (ii) Interoperability issues in data management;
- (iii) Used KM platforms.

D – Guidance for Intellectual Property management

1. An IMI Intellectual Property Guidance Note for applicants and participants was issued in November 2010 by the Executive Office following discussions of the Intellectual Property Working Group (IPWG) to explore the ways to handle IP related issues as well as pitfalls that participants may encounter during the preparation, negotiation and completion phases of the Project Agreements.

The Executive Office intends to ensure adequate follow up of this Guidance Note by increasing communication to all stakeholders and by providing support to applicants and participants during the submission, negotiations and implementation phases of IMI proposals and projects.

The Executive Office will continue the activities of the IPWG through regular meetings that will focus on exchanges and feedback from ongoing projects and negotiations. Concrete best practices could, as a result, be drawn up from these exchanges.

2. In addition, the Executive Office also foresees the:

¹ See further "procurement and grants"

- setting up and maintenance of the IP Helpdesk.
- development of continuous activities to promote and explain the IMI IP Policy;
- participation in a forum organised at European level on IP management and best practices (e.g. the European Open Innovation Practitioners Consortium, the European Policy for Intellectual Property). For this purpose, the Executive Office will pay contributions as well as subscriptions to bodies of which it is member.²

E – Performance indicators

The performance of IMI will be monitored and measured through various key performance indicators, both on a short term (to assess the IMI JU's achievements) and on a long term basis (to assess the impact of IMI JU).

On this basis, the Executive Office will produce short, medium and long term indicators with a view to assess the value creation of IMI and its impact on the European competitiveness in the health sector. During the course of 2011, the methodology to measure these indicators will be established in order to initiate measurement.³

III – MANAGEMENT OF EXECUTIVE OFFICE

The Executive Office will implement its activities in compliance with the applicable rules and procedures to support the appropriate management of public and private funds, under the leadership of the Executive Director who is responsible for the day-to-day management of the IMI JU.

A – Staff implementation

In order to implement the strategy defined by the present plan for 2011, the following needs of the Executive Office in terms of staff and recruitment (see Staff Establishment Plan in Annex II⁴) will be addressed:

- A Legal Officer will be recruited in 2011 in line with the request of the Governing Board to establish an IP Help-Desk to develop and enhance the support to projects' applicants and consortium partners in the field of Intellectual Property (IP).
- A Head of Administration and Finance will be engaged to cope with the increased volume of work at management level.

² According to Article 94 (2c) of the IMI JU Financial Rules and Article 160(a) of the Implementing Rules applicable to the general budget of the European Union.

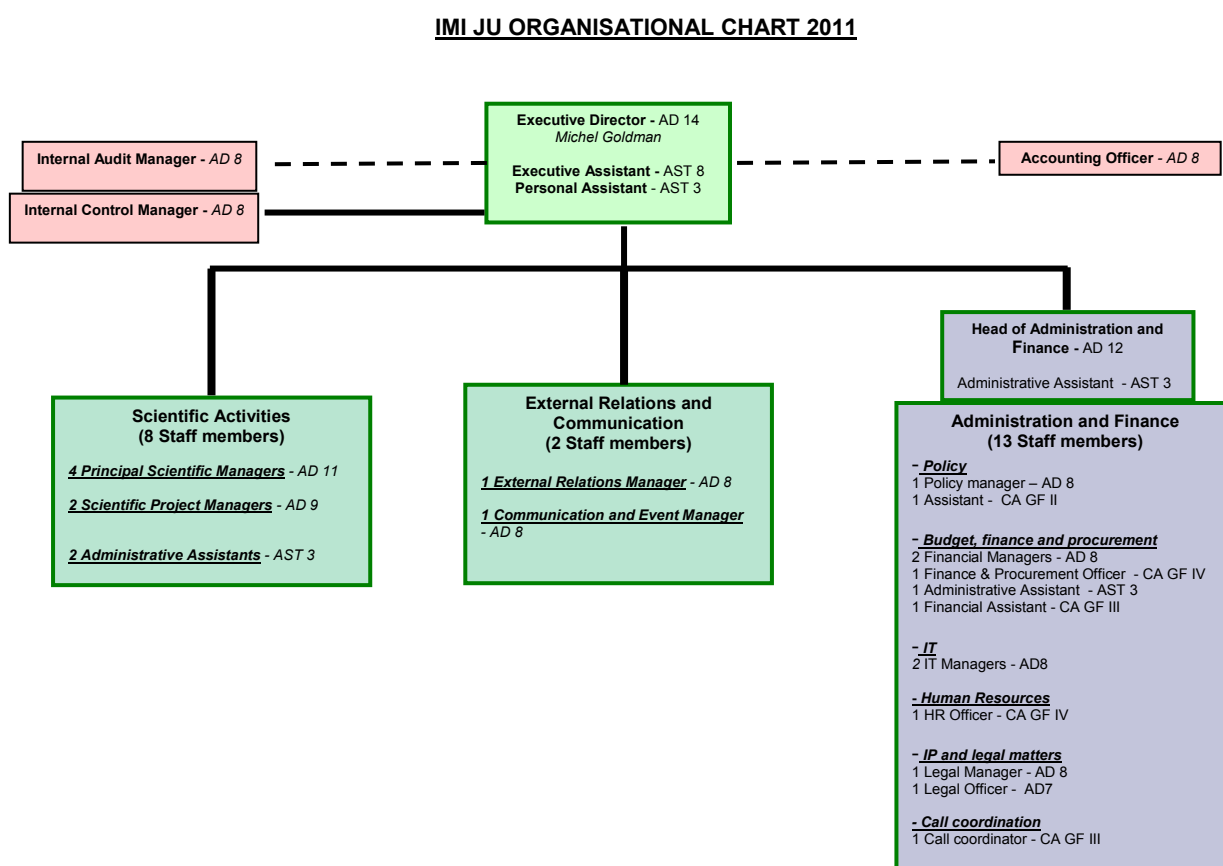
³ See further § III.B "Procurements"

⁴ The Commission gives its agreement on IMI's AIP under the conditions that will be set in the final opinion of the Commission on IMI's draft MSPP for 2012 – 2014 that will be adopted during the month of March. The final configuration and number of staff for 2011 and 2012 will therefore be decided once the AIP, budget and MSPP for 2012 – 2014 are adopted.

- In parallel, the three remaining posts of Scientific Manager (AD9 positions) initially foreseen in 2010 will be postponed to 2012 in order to tailor the timing of their respective appointments with the schedules of remaining Calls and related activities of the projects. This will also provide the opportunity to align their profiles with the new priorities to be established through the revised Scientific Research Agenda.

The recruitment of these positions (Temporary Agents) does not change the volume of staff appropriations or the limit of the total number of authorised posts as were originally foreseen in the multiannual staff establishment plan 2010-2012.

The organisational chart for 2011 is presented below:



B – Administrative/ legal matters

In 2011, IMI JU will continue to develop its processes and activities paying particular attention to the simplification of procedures and taking into account the specific needs and the size of the IMI JU.

Following the conclusions of the EC's interim evaluation report as foreseen in the Council Regulation setting up the IMI JU, the Executive Office will work on a plan to follow up on the recommendations of this report.

- Internal Audit Capability

IMI JU has established its own internal audit capability to provide independent, objective assurance and internal advisory services on the suitability, efficiency and effectiveness of the organisation's risk management, control and governance processes, taking into account the size and the scope of the JU.

In 2011, the Executive Director and the Internal Auditor will define the IMI JU Internal Audit Activity Charter, with due consideration being given to the role and responsibilities of the Internal Audit Capability (IAC).

In addition, by Q3 2011, the Internal Auditor will submit to the Executive Director a final version of the Multiannual Internal Audit Plan 2011-2013 as well as an annual work plan for the following calendar year.

- Internal control & Risk assessment

Internal control and risk management are two strategic pillars for optimising the ability of IMI JU Executive Office to: (i) ensure sound management, (ii) identify and evaluate the risks that IMI JU faces, and (iii) for deciding how these are to be managed in an effective and appropriate manner.

With these objectives in mind the strategy of the Executive Director for 2011 shall be based on:

- a) the existing methodology of performance reports, as well as for the provision of oversight and strategic direction
- b) special monitoring and actions to improve the following activities:
 - the implementation of the Internal Control Standards;
 - the implementation of the Ex-post Audit strategy;
 - the managerial supervision of activities. This will be concentrated on the main risks detected following the risk analysis performed in 2010-Q3/Q4 and will be performed from a sample of files in selected processes and through discussions with concerned staff. Namely, the assessment will focus on:
 - HR management and staff organisation;
 - Grant Agreement negotiation procedures;
 - Financial circuit and payments;
 - IT infrastructure and security policy.

The implementation and monitoring of point b) referred above will guarantee that the main operational and financial processes and procedures are adequately documented and comply with applicable provisions, in particular the Financial Rules.

- Procurement

In order to reach its objectives IMI JU will allocate funds for the support of its operational activities. For this purpose, the Executive Director will use public procurement procedures.

The tendering process will be carried out according to the IMI JU Financial Rules⁵. For the award of contracts an open procedure shall be used. A contract notice with reference to

⁵ Complying with Title V (Articles 76 to 92) of the IMI JU Financial Rules adopted by the IMI JU Governing Board on 2 February 2009 and to the Implementing Rules applicable to the general budget of the European Union.

detailed tender specifications shall be published in the S series of the Official Journal in line with preliminary timetable indicated below. The public procurement planned for 2011 is in relation to:

- Multiple framework contracts in the field of financial audits, other assurance engagements and related services;
- Call Evaluation platform;
- Communication Framework Contract; and,
- Performance Indicators.

The Executive Office is also planning to organise, during the Hungarian Presidency, the Stakeholders Forum 2011 in coordination with the ministerial conference on eHealth that is scheduled to be held in Budapest between 10 and 13 May 2011.

In addition, supporting activities in KM related matters are planned with the objective being to ensure implementation of a KM service infrastructure and coordination of KM activities through the KM working group.

Furthermore supporting activities in IP related matters are also planned with the objectives being to ensure complementary and coordination with IMI activities, as well as to answer to unforeseen needs in relation with the open innovation concept.

C – IT

In 2011, IT will concentrate on the following objectives:

- Consolidation of the new IT infrastructure

Regarding the new IT infrastructure, effort will be made to consolidate the implemented architecture. This will involve fine-tuning activities to optimise and increase performance. More importantly attention will be given to keeping maintenance and operational costs at the lowest possible level.

- IMI submission tool

The submission tool will undergo a series of functional improvements that will cover a major part of the call management process. These functional extensions will include the negotiation and the Grant Agreement signature phase, and the Grant Agreement amendments during the life cycle of a project. A set of functional enhancements to the existing modules (EoI and FPP submission and evaluation) based on continuous feedback received from internal and external users will also be implemented.

- Knowledge Management

An online environment for sharing knowledge generated by IMI Scientific Projects will be put in place. The aim is to create a single environment in which collaboration can take place and through which the project content will be structured, indexed and searchable. The IMI JU will give the necessary attention to the confidentiality issues involved in the creation and implementation of this tool.

- Internal administrative systems:

Particular attention will be paid towards the strengthening of the efficiency of the internal processes. For this purpose, it is envisaged that documents will be digitalised and they will be easily searchable and auditable, while workflows will be automated.

Process automation will also enable a more efficient and reliable management of human resources.

D – Financial operations

The Executive Office shall; ensure compliance with the IMI JU Financial Rules and the respective implementing provisions; forecast of the IMI's annual revenue and expenditure and prepare, implement and control the budget; ensure the accounting and financial management and reporting; draw up the IMI annual accounts; ensure the efficient utilisation and maintenance of IMI office space; and manage relations and coordinate activities related to the European Court of Auditors and the Commission's Internal Audit Service and the accounts discharging process.

- Financial Grant Management

In 2011, IMI will manage twenty-three IMI Projects/Grants (fifteen projects from Call 1 and eight projects from Call 2).

As the number of grants and the subsequent reporting documents is expected to grow significantly, a Web-based application will be developed to improve the process and to help beneficiaries in their reporting.

- Budget

The detailed provisional preliminary draft annual budget plan for 2011 is annexed with the AIP (refer to the document 'Provisional Preliminary Draft Annual Budget Plan'). The table below provides an overview of the budget:

Commitment appropriations:

Running costs:	9.418.960€
Operational costs:	285.379.570€

Payment appropriations:

Running costs:	9.418.960€
Operational costs:	89.653.637€

In the case of running costs, these include:

- Title 1: All costs linked to staff, employment and recruitment costs, cost of travel (missions), training and social measures (4.010.000€).
- Title 2: Running costs of the IMI JU office, such as office equipment, IT and telecommunications, housing, communication and events, the evaluation process, formal meetings, and expenditures in connection with research activities (workshops, meetings and events targeting the IMI projects) (5.408.960€).

With regard to operational costs implementing the IMI research agenda, these comprise of:

- Title 3: The available commitment appropriation for Call 4 is budgeted at 159 M € in 2011. Additional commitment appropriations will also be available such as the amount carried-over from unused appropriations for Call 3 of 114 M €. Call 3 budget is foreseen to be committed (global envelope/commitment) after the stage 1 of the evaluation phase. Out of the carried-over payment appropriation (64.5M€), 27€M will be used in 2011 after full consumption of the 2011 budget (15.7M€) and this amounts in total to around 42.5 M €.

IV – RELATIONS WITH GOVERNANCE BODIES

The IMI JU provides facilities and services for the meetings of the governance bodies and working groups. The IMI JU assists members and delegates with practical arrangements and logistics.

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.

The IMI JU Executive Office will continue to support the activities of the Governing Board in accordance with the established rules. The agenda of Governing Board meetings will be arranged in order to allocate sufficient time for strategic discussions. A review of the procedures preceding Governing Board decisions will be initiated in Q2 with a view to streamline approval processes.

The Governing Board will meet three times during 2011, namely in Q1, Q2, Q4.

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 will meet at least twice during the year 2011. It will advise on the revision of the IMI SRA and recommend amendments. The revision of the SRA was launched in 2010 as a major goal to be concluded by Q2 2011.

With a view to enhance the input of the academic community into IMI JU, Scientific Committee members will also be invited to contribute to the definition of IMI Scientific Priorities and Call Topics as well as to the assessment of ongoing projects.

C – Member States Representative Groups

The IMI States Representatives Group (SRG), as an 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.

At least two meetings of the SRG are foreseen for 2011. The IMI JU will provide the secretarial, organizational and administrative support for these meetings.

The Executive Office will also set up a Content Management Service (CMS) platform to ensure adequate sharing of data and information with the States Representatives Group Members in a secure environment.

D – Stakeholder Forum

Through a one-day event in May, IMI aims to engage key stakeholders in discussions about the activities of IMI. Furthermore, the 2011 Stakeholder Forum will offer IMI the opportunity to present the 2nd Call projects and to showcase success stories from the 1st Call projects.

Further information on the Stakeholder Forum is provided in the section on Communication activities.

V – RELATIONS WITH EXTERNAL INSTITUTIONS

These activities cover co-operation and coordination at European and international level in the areas that can best contribute to fulfilment the objectives of the IMI JU.

The collaboration and interaction is being tailored according to the impact that these activities may have in promoting research on the biopharmaceutical sector in Europe.

a) Critical Path Institute

C-Path, founded in 2005 as a corporation based in Arizona, operates under a Memorandum of Understanding with the FDA to jointly support collaborations that result in improved testing methods for new medical products.

b) Juvenile Diabetes Research Foundation

The Juvenile Diabetes Research Foundation (JDRF) is the worldwide leader for research to cure type 1 diabetes. It sets the global agenda for diabetes research, and is the largest charitable funder and advocate of diabetes science worldwide.

Memoranda of Understanding are foreseen to be concluded between the IMI JU and C-Path on one hand and with the Juvenile Diabetes Research Foundation on the other hand, to establish a framework for collaboration.

VI – COMMUNICATION ACTIVITIES

The 2011 IMI JU Communication Plan aims to execute a fully pro-active communications programme for 2011 using the broadest range of methods and means available to deliver measurably greater visibility and awareness of IMI JU and its activities. The 2011 communication strategy directly reflects the changing needs of the IMI JU which are evolving as the organisation develops and first concrete achievements become available for dissemination. The effective implementation of the Communication Plan will be made possible by engaging one additional staff members and through the procurement of additional

specialist support for specific activities, such as the on-going procedure for the appointment of a suitable Public Relations agency.

A – Regular Events and Communications Milestones 2011

- Stakeholders forum, Q2, 2011
- Open Info Day, Q3, 2011
- Drug Safety Event, Q4, 2011
- Hever meeting, Q1, 2011

B - Actions to be taken

- Create communications opportunities by pro-active interaction using internal/ external communication 'hooks' which will increase the quantity of IMI-initiated communication towards key stakeholder groups and the media. A communication 'hook' is the linking of either an external or IMI-initiated point of interest which can be translated into a communication opportunity for IMI JU. Such opportunities include but are not limited to good news from the Projects, success of IP Policy implementation, selection/launch of 3rd Call projects and launch of 4th Call 'Think Big' projects, International research developments/ forums and debates
- Establish and develop an IMI JU media network of general and privileged press and media contacts using current contacts/EFPIA contacts and building new contacts during 2011
- Increase IMI output to this media network in producing real-time Press Releases and through longer-term collaborations to produce specific articles for publications identified as high-level scientific journals.
- Identify and develop a number of key relationships with 'ambassadors' and 'champions' for IMI JU who will help to raise awareness of and promote additional support for IMI and its activities within all identified target audience groups.
- Pro-actively link communication material to IMI/EFPIA/Commission and external events, meetings, publications etc
- Complete the procurement of a long-term contract with a PR-company for media monitoring, stakeholder surveys, communication strategy and communication support.
- Participate in various scientific conferences with information on IMI, including booths