Innovative Medicines Initiative

Annual Activity Report
2011

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1. FOREWORD

2011: SETTING THE SCENE FOR A SOLID FUTURE

The year 2011 was the second full year of autonomous operation for the Innovative Medicines Initiative Joint Undertaking (IMI), a year marked by consolidating its operations and structures and making further significant developments in establishing itself as a new model for drug development based on pre-competitive research and open collaboration, in line with the vision of its Founding Members.

Overall, with 13 additional Grant Agreements concluded in 2011, IMI will be managing a portfolio of 30 projects by early 2012. In parallel with such an increase in workload, major operational changes have been introduced in order to make the initiative more efficient in delivering its core business to stakeholders. The IMI Scientific Research Agenda was revised in order to provide a new framework for the preparation of future IMI Calls for proposals with a focus on large-scale, game-changing projects. Two such topics were already introduced in the 4th Call for proposals launched in 2011.

Several operational procedures have been simplified and streamlined in order to reduce the administrative burden for consortium partners, to shorten the time interval between the launch of the Calls for proposals and the initiation of the projects, and to improve the budget execution. In particular, the revision of the model Grant Agreement clarified several pending issues, including the reporting of in-kind contributions by EFPIA companies.

Significant efforts have been made to improve the visibility of IMI among different stakeholders and to harness the involvement of academic teams, small and medium sized enterprises, regulatory agencies and patients' organisations. Furthermore, a new collaborative environment has been developed to enhance the interactions and connectivity between IMI's governance and consulting bodies, applicants and partners, using dedicated IT tools and platforms.

The first interim reviews of projects have been successfully conducted and new management tools have been put in place to assess the performance of IMI with initial measurements being included in this report.

I am very pleased with the significant achievements of IMI Executive Office in 2011 and am confident that we are creating a solid base for IMI's work in the coming years.

Michel Goldman
Executive Director

2. OVERVIEW OF 2011 MAIN ACHIEVEMENTS

In order to provide an overview of the IMI activities during 2011, the following table presents the major actions conducted against the objectives set out in the Annual Implementation Plan 2011.

Objective in AIP 2011	Action and outcome
Research Activities	
1. Revision of the Scientific Research Agenda	Approved by the Governing Board in Q3 of 2011
2. 1st Call Follow-up implementation of 15 projects. Ex-post financial and scientific audits	- Achievements of the projects widely disseminated - Positive reviews by independent experts of the work carried out in first years by projects MARCAR and SAFE-T - Request of additional funding by NEWMEDS project - Ex-post audits initiated in Q4 of 2011
3. 2nd Call Sign Grant Agreements of 8 projects by Q1 and follow up their implementation	Grant Agreements signed allowing the research activities to be initiated during Q1 of 2011
4. 3rd Call Evaluate, select and negotiate 7 research topics by Q1 2012	- Grant Agreements signed for 5 successful projects in Q4 2011 - Two remaining projects will conclude negotiations on Q1 2012
5. 4th Call and future Calls More streamlined process	- Call 4 Stage 1 evaluation concluded in Q4 of 2011 - Simplification taskforce set up in Q3 2011 together with EC and EFPIA for simplification and streamlining of IMI processes - Simplified Call process introduced to 4th Call Stage 2 - Taskforce to finalise in Q1 2012 the preparation of supporting documents and forms for future Calls
6. Knowledge Management (KM) Set up of a KM working group	- KM workgroup set up in Q1 of 2011 - IMI subscribed to Clinical Data Interchange Standards Consortium to ensure data standards homogenisation in IMI projects
7. Intellectual Property Rights Set up a IP help desk, promote continuous activities to promote and explain IMI IP policy	- IP helpdesk set up in Q4 of 2010 - IP Guidance note widely communicated - Amendments to IP introduced by the revised Grant Agreement in Q4 of 2011 - Continuous support to projects
8. Key Performance Indicators IMI will produce short medium and long term indicators with a view to assess the value creation of IMI impact on the European competitiveness in the health sector. During 2011 the methodology will be established	- KPI framework endorsed by the Governing Board in Q2 of 2011 - KPI targets for 2012 approved by the Governing Board in Q4 of 2011 - First KPI measurements presented in this Annual Activity Report 2011

Management of the Executive Office	
9. Office relocation	Office relocation achieved in January 2011
10. Recruitment Head of Administration and Finance, 1 Legal Officer, 1 Scientific Manager. Recruitment of 3 Scientific Managers postponed for 2012.	- Head of Administration and Finance took up duties in Q4 of 2011 - Legal Officer took up duties in Q4 of 2011 - Scientific Manager took up duties in Q2 of 2011
11. Internal Audit Capability Approval of the Internal Audit Charter and the Multi-annual Internal Audit Plan and work plan.	- Internal Audit Charter approved in Q1 of 2011 - Multi-annual Internal Audit Plan and work plan approved in Q4 of 2011
12. IT Consolidation of the new infrastructure, set up of IMI submission tool, of Knowledge Management (on line environment for sharing information), and of internal collaborative platform.	- Consolidation of new infrastructure started in 2011 - An ePortal and IT environments for ILG/EFPIA/EC, States Representatives Group and Scientific Committee created in 2011 - A submission tool for project applicants fully developed in Q4 of 2011 - Information on KM shared on-line via existing network tools - A tool for internal collaborative platform under development
13. Financial operations Revised Grant Agreement and IMI Financial Guidelines approved by Q1, first EFPIA reporting on "in-kind contribution" based on the usual accounting principles and on approved methodology, and simplification of forms and procedures for IMI beneficiaries.	- Revised Grant Agreement approved by the Governing Board in Q4 of 2011 - Financial Guidelines finalized and approved in January 2012 - EFPIA reporting on in-kind contribution as from Q1 2012 - Simplification: see point 5. above
14. Relations with External Institutions Set-up of Memoranda of Understanding with C-Path, JDRF and CDISC.	Memoranda of Understanding with Clinical Path Institute, Juvenile Diabetes Research Foundation and Clinical Data Interchange Standards Consortium signed in Q2 of 2011
15. Communication Activities Promote IMI programme as the most attractive in Europe, raise awareness amongst stakeholders and take advantage of success stories and testimonies of on-going projects and disseminate among key stakeholders.	- Positive coverage in media and specialised journals - Increased web presence and growing interest in IMI Newsletter and participation in IMI social fora - Outreach extended to new stakeholders across Europe through IMI events and external events - Increased communication efficiency by engaging multipliers, ambassadors and networks organisations - Development and broad dissemination of IMI publications - Media coverage of key publications in relation to IMI projects - Organisation of key events in the European Parliament (jointly with other JU) and within the activities of the EU Presidency in Krakow

3. IMPLEMENTING THE SCIENTIFIC RESEARCH AGENDA

3.1 REVISION OF THE SCIENTIFIC RESEARCH AGENDA

The Scientific Research Agenda (SRA) is the multiannual plan setting out the research priorities of IMI that are translated into Calls for proposals. To reflect the scientific advances and changes in industry, the IMI Scientific Committee initiated the revision of the initial SRA in 2010. After consultation with various stakeholders, the IMI Executive Office finalised the revision of the SRA in 2011 in conjunction with both Founding Members.

3.2 PROJECTS AND CALLS FOR PROPOSALS

3.2.1 State of play

Twenty-eight projects launched as a result of the first 3 Calls for proposals are currently up and running and 2 more will be launched in Q1 of 2012. Furthermore, seven additional projects are expected to be launched in Q3 2012, following the 4th Call for proposals including two large-scale projects derived for the revised SRA. Key figures of these 37 on-going and on-track projects are given in table 1.

Participation and budget in on-going and on-track projects

	Call 1	Call 2	Call 3	Call 4 *(forecast)*	TOTAL *(forecast)*
No. of projects	15	8	7	7	37
No. of EFPIA teams	160	66	54	61	341
No. of academic teams	194	105	101	108	508
No. of SME teams*	26	22	14	30	92
No. of patients' organisations	10	1	6	0	17
No. of regulatory agencies	7	0	2	1	10
No. of other partners	3	0	3	4	10
IMI JU contribution (€ millions)	109,6	80,7	111,8	93,6	395,7
EFPIA in-kind contribution (€ millions)	132,6	65,9	70,8	93,6	362,9

*Small and Medium sized Enterprises

From the information included in the Grant Agreements, we estimate that the number of scientists on board of IMI projects to be currently around 2800 among which 27% are with EFPIA companies.

The activities conducted in 2011 in relation with these projects are summarized here after.

3.2.2 Interim reviews of 1st Call projects

The 15 projects which were initiated in Q1 of 2010 have started to deliver important results in 2011. These achievements have been summarized in a booklet on 'Early Achievements' which has been widely disseminated to IMI's stakeholders and published on the IMI website.

The first interim reviews were conducted in 2011 for two projects: MARCAR (research topic: non-genotoxic carcinogenesis) and SAFE-T (research topic: biomarkers of drug safety for clinical use). The aim of the interim reviews is to assess the work carried out in the initial phase of the projects and to provide recommendations to corresponding consortia. These reviews are carried out by external independent experts, including experts from the IMI Scientific Committee, and cover scientific, technological and other aspects relating to the proper execution of IMI-funded projects. The MARCAR and SAFE-T projects were positively evaluated. Both industry and academic partners from the consortia appreciated the feedback they received and recognised the value of the exercise.

3.2.3 Launch and pre-financing of 2nd Call projects

Grant Agreements were signed in 2011 for the 8 projects selected for funding from the 2nd Call for proposals, enabling IMI JU to proceed with pre-financing payments for a total of EUR 28.5 million as shown in the table below.

2nd Call projects: IMI JU budget and pre-financing

Consortium Acronym	2nd Call Topic	Prefinancing (EUR million)	Total IMI JU contribution (EUR million)
BTCURE	New diagnostic tools for stratification of patients with rheumatoid arthritis	5,2	16,1
DDMORE	A drug and disease model library as a public resource	3,1	9,6
EH4RCR	Electronic health records systems for clinical research	2,8	7,0
ONCOTRACK	Novel oncology biomarkers	5,1	16,1
OPENPHACTS	Open access innovation platform for drug-oriented research	5,3	10,0
PREDECT	Innovative models for cancer research	2,6	8,1
QUIC-CONCEPT	Quantitative imaging biomarkers in cancer	2,2	7,0
RAPP-ID	Rapid detection of infectious agents	2,2	6,8
	TOTAL	28,5	80,7

3.2.4 Implementation of 3rd Call for proposals

Call Topics

The 3rd Call for Proposals, launched in October 2010, included the following seven topics:

- Improving early prediction of drug-induce liver injury (DILI) in humans;
- Immunogenicity: assessing the clinical relevance and risk minimization of antibodies to biopharmaceuticals;
- Immunosafety of vaccines – new biomarkers associated with adverse events;
- Improving the preclinical models and tools for tuberculosis medicines;
- Translational endpoints in autism;
- Personalized medicine in diabetes treatment;
- Fostering patient awareness on pharmaceutical innovation.

Budget Figures

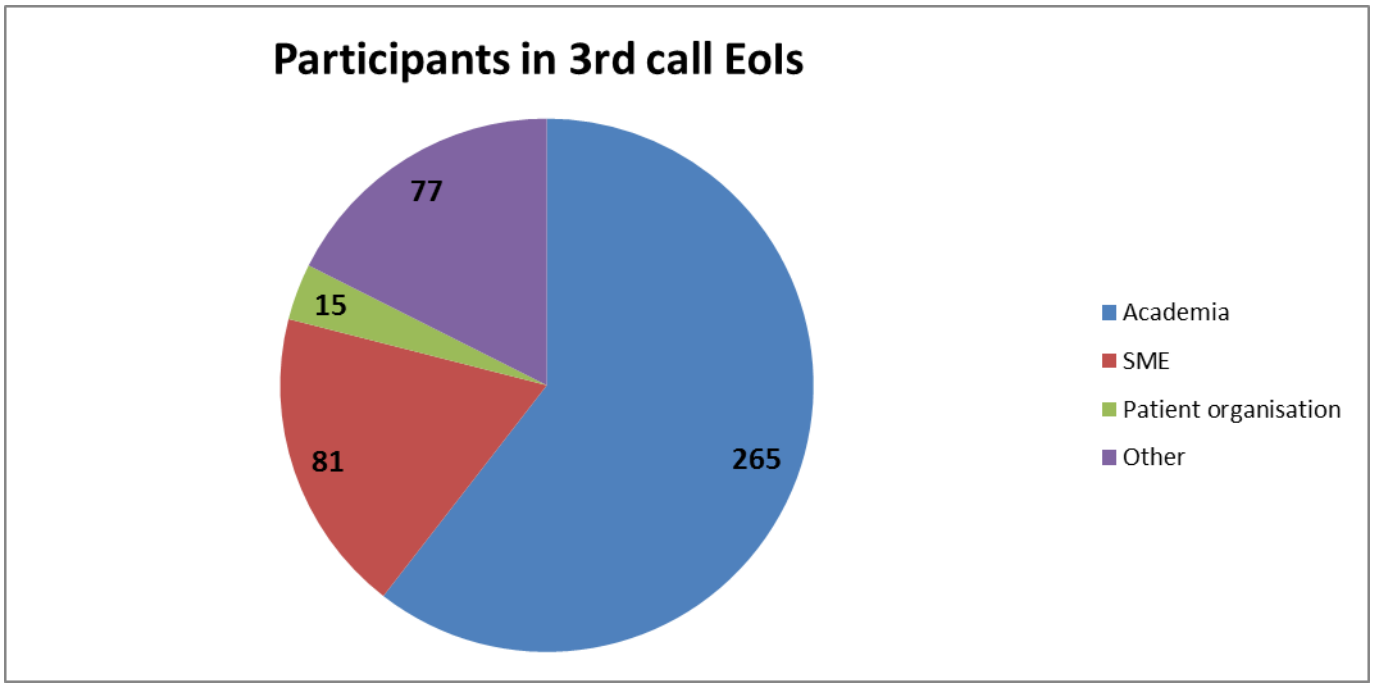
The EFPIA in-kind contribution currently committed to the 3rd Call projects is EUR 70.8 million. The IMI JU contribution currently committed to these projects is EUR 111.8 million.

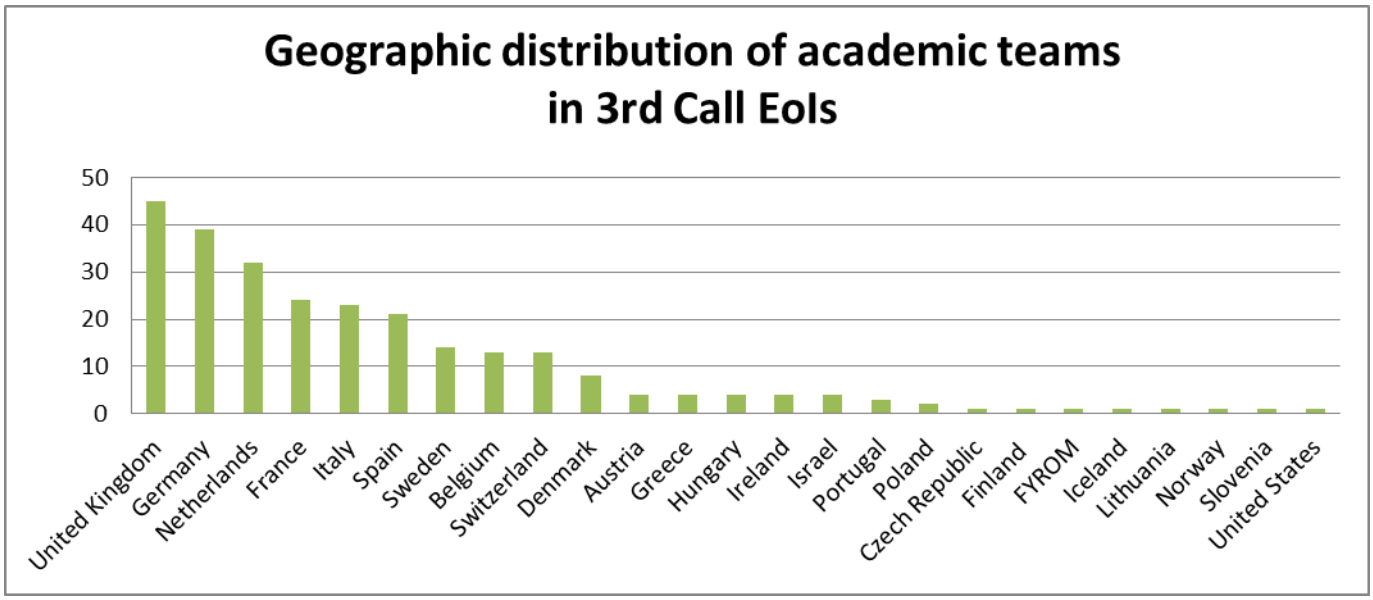
Stage 1 – Expressions of Interest

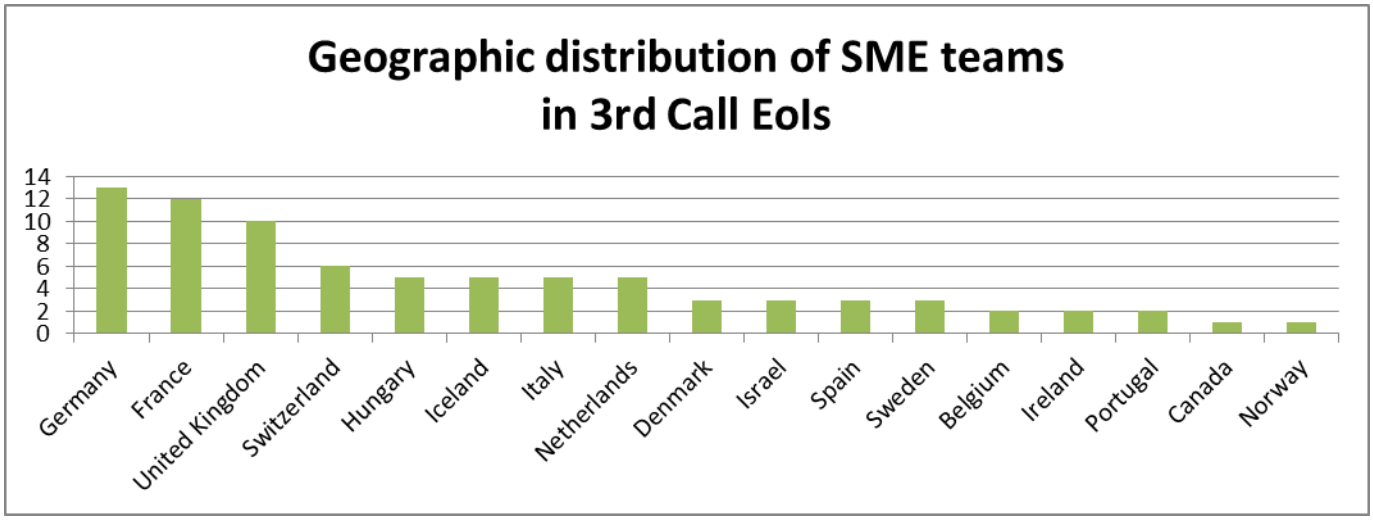
Thirty-two Expressions of Interests (EoIs) were received from the 3rd Call for Proposals, among which thirty were eligible. Key figures regarding submitted EoIs are presented here below:

Number of EoIs per topic in the 3rd Call

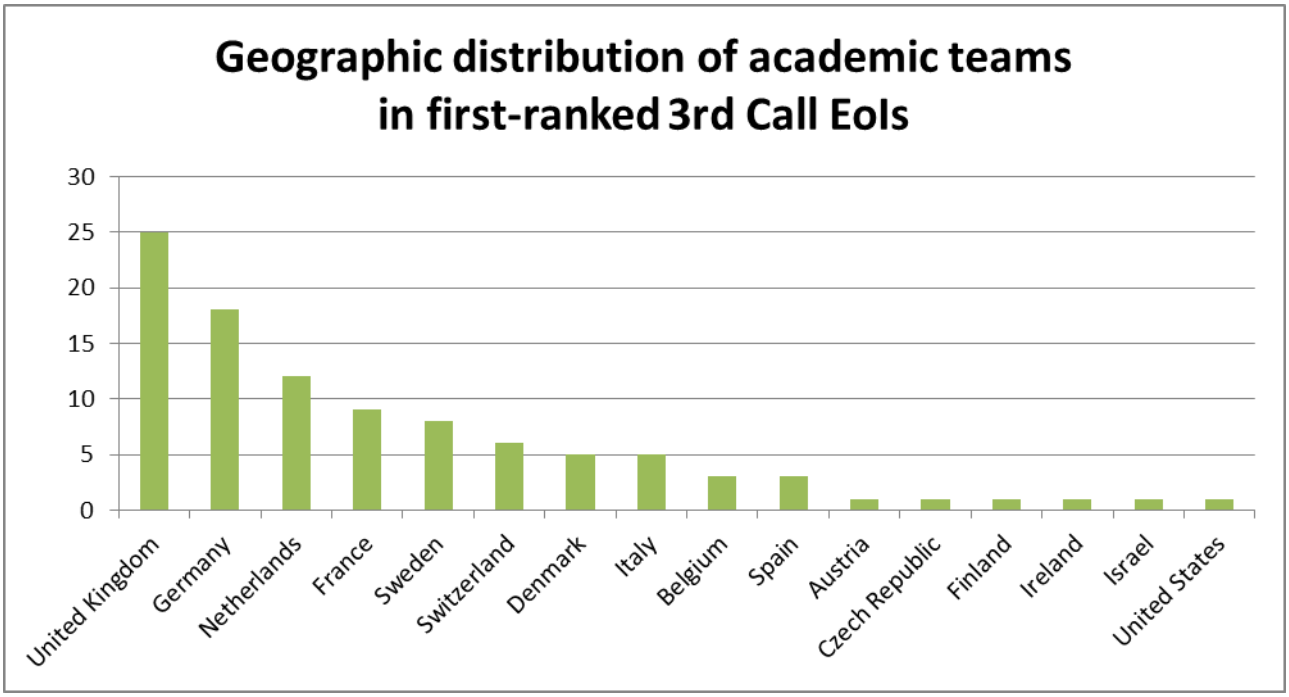
3th Call Topic	Number of eligible EoIs
Early prediction of drug induced liver injury	8
Immunogenicity	3
Vaccine safety	3
Preclinical models for tuberculosis	4
Translational endpoints in autism	4
Personalized medicine in diabetes	5
Patient awareness on pharma research	3
Total	30

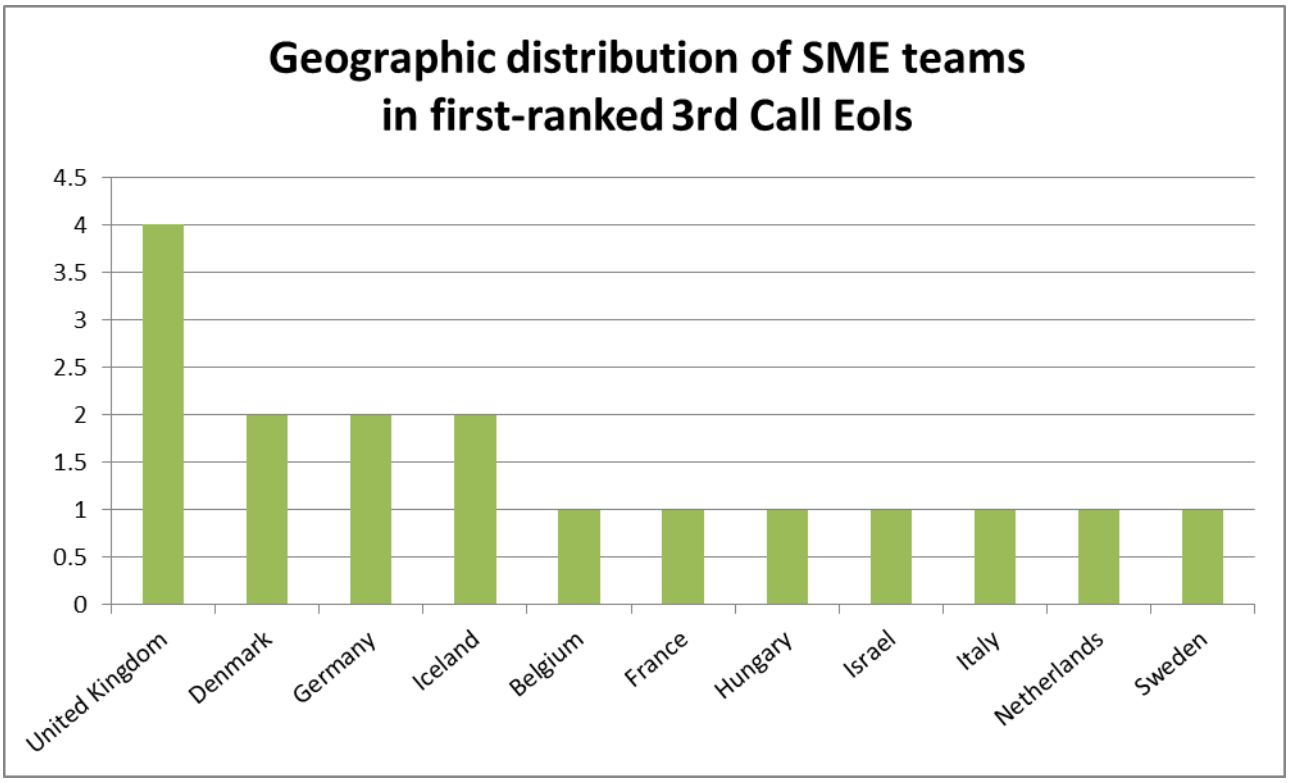

Participants in 3rd call EoIs
77
15
81
265
Academia
SME
Patient organisation
Other


Geographic distribution of academic teams in 3rd Call EoIs
50
40
30
20
10
0
United Kingdom
Germany
Netherlands
France
Italy
Spain
Sweden
Belgium
Switzerland
Denmark
Austria
Greece
Hungary
Ireland
Israel
Portugal
Poland
Czech Republic
Finland
FYROM
Iceland
Lithuania
Norway
Slovenia
United States


Geographic distribution of SME teams in 3rd Call EoIs
14
12
10
8
6
4
2
0
Germany
France
United Kingdom
Switzerland
Hungary
Iceland
Italy
Netherlands
Denmark
Israel
Spain
Sweden
Belgium
Ireland
Portugal
Canada
Norway

The evaluation of the EoIs was conducted in February 2011 by panels of independent experts from Europe and the United States of America (USA) working initially remotely and then at a consensus meeting. Forty-five external experts worked in 7 panels (1 panel per topic) moderated by IMI's Scientific Officers, in accordance with the 'IMI Rules for submission, evaluation and selection of Expressions of Interests and proposals'. Key figures of the first-ranked EoIs are presented here after:





Following the approval of the recommendations of the evaluation panels by the Governing Board, the seven first-ranked EoIs were invited to prepare a Full Project Proposal (FPP) together with the pre-established EFPIA consortium. The evaluation of the seven FPPs was again conducted by the external experts working initially remotely and then at a consensus panel meeting. All seven Full Project Proposals were recommended for funding by IMI and approved by the Governing Board.

Grant agreements were signed in December 2011 for 5 projects. This enabled IMI to proceed with pre-financing payments of EUR 25,2 million as shown in the table below.

The five 3rd Call projects that were pre-financed in 2011

Consortium Acronym	3rd Call Topic	Prefinancing (EUR million)	Total IMI JU contribution (EUR million)
BIOVACSAFE	Vaccine safety	5,6	17,4
DIRECT	Personalized medicine for diabetes	6,8	21,4
EU-AIMS	Innovative approaches for autism research	6,2	19,5
EUPATI	Informing patients on drug development	1,7	5,3
MIP-DILI	Drug-induced liver injury	4,9	15,3
TOTAL		25,2	78,9

The Grant Agreements for the two remaining projects will be signed during Q1 of 2012 and all seven Call 3 projects will kick-off their research activities in early 2012.

3.2.5 Implementation of 4th Call for proposals

Call Topics

The 4th Call for proposals, published on 18 July 2011, consisted of the following seven topics, already reflecting changes introduced in the revised Scientific Research Agenda:

Knowledge management:

- EU Medical Information System (EMIF)
- Building up a European Medical Information Framework of patient-level data to support a wide range of medical research.
- This Call theme consists of three "sub-topics":
    - Information Framework / Knowledge Management Service Layer
    - Metabolic complications of obesity
    - Protective and precipitating markers for the development of Alzheimer's disease (AD) and other dementias
- European Translational Research Infrastructure & Knowledge Management Services (eTRIKS)

Chemistry, Manufacturing and Control:

- Delivery and targeting mechanisms for biological macromolecules

- *In vivo* predictive biopharmaceutics tools for oral drug delivery
- Sustainable chemistry – delivering medicines for the 21st century

Technology and Molecular Disease Understanding:

- Human induced pluripotent stem (hiPS) cells for drug discovery and safety assessment
- Understanding and optimising binding kinetics in drug discovery

Forecast Budget Figures

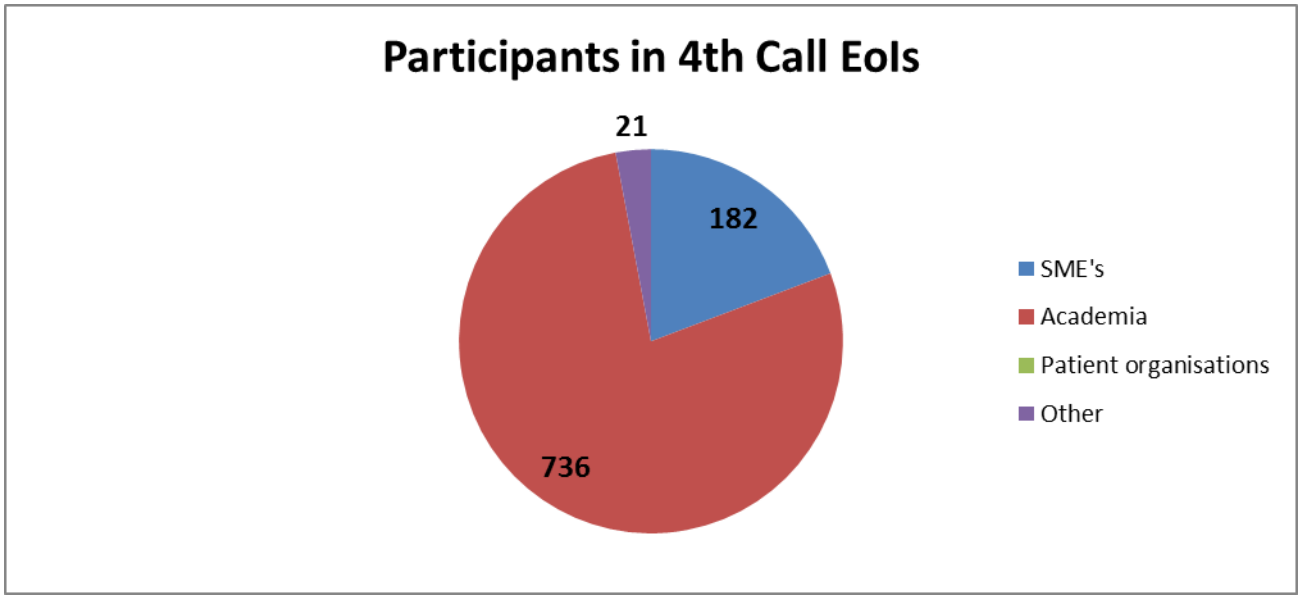
The EFPIA in-kind contribution committed to the 4th Call for proposals is EUR 93,6 million. Requested IMI JU contribution totals EUR 93,6 million.

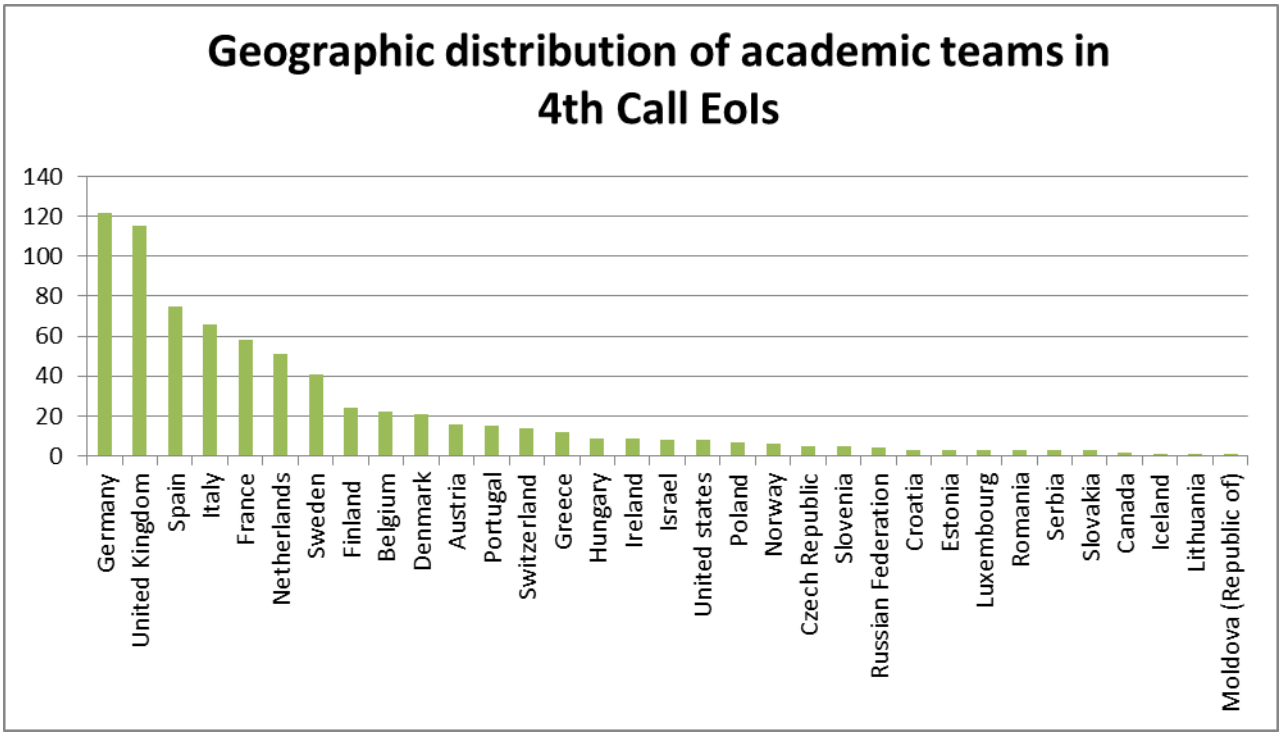
Stage 1 – Expressions of Interest

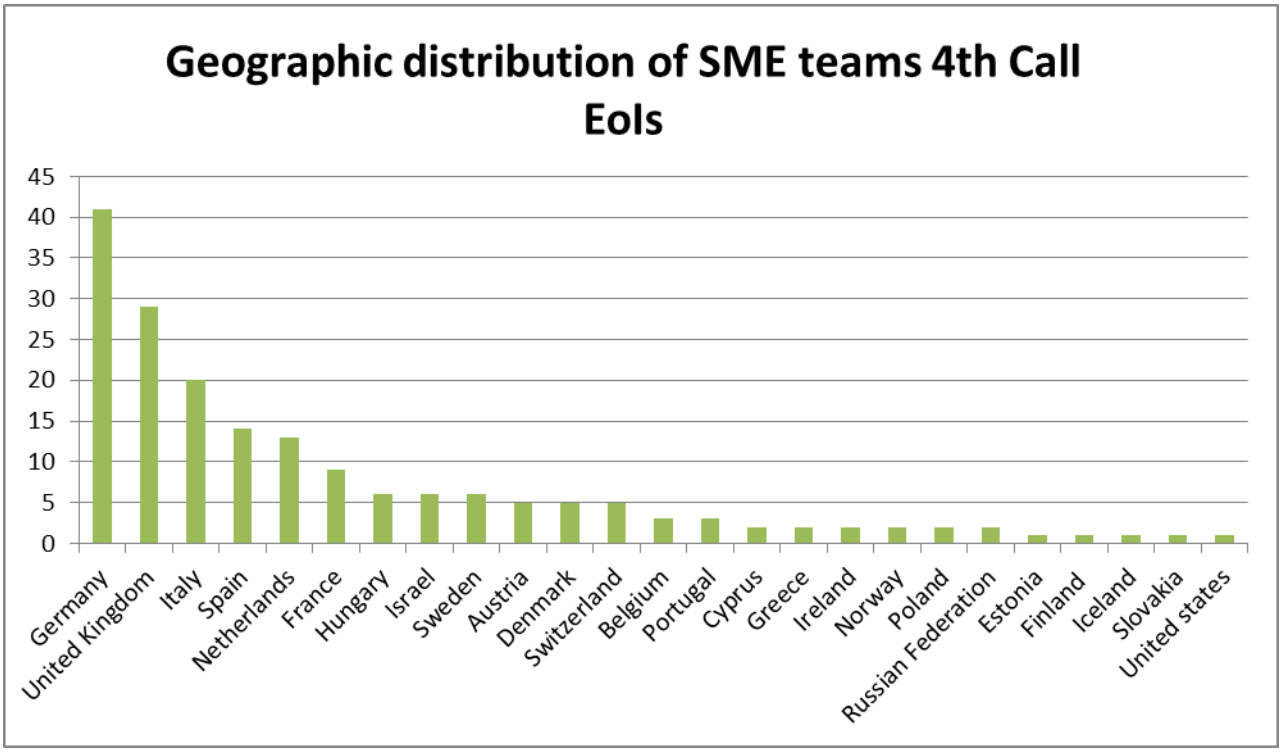
The successful dissemination of information about the 4th Call to potential IMI stakeholders translated into an increased number of Expressions of Interests (EoIs) being submitted in comparison to the 3rd Call. In fact, 86 EoIs were received, of which 80 were eligible; these involved 946 participants from 34 countries. Key figures regarding submitted EoIs are presented here after:

Number of EoIs per topic in 4th Call

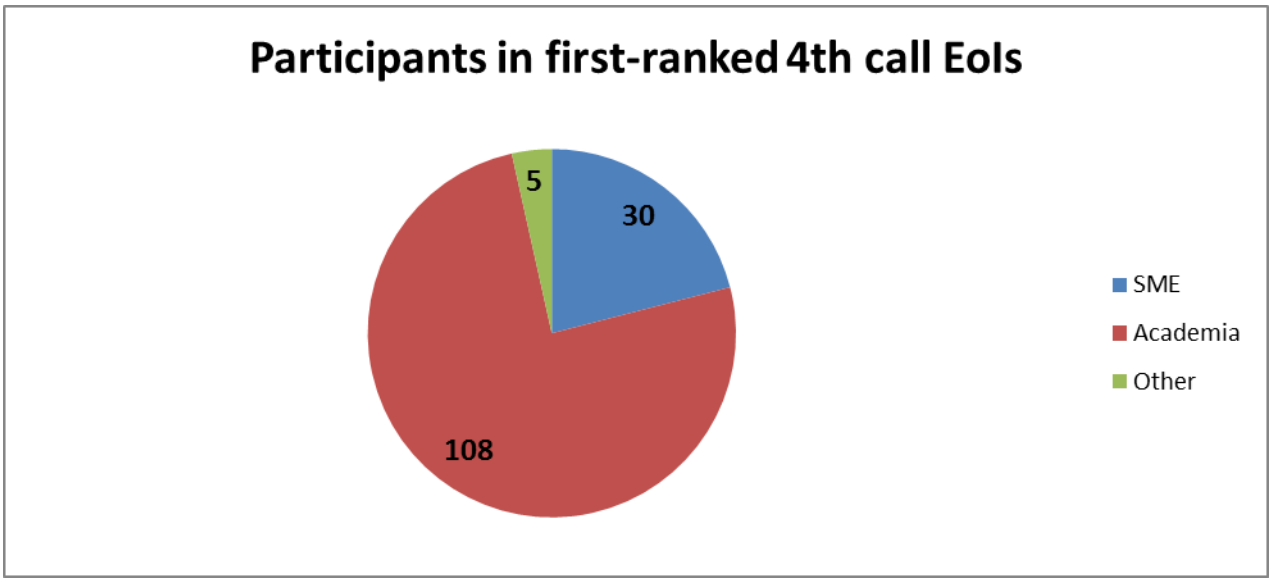
4th Call Topic	Number of eligible EoIs
EMIF	24
▪ *Service Layer*	*[13]*
▪ *Obesity*	*[7]*
▪ *Alzheimer*	*[4]*
eTRIKS	4
Biological macromolecules	20
Oral drug delivery	2
Sustainable chemistry	9
Induced pluripotent stem cells	10
Binding kinetics	11
Total	80

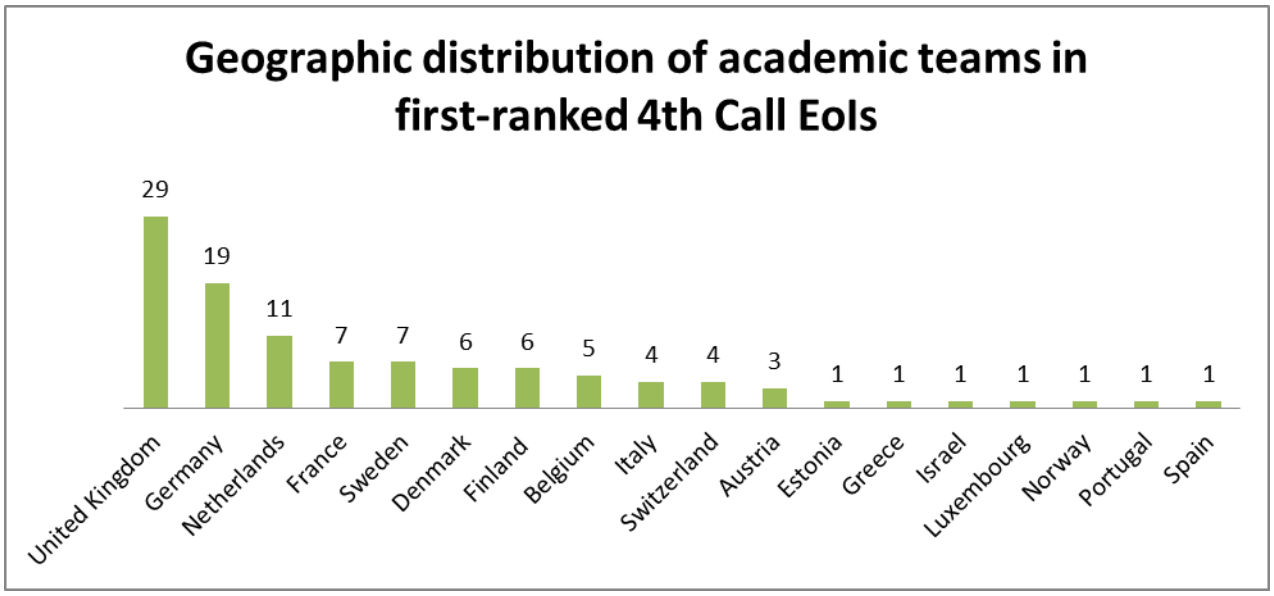


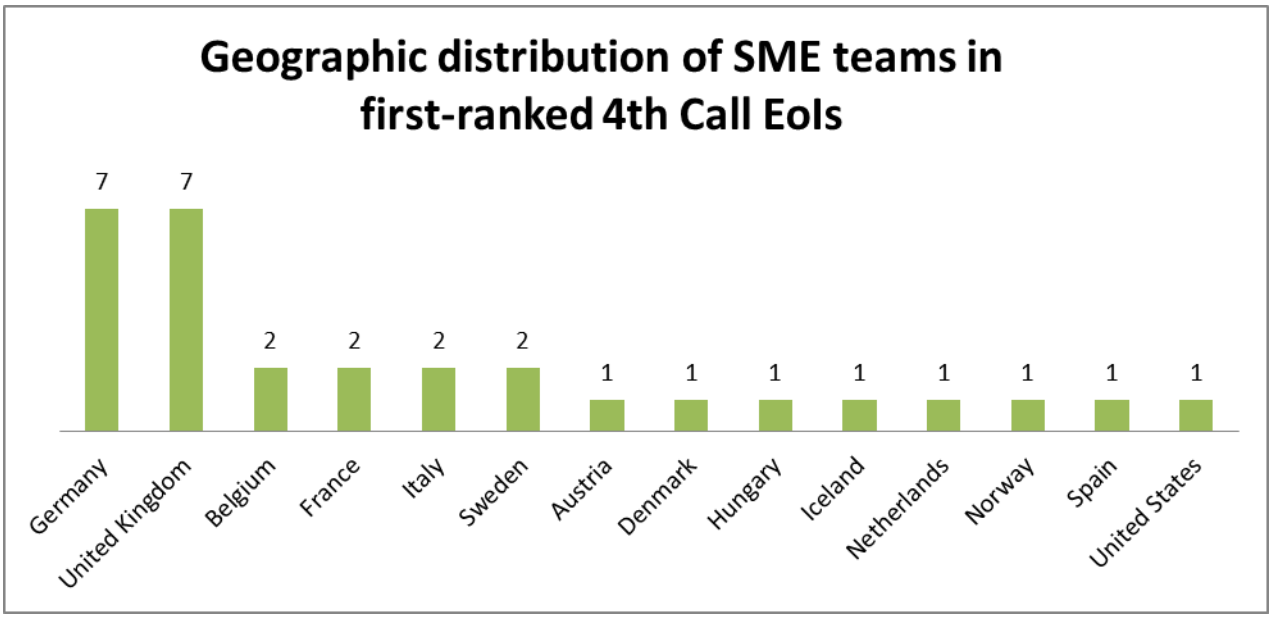




The evaluation was conducted following the same principles as described for the 3rd Call for proposals. Based on the independent observers' recommendations made during the previous Call, teleconferences were organized with the four best-ranked Expressions of Interest following the remote evaluation. The two independent observers invited to the evaluation process considered that the hearings significantly improved the evaluation process. Key figures of the first-ranked EoIs by the evaluation panels are presented below:


Participants in first-ranked 4th call EoIs
5
30
108
SME
Academia
Other


Geographic distribution of academic teams in first-ranked 4th Call EoIs
29
19
11
7
7
6
6
5
4
4
3
1
1
1
1
1
1
1
United Kingdom
Germany
Netherlands
France
Sweden
Denmark
Finland
Belgium
Italy
Switzerland
Austria
Estonia
Greece
Israel
Luxembourg
Norway
Portugal
Spain


Geographic distribution of SME teams in first-ranked 4th Call EoIs
7
7
2
2
2
2
1
1
1
1
1
1
1
1
Germany
United Kingdom
Belgium
France
Italy
Sweden
Austria
Denmark
Hungary
Iceland
Netherlands
Norway
Spain
United States

Requested IMI JU contribution by 4th Call consortia

4th Call Topic	Requested IMI JU contribution (EUR million)
EMIF	31,3
▪ *Service Layer*	*[12,0]*
▪ *Obesity*	*[11,3]*
▪ *Alzheimer*	*[8,0]*
eTRIKS	9,6
Biological macromolecules	10,1
Oral drug delivery	7,6
Sustainable chemistry	9,8
Induced pluripotent stem cells	25,7
Binding kinetics	7,4
Total	101,5

Stage 2 – Full Project Proposals

Further to the Governing Board decision of December 2011, the IMI Executive Office invited the highest-ranked Expressions of Interest to submit a Full Project Proposal (FPP), together with the pre-established EFPIA consortium, by 13 March 2012. For the topic EMIF, the first-ranked consortium for each of the sub-topics will merge to form a single consortium.

3.2.6 Preparation of 5th Call for proposals

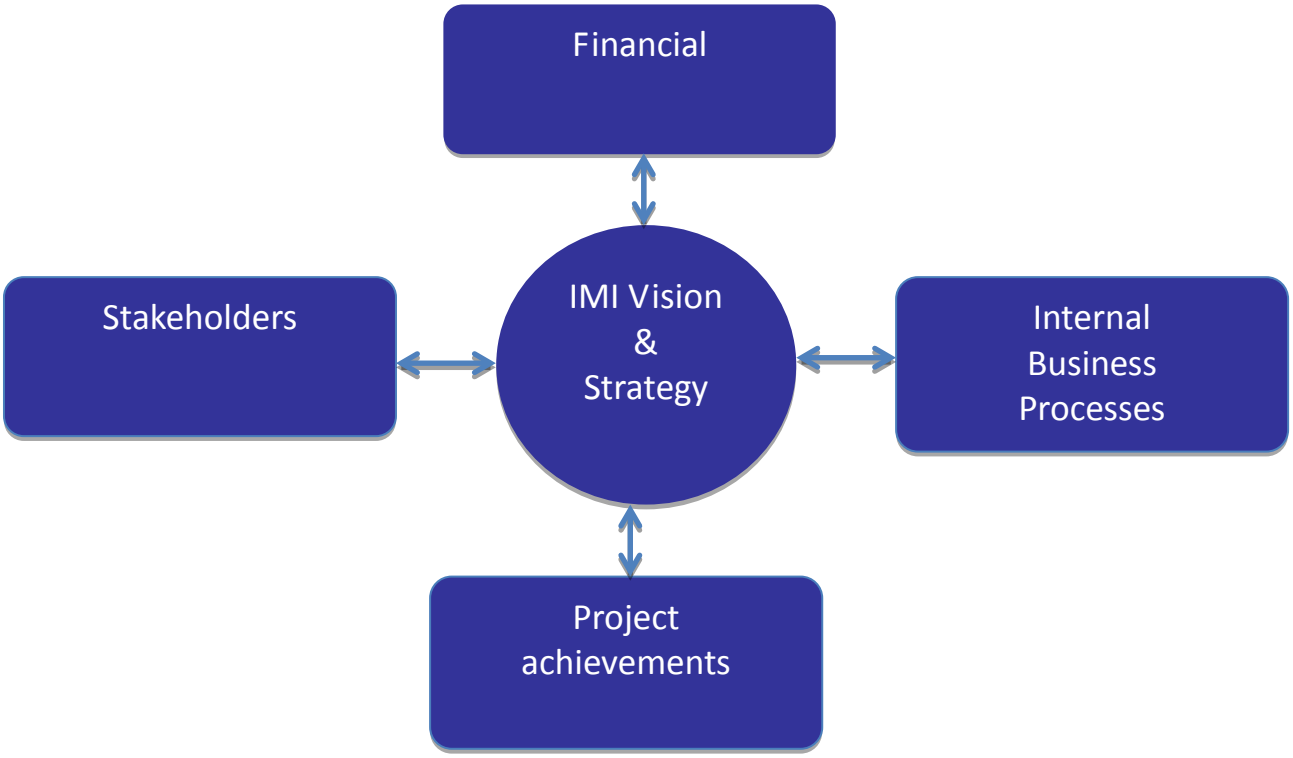
A Scientific Committee workshop was organized on 16 November 2011 to discuss the two topics defined by EFPIA for the next Calls: the European Lead Factory and Antimicrobial Resistance. Experts in these fields were invited to provide their views on the proposed topics at the workshop. The recommendations from the workshop are being taken into consideration for the finalization of the topics by the EFPIA topic writers with the assistance of IMI's Scientific Officers. The launch of the 5th Call for the European Lead Factory topic is currently scheduled for 28 February 2012.

3.3 MONITORING THE PERFORMANCE OF IMI JU

In 2011, IMI identified a set of Key Performance Indicators (KPIs) for the measurement of performance and results against two strategic overarching priorities that have been identified as critical for overall success of IMI, namely:

- The strategic relevance and added value of IMI as a public-private partnership (Reinforcing pharma R&D in Europe by addressing bottlenecks and gaps in drug research');
- The operational performance of the Executive Office.

The Executive Office has developed KPIs based on a 'Balanced Scorecard Framework', as a means to present the strategic performance of IMI according to 4 axes.



Using the above perspectives, a preliminary list of KPIs was established and used to provide first indicators given here after.

PROJECT ACHIEVEMENTS	
Percentage of projects reporting at least 75% milestones achieved	89 %*
Scientific peer-reviewed publications ▪ Number ▪ Median impact factor of journals	45 (in 38 different journals) 5.192
SELECTED ACHIEVEMENTS	CONSORTIA
▪ Data pooling ▪ New tools, models, standards	NEWMEDS (schizophrenia, depression) IMIDIA (diabetes) eTOX (drug induced cardiotoxicity) SAFE-T (safety biomarker candidates) EUROPAIN (chronic pain) SUMMIT (diabetes) MARCAR (carcinogenesis) U-BIOPRED (severe asthma) PHARMA-COG (Alzheimer's disease) Open PHACTS (nanopublications)
Education and training programmes and platforms	EMTRAIN Eu2P PHARMATRAIN SafeSciMET

*Unachieved pre-set milestones may be justified by re-design of work packages or changes in the partnership

INTERNAL BUSINESS PROCESSES			
Time to Grant (average)	number of days		
	1st Call	2nd Call	3rd Call
	587	453	335*
Time to recruit in 2011 (average)	66		
Execution of staff plan (%)	2010	2011	
	62 %	100%	

*based on the 5 signed Grant Agreements as of 31/12/2011

FINANCIAL			
Time to pre-financing payment following signature of GA (average)	number of days		
	1st Call	2nd Call	3rd Call
	20	7	2
BUDGET EXECUTION	2010	2011	
Commitments	(%)		
▪ Running costs	49	56	
▪ Operational costs	2	79	
Payments	(%)		
▪ Running costs	37	48	
▪ Operational costs	46	87	

STAKEHOLDERS	
SMEs in signed Grant Agreements (Calls 1-3) ▪ % of IMI JU beneficiaries ▪ % of budget allocated by IMI JU	 13 % 13 %
Average monthly visits to IMI website by unique visitors	6.559

3.4 SIMPLIFICATION OF PROCESSES AND PROCEDURES

In September 2011 a Simplification Task Force was created between IMI Executive Office, the EFPIA Industry Liaison Group (ILG) and the European Commission (EC). The Task Force achieved simplification and streamlining of the IMI administrative processes (Call cycle, evaluation process, documents for submission of proposals and reports, guides for applicants) for the benefit of all stakeholders. The work of the Task Force was completed on schedule by the end of January 2012.

As a consequence of this exercise, IMI will move towards a process of continued Call submission and evaluation so that once the EFPIA companies are ready with a Topic, the corresponding Call can be launched. The new streamlined Call process and the simplified submission procedures and templates will significantly shorten the time needed to finalize the grant of funding. A key change is that the consortium will start to work on the Project Agreement in parallel with the preparation of the Full Project Proposal. The new processes will be implemented partially for the 4th Call Stage 2 and fully for the 5th Call Stage 1.

To implement the agreed simplification, the electronic submission tool is currently adapted for the benefit of applicants, projects' coordinators, projects' partners and IMI's staff.

3.5 FINANCIAL FRAMEWORK

Revision of the model Grant Agreement

Following the approval of the modified IMI model Grant Agreement by the Governing Board in November 2011, the Executive Office implemented the amendments for all on-going projects. In parallel, clarification and simplification were provided on the new rules related to methods of calculation of indirect costs and for the reporting of in-kind contributions by EFPIA companies.

Financial Guidelines

Following consultation with representatives from IMI Founding Members, the Executive Office will issue IMI Financial Guidelines to clarify the features that are specific to the IMI model Grant Agreement in early 2012. These Guidelines will effectively answer the needs of all IMI projects.

Non-EU in-kind contribution

Following the EC proposal to accept in-kind contribution from EFPIA companies in relation to prospective research activities carried out outside Europe for areas with high public health need, discussions have started with IMI's Founding Members. This will involve a modification of the IMI model Grant Agreement to be approved by the Governing Board which should be implemented early 2012.

The general rule will be to apply a limit of 5% to the committed in-kind contribution with the possibility for an individual project to have a non-EU EFPIA contribution of up to 10%. The overall limit of the non-EU in-kind contribution may be exceptionally increased to 30% of the budgeted in-kind contribution of EFPIA companies to allow implementation of some topics of major importance.

Additional support to on-going successful projects

Following the request of the IMI Governing Board, the IMI Executive Office made a proposal for additional support that may be provided to successful on-going IMI projects for optimal exploitation of their results, through the launch of a competitive Call. The States Representatives Group has been consulted, and revised Call documents are under discussions with the two Founding Members.

3.6 SUPPORT TO SMALL AND MEDIUM SIZE ENTERPRISES

Sixty two R&D teams from 56 small and medium size enterprises (SME) are involved in IMI consortia derived from the first 3 Calls for Proposals. The types of SME and corresponding IMI JU funding are given in the table here below. The funding allocated to SME represents 13% of the total IMI JU funding allocated to beneficiaries of the first 3 Calls.

Type	SME in Calls 1-3 n	IMI JU Funding (€ Million)
Biotech	43	29,4
IT/data management	10	4,2
Project management	3	4,7
Total	56	38,3

The IMIDIA consortium is an excellent example of successful involvement of SME. Indeed, the optimal exploitation of the first human beta cell line useable for drug development is made possible in this IMI project by the partnership between the academic team that made the basic discovery, a small enterprise which commercializes the cell product, and the large pharmaceutical enterprises which will develop drug screening assays relying on this innovative tool. Furthermore, several SME involved in the eTOX project recently emphasize the importance of IMI for their future development (*Nature Biotechnology* 29, 789-790, doi:10.1038/nbt.1973, 2011)

During 2011, IMI continued to work with its founding partners and external organizations to increase the support to SMEs. A dedicated staff member in the science pillar was assigned to work directly with SMEs and pan-European umbrella organizations such as Biopharmaceutical Enterprises, EuropaBio and European Biotechnology Network. The aim of this interaction is to promote and communicate the activities of IMI, to encourage increased engagement of SMEs with IMI and to share knowledge and data that advance the mutual interest of the parties in accordance with policies and procedures for each party.

The IMI Executive Office sought contributions from SMEs and SME organizations to help inform IMI policies and procedures e.g., a survey of SMEs already involved in IMI projects to understand better their experience of IMI was conducted, SME umbrella organizations were involved in the consultation exercise for forthcoming call topics. As part of the ongoing efforts to improve communication with the sector members of the Executive Office attended and presented at external meetings targeting SMEs e.g., Biopartnering Europe, European Biotechnology Network.

3.7 INTERNATIONAL SCIENTIFIC COOPERATION

2011 has been an important year for IMI in terms of establishing collaboration with external partners, in particular with the signature of Memoranda of Understanding (MoU) with the following organizations:

- Juvenile Diabetes Research Foundation (JRDF) in April 2011;
- Critical Path Institute (C-Path) in June 2011;
- CDISC (Clinical Data Interchange Standards Consortium) in August 2011.

IMI project achievements were presented at a joint meeting organized by the Critical Path Institute and the Food and Drug Administration (FDA) in the US on 1st December. All parts recognized the importance for more transatlantic collaboration in different areas, including tuberculosis, with the potential support of the Tuberculosis Alliance funded by the Bill & Melinda Gates Foundation.

A first IMI-CDISC overview training and workshop was held at IMI's offices in September 2011 with a view to foster harmonization of clinical investigations in IMI projects. It brought together 28 participants belonging to 14 different IMI 1st and 2nd Call consortia. The training provided during this workshop was appreciated, as indicated by the results of a survey. The next overview training is planned for Q1 2012.

Finally, interactions with regulatory authorities, the European Medicines Agency and the Food and Drug Administration took place in particular to get insight on Call 5 topics. These interactions will expand next year.

3.8 INTELLECTUAL PROPERTY

Following on from actions taken in 2010 (publication of an IMI Intellectual Property (IP) Guidance Note and setting up of a dedicated IP-Helpdesk), the Executive Office undertook the following in 2011:

- Communication on the rules applicable to the IMI IP policy notably by its recalling objectives and highlighting the flexibility provided therein, and
- Assisting stakeholders with specific IP queries during the preparation, negotiation and completion phases of the IMI projects.

Thirty IP queries were recorded from originating potential applicants (3rd Call) and on-going projects' participants (e.g. PharmaTrain, Safe-T, Predect and OpenPhacts).

In addition to the presentations made to consortia during the preparation of full projects proposals, the Executive Office participated to several events, with a view to:

- Providing guidance on the IMI IP model and explaining ways to handle IP related issues and pitfalls that stakeholders may encounter;
- Illustrating the IMI IP policy in the context of open innovation/collaborations.

Based on the experience gained from the negotiations of the project agreements of the 1st Call, IMI took part to most of the IP negotiations of the 2nd and 3rd Calls projects (respectively 7 over 8 projects and 6 over 7 projects).

In the context of the IMI model Grant Agreement revision, the IMI IP policy was slightly adapted in order to:

- Recognise the contribution from EFPIA companies in patent applications and in publications relating to foreground;
- Consider national requirements linked to confidentiality obligations.

4. COMMUNICATIONS AND EVENTS

4.1 OVERVIEW OF 2011 ACTIVITIES

The IMI Communication Strategy and key messages have been further developed, approved and implemented. As the overviews below shows, IMI has generated wider visibility and improved its image vis-à-vis its stakeholders through various events, publications and other communication actions.

In the second half of 2011, communication focused on IMI Calls, achievements and on process improvements. These topics have been widely covered by various target-oriented websites and other publications and have generated a positive interest among stakeholders and also outside the EU. The Communication Strategy of 2012 will further expand on these themes, in a more in-depth and target-group oriented way.

Key figures
6 events organized in 4 countries by the IMI office, gathering 60 to 250 participants per event
7 webinars held attended by 25 to 45 participants each
6 press releases published and sent directly to ~180 relevant journalists
Up to 9000 unique visitors /month on the IMI website
1500 IMI Newsletter subscribers
350 IMI LinkedIn Group members
56 tweets followed by 240 IMI Twitter followers
~30 articles in key media and journals of which 6 in key scientific journals (not counting scientific publications by IMI projects)
5000 brochures disseminated to relevant audiences

Key Events	Place Date (2011)	Target audience	Message	Comments
Press conference	Brussels 8 March	Press	Kick-off 2nd Call projects	14 journalists attending, positive media coverage
IMI Stakeholder Forum at eHealth week	Budapest 12 May	All stakeholders, Central/Eastern Europe + eHealth related audience	Achievements + announcement 4th Call	250 participants in morning plenary session, afternoon's IMI session less attended
Open Info Day 4th Call & webinars	Brussels 17 June & beyond	Potential applicants + multipliers	Opportunities of the 4th Call	Successful 4th Call launch, as indicated by the increased numbers of Expressions of Interest as compared to 3rd Call
IMI exhibition stand at FP7 Health Info Day	Brussels 9 June	Potential applicants + multipliers	Opportunities of the 4th Call	Visibility to large and interested audience
European Parliament session + exhibition	Brussels 4-6 Oct	Policy makers	Achievements of IMI	60 participants in IMI session, positive feedbacks from attendees, dialog initiated with several MEPs
IMI session at EuroBiotech	Krakow 12-14 Oct	Potential applicants in Central/Eastern Europe	What is IMI + Opportunities of future IMI Calls	Visibility to ~500, 50 participants in IMI session

4.2 IMPLEMENTATION OF THE 2011 ACTION PLAN

COMMUNICATION OBJECTIVE	ACTIONS, TACTICS	TARGET GROUP	WHEN	REPORT
Generating awareness and interest in IMI	▪ Newsletter, website, social media ▪ Achievements booklet ▪ IMI corporate brochure	Potential applicants, policy makers	Continuous	▪ Newsletter: one edition per month, to ~1500 subscribers ▪ Website: up to 9000 unique visitors/month ▪ ~5000 brochures distributed ▪ LinkedIn: ~350 members in IMI Group ▪ Twitter: > 200 followers
	▪ Testimonials by project participants	Potential applicants (SMEs, patient orgs.) policy makers	First half 2012	
	▪ Promoting revised Grant Agreement: Press release, website, social media, email	Potential applicants + critics	December 2011	▪ Positive media coverage ▪ Positive EARTO press release
	Press releases: ▪ Launch 2nd Call projects ▪ Launch 4th Call ▪ MoU C-Path ▪ EP event - Achievements ▪ Revised Grant Agreement ▪ MoU CDISC see also section 'Media coverage'	Media, general audience		
Generating interest in IMIs 4th Call	▪ IMI Open Info Day ▪ Webinars ▪ Press release 4th Call	Potential applicants	May – Oct 2011	Good response to 4th Call (86 EoIs, high-level quality)

	▪ IMI website, Newsletter, social media ▪ Email campaign ▪ IMI corporate brochure + IMI leaflet ▪ Info pack for multipliers, support and participation to national info days ▪ Partner Search Tool			
Awareness and interest in 5th Call	▪ IMI website, social media, Newsletter ▪ Distributed to multipliers ▪ More actions in 2012	Potential applicants	As of Nov 2011	To be continued into 2012
Dialogue with hard-to-engage groups	▪ Dialogue with SMEs networks	SME-multipliers	On-going	▪ EuropaBio survey on IMI planned ▪ Enterprise Europe Network, EBE and European Biotechnology Network disseminate IMI info ▪ Discussions for events on-going
	▪ Information on IP and funding rules: IP Guidance Note, IP Helpdesk, other info material	Critics, potential applicants, multipliers	As of June 2011	▪ IP portal launched on IMI website ▪ Nature Biotechnology correspondence on IP
	▪ Stakeholder Forum Budapest ▪ Participation in FP7 Info Day Warsaw ▪ Biotech conference Krakow	Central and Eastern European stakeholders	May – Oct 2011	▪ Overall positive response
	▪ Dedicated SME web portal	SMEs as potential applicants, multipliers	Foreseen early 2012	

Dialogue with EC, EFPIA, policy makers	▪ IMI Key messages ▪ Updates on success stories, achievements ▪ Event in the European Parliament	EC, EFPIA, policy makers	As of June 2011 Continuing	▪ Exec. summary on achievements (GB June 2011) ▪ Achievements booklet (Sept 2011)
Engaging multipliers/ambassadors	▪ IMI info pack for multipliers	Multipliers/ambassadors		Circulated to multipliers + Available online
	▪ Educational session for ambassadors		Scheduled early 2012	
	▪ Template communication plan for IMI projects	Project coordinators	Distribution foreseen early 2012	
	▪ Guide for project website		Distribution foreseen early 2012	
	▪ Standard IMI presentations for target groups	SMEs, patient organizations…	On-going	
	▪ Communication training	IMI staff, others	First half 2012	
	▪ Web-based collaboration platform (IT)	IMI staff, project participants	1st half 2012	

4.3 MEDIA COVERAGE

Key media features in 2011 are set out below:

- *Nature Reviews Drug Discovery*, Vol.10, p. 883 (December 2011),
  Expanding precompetitive space (editorial)
- *TV5Monde*, 3 December 2011: Bar de l'Europe
- *Pharmaceutical Market Europe*, December 2011,
  Interview: Michel Goldman, Innovative Medicines Initiative
- *Nature News*, 22 November 2011,
  Antibiotic resistance marching across Europe
- *Nature Reviews Drug Discovery*, Vol. 10, pp. 321-322, Goldman, M. (2011),
  Reflections on the Innovative Medicines Initiative
- *Nature Biotechnology*, Vol. 29 (9), pp. 789-790, Mestres, J. et al. (2011),
  Shaping the future of safer innovative drugs in Europe
- *Nature Biotechnology*, Vol. 29, pp. 689–690, Strohmeier, R. et al. (2011),
  IMI moves forward
- *BioCentury TV*, 31 July 2011: Public + Private Part 2: Turning Great Science into Medicine -- and Jobs
- *BioCentury TV*, 24 July 2011: Public + Private: Turning great science into medicine – and Jobs
- British MJ, 10 March 2011, Vol. 342:d1577,
  Europe provides €172m for research into innovative medicines

More media coverage listed at: www.imi.europa.eu/content/media-coverage

Scientific publications listed at: www.imi.europa.eu/content/scientific-publications

5. MANAGEMENT OF THE EXECUTIVE OFFICE

Improvements to enhancing the efficiency and effectiveness of the IMI Executive Office were implemented in 2011 with a view to consolidating the provision of non-bureaucratic, timely and efficient services as the working environment needs to be supported by unobtrusive, flexible and effective processes and systems. This was made easier in 2011 with more maturity gained in the 2nd full year of operation.

Main initiatives included clarifications of reporting lines and job profiles, creation of a management team to assist the Executive Director in formulating policies and tracking activities and critical review of and adaptations to a series of processes and workflows governing IMI's internal operations.

5.1. HORIZONTAL SUPPORT SERVICES

5.1.1 Governance

The Executive Office provides support to the activities of IMI's governance and consultative bodies.

Governing Board

The Governing Board oversees the implementation of IMI's activities. As from April 2011, the European Commission is chairing the Governing Board for a one year mandate. The Governing Board met three times during 2011 and held teleconferences for information purposes as from May 2011 on a monthly basis.

The main decisions taken in 2011 by the Governing Board were:

- Adoption of the Annual Implementation Plan for 2012, including the Annual Budget Plan for 2012 and the preliminary budget for 2013,
- Adoption of the Annual Activity Report for 2010, including the Annual Accounts for 2010,
- Adoption of the Mission Charter of the Internal Audit Service of the European Commission,
- Adoption of the Internal Audit Strategy,
- Adoption of the Annual Activity Report for 2010, including the Annual accounts for 2010,
- Adoption of the revised Strategic Research Agenda,
- Adoption of the revised Grant agreement,
- Adoption of Call 3 Stage 1 and 2 outcomes,
- Adoption of Call 4 topics, documents and Stage 1 outcomes,
- Endorsement of Key Performance Indicators,
- Endorsement of the Communication Strategy and Action Plan,
- Nomination of Scientific Committee members.

Scientific Committee

The Scientific Committee (SC) is an advisory body to IMI Governing Board.

The SC met twice in 2011 on 30 June and 16 December 2011. Key activities can be summarised as follows:

- Advised on the revision of the Scientific Research Agenda as well as with the new scientific priorities of the 4th and 5th Call for proposals.

- Advised on the format and process of the interim review of the IMI 1st Call projects and participated as independent experts in the interim review of IMI 1st Call projects.

Ten of the twelve members renewed their membership for a second mandate and will continue to serve on the IMI Scientific Committee until June 2013.

The Governing Board appointed four candidates in November 2011 following the proposal made by the Executive Director following consultation of Member States through the IMI States Representatives Group. The new members' expertise is in the areas of regenerative medicine, regulatory matters, brain disorders and clinical trials.

States Representatives Group

In 2011, the IMI States Representatives Group (SRG) elected a new Chair, Gunnar Sandberg from Sweden.

The meetings of the IMI States Representatives Group were held on 20 January, 23 May and 20 October 2011. The following table lists the key activities of the group during 2011:

IMI States Representative Group - key activities 2011	
Advised on the Scientific Priorities for 2012, including the synergies with the Framework Programme	Q4
Ensured and facilitated the dissemination of information related to the Calls for proposals	Q1 to Q4
Information on the outcome of the evaluation process	Q2 to Q4
Opinion on the update of the Scientific Research Agenda	Q1
Advised on the activities of IMI	Q1 to Q4
Advised on the changes to the Call and evaluation process	Q2 & Q4

In addition, the States Representatives Group was consulted on the 4th & 5th Call topics, on the 4th Call documents, on the process for additional support to on-going IMI projects and on the revision of the Scientific Research Agenda. In addition, it proposed candidates for the partial renewal the Scientific Committee membership.

In order to facilitate its operations, a dedicated and 'members only' secured IT platform was launched.

Finally, IMI Info Days were organised in two Member States (i.e. Spain, Poland).

The dialog with the States Representatives revealed a clear need to better organize the consultation process that precedes the launch of each Call. This will become even more important with the increased number of Calls each year. The consultation process for the Calls to be launched in 2012 and beyond will be further defined regarding the time period dedicated to the SRG consultation after the full Call topic text is finalized - including the budget -. Furthermore, additional efforts were initiated in 2011 and will be pursued in 2012 regarding the presentation of statistics for each Call.

Stakeholder Forum

Through its annual Stakeholder Forum, IMI engages key stakeholders in discussions about its activities.

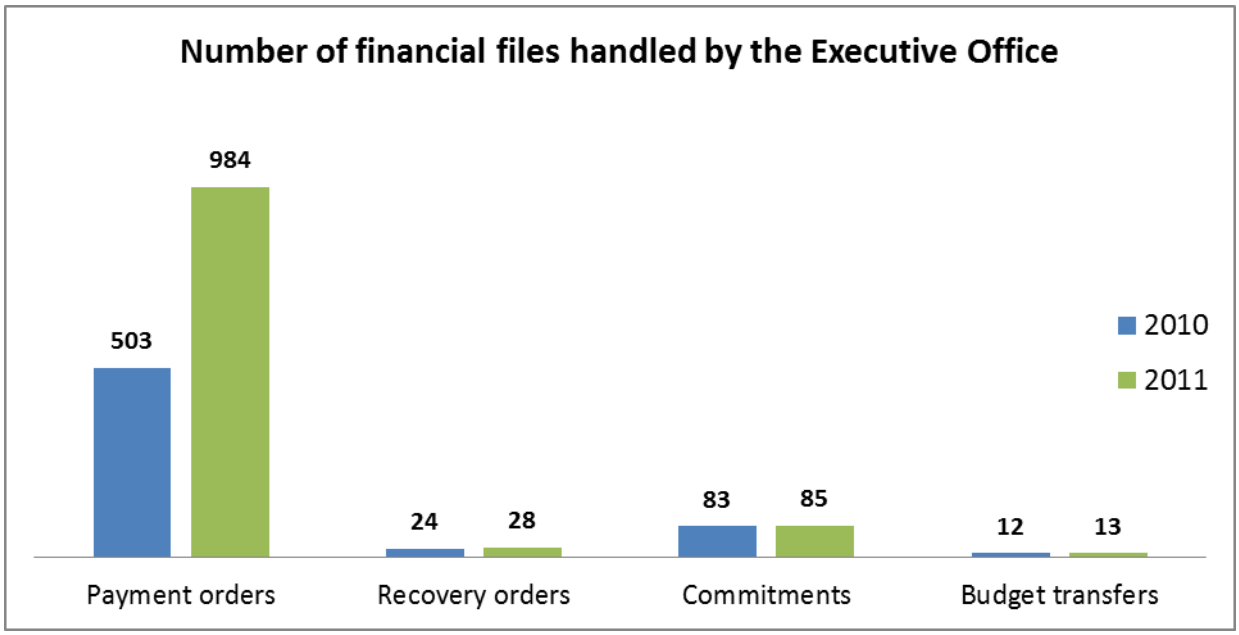
IMI held its 2011 Stakeholder Forum on 12 May in Budapest as part of the World of Health IT (WoHIT) eHealth week, aiming to make IMI known to a new audience in the area of electronic health. A plenary session, jointly organised by IMI and the European Commission, was attended by approximately 250 participants. The subsequent IMI session attracted 90 participants. The IMI session featured presentations by leading scientists of the first achievements of on-going IMI projects as well as an overview of IMI's plans for the future and a glance at 4th Call for proposals.

The 2011 Stakeholder Forum offered IMI the opportunity to present achievements and success stories from on-going IMI projects.

5.1.2 Budget and Finance

Financial Operations

During 2011 the financial team was reinforced through the addition of staff, enabling IMI to better structure its financial operations and cope with workload increase.
In 2011, the IMI handled a total of 1110 financial files (payments, commitments, and recovery orders).

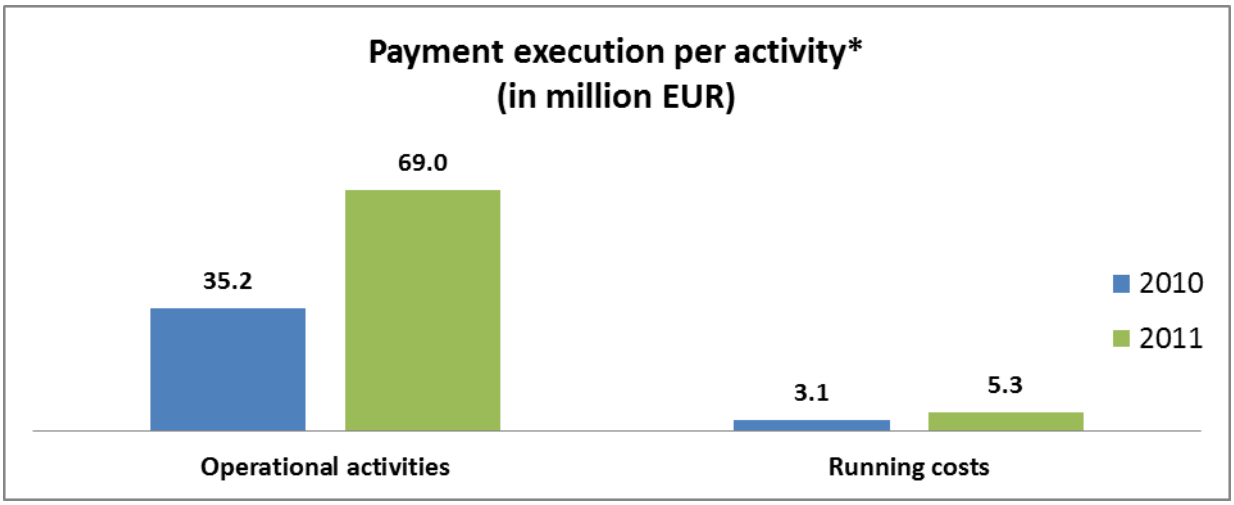


	Prefinancing of grants				Interim payments on grants				Running costs payments			
Year	Nr	% On time	% Not on time	TTP	Nr	% On time	% Not on time	TTP	Nr	% On time	% Not on time	TTP
2010	30*	93.30%	6.70%	19.4	1	100.00%	0.00%	66	472	50%	50%	43
2011	13	100%	0%	5.3	16	93.75%	6.25%	54.4	955	57%	43%	43

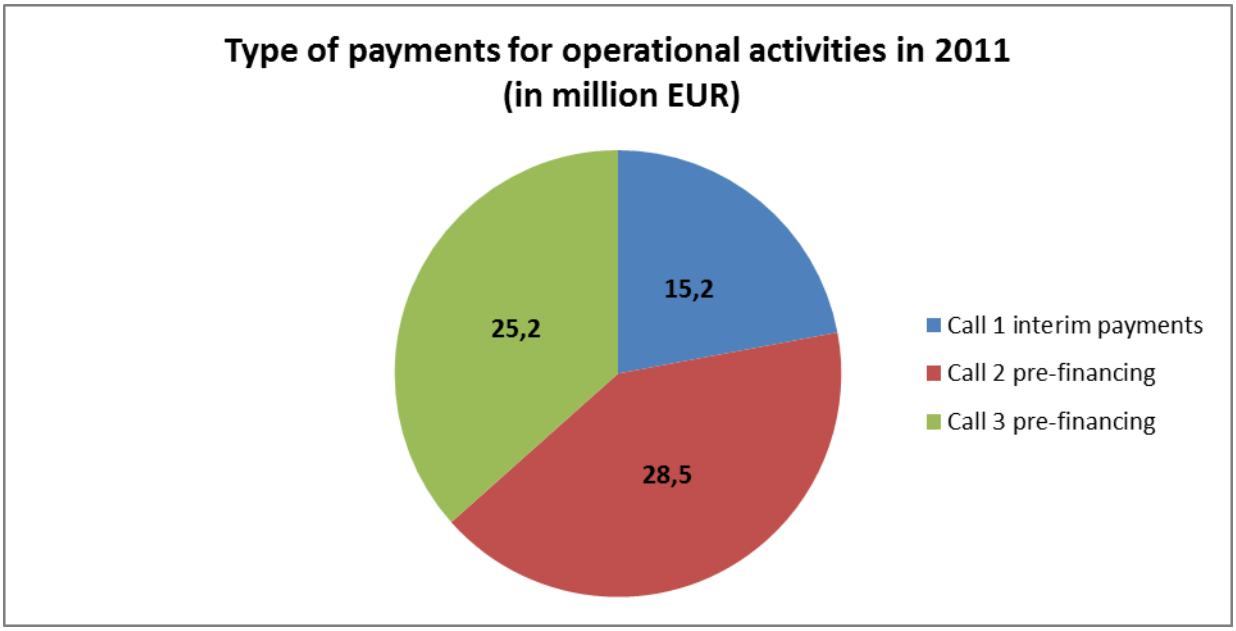
*There was an additional pre-financing for each of the 15 Call 1 projects due to an increase following Grant Agreement amendments.

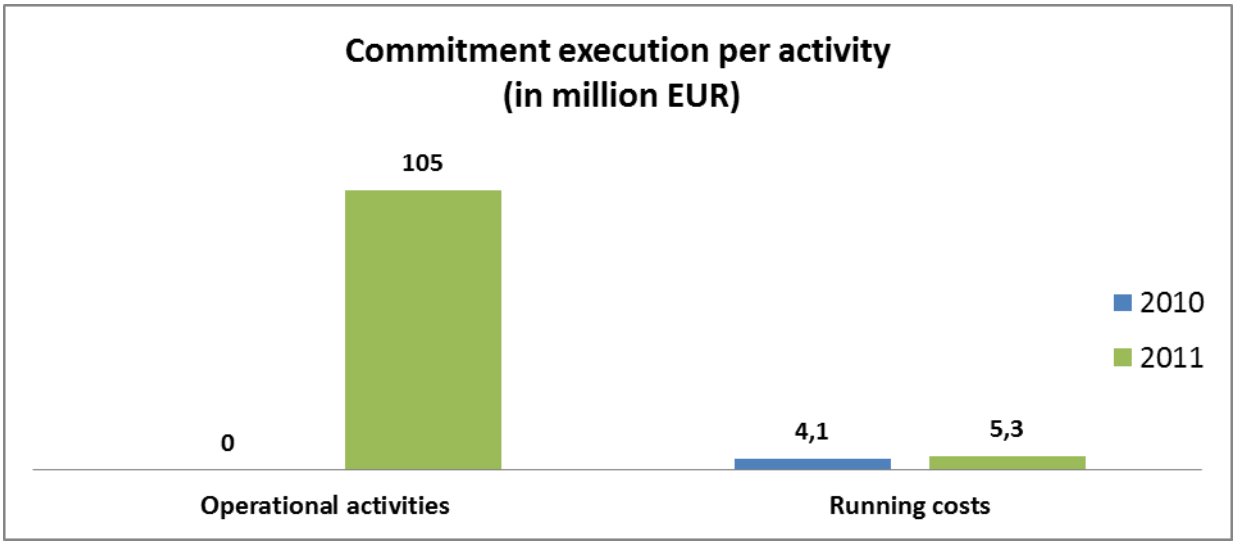
Budget execution

In the second full year of operations, the budget execution improved significantly compared to 2010. The graphs below set out achievements both in terms of commitment and payment appropriations, for operational activities (Call-related) and for the running costs of the Executive Office (staff and infrastructures).



*includes payments on 2010 commitments carried forward to 2011





5.1.3 Information Technology

In 2011, IMI capitalised on its investments to set up and avail itself of a modern and efficient IT work environment.

In essence the IMI IT architecture is structured around three environments:

- Submission OF Information Application (SOFIA) supporting the IMI core business. SOFIA is, hosted by an external service provider and supported on a 24/7 basis;
- Platform environment supporting the IMI's Governance bodies (Governing Board, SRG, SC and EPFIA collaboration platforms) and supporting IMI executive office (IMI Intranet and ISA - Information System for Absences). The platform environment is managed by IMI staff with the collaboration and support from a contractor;
- Internal environment (e-mails and shared drive) set on a server in the premises building of IMI. The server is shared with other JTIs and supported by a contractor

As for the application supporting IMI core business, which had been donated by EFPIA at the start-up of IMI, the migration between contractors was completed in 2011. This enabled the development work on new functionalities and data quality control features, following users' feedback, to start. The tool, referred to as Submission OF Information Application (SOFIA) was launched in January 2012; it includes many new features and improvements emanating from EFPIA's Industry Liaison Group through a dedicated collaborative platform, in particular reflecting the outcome of the simplification exercise *(see also section 3.4).*

Dedicated and secured IT platforms for IMI's Governance bodies was setup, in particular for the SRG from September 2011, for the Scientific Committee from December 2011 and for the Governing Board from February 2012.

Internal IT systems were also put in place with modern computer hardware, reliable network and telephone system. An internal IT environment was set up and the IMI Intranet was launched providing IMI staff with a single interface to access information and connect with other systems. The Information System for Absences (ISA) was launched and progress was to enable IMI to automate and digitalise a series of internal workflows.

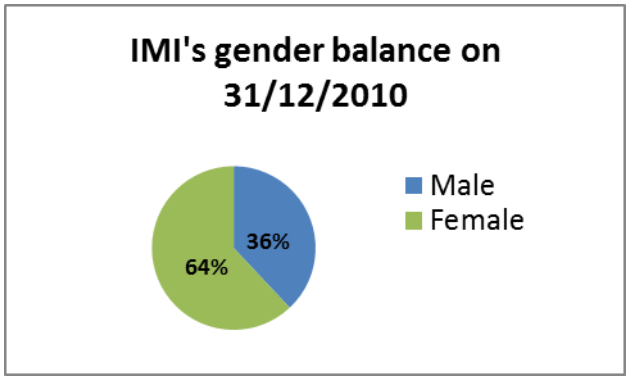
5.1.4 Human Resources

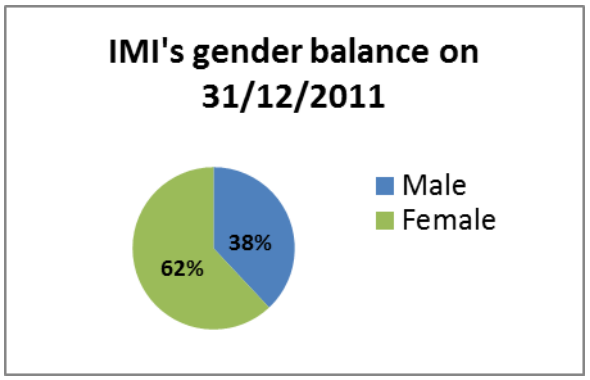
Recruitments were conducted in 2011 in line with the Staff Plan approved by the Governing Board. Despite three resignations, the authorised maximum ceiling of 31 staff members was reached.

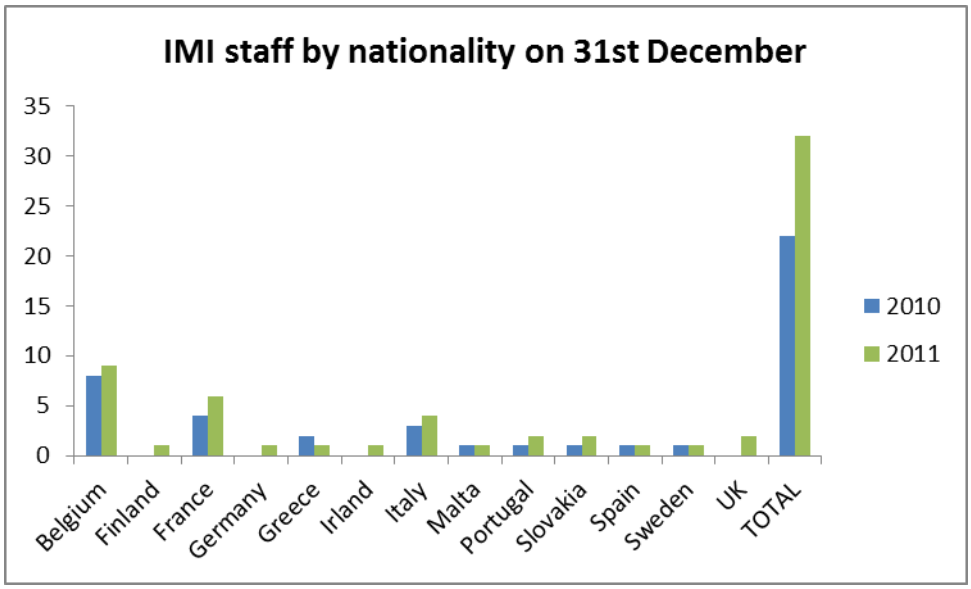
IMI integrated 12 new staff members in 2011 as follows:

- The Science pillar increased by 2 additional Scientific Project Officers and 1 Administrative Assistant.
- The Communications pillar grew by 1 Communication Officer (events) and 1 External Relations and Communications Assistant.
- The Administration and Finance pillar also expanded, with the following new staff joining: 1 Financial Manager, 1 HR Officer, 1 Finance and Procurement Officer, 1 Administrative Assistant, 1 IT Manager, 1 Legal Officer and the Head of Administrative and Finance.

These new recruits enabled IMI to improve both its gender balance and geographical balance (see charts below).







The following selection processes launched in 2011 will be completed in 2012:

- Contract agent (FG III) to start on 01/01/2012;
- 3 Scientific Project Managers (AD7);
- Administrative Assistant (AST3).

In October 2011 a revision process of all Job Descriptions has been launched and will be followed by a new staff performance appraisal system to be implemented in Q1 of 2012.

Progress was made as regards Staff implementing rules, with IMI agreeing with the European Commission (DG HR) on the so-called third batch (set-up of a staff committee, staff appraisals and policy preventing harassment).

5.1.5 Procurement and contracts

The majority of IMI's tendering needs are in the fields of Communications and IT. In the year 2011 tenders also covered such areas as human resources (interim staff), meeting organisation and ex. post audits.

The tender and contract management are being simplified as far as possible through the use of multi-annual framework contracts. In order to avoid duplication of administrative work, IMI also cooperates with the other Joint Undertakings in tendering services: two of the major framework contracts in 2011 were carried out jointly with other Joint Undertakings, with IMI as the lead contractor. In the same spirit of rationalising the use of resources, IMI participates where possible in the European Commission's framework contracts.

The table below lists the tenders initiated and/or awarded in 2011 by IMI and sets out the procedure used in each case, the publication date, the award date and the name of the contractor where applicable. Only tenders with a value exceeding EUR 60,000 are listed here.

Tender procedures in 2011				
Reference and subject	Procedure	Publication date	Award date	Contractor(s)
JTI/EPAS/2010/OP/02: Multiple framework contracts in the field of financial audits, other assurance engagements and related services for IMI, Clean Sky and FCH Joint Undertakings.	Open procedure – framework contract with a cascade of max. three contractors	27/10/2010	08/06/2011	1. Pricewaterhouse Coopers Accountants NV, The Netherlands 2. KPMG AG, Germany 3. Littlejohn LLP, United Kingdom
JTI/INTERIM/2011/OP/03: Framework contract in the field of interim services for IMI, ARTEMIS, ENIAC, Clean Sky and FCH Joint Undertakings.	Open procedure – framework contract with single contractor	08/06/2011	14/11/2011	Start People nv/sa, Belgium
IMI/2011/SC/127: Framework contract for the provision of meeting services for the IMI JU call evaluation.	Negotiated procedure with 5 candidates – Framework contract with a cascade of max. three contractors	23/09/2011	07/12/2011	1. Crown Plaza, Belgium 2. The Hotel, Belgium

5.1.6 Data protection and access to documents

Data Protection

In line with its legal obligations, in 2011 IMI continued to ensure that personal data is protected and that Regulation (EC) No 45/2001 is complied with.

Several measures were taken in this regard during 2011. These included:

- Decision of Executive Director on implementing rules for the Data Protection Officer (DPO);
- Creation of register of processing data operations;
- Prior checking notification for IMI Recruitment Guidelines;
- Reply to the request of information on implementation of Data Protection by the EDPS;
- Participation in the network of DPOs of EU Institutions, agencies and other bodies.

Access to documents

IMI did not receive any requests for access to documents under Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to documents.

5.2. INTERNAL CONTROL ENVIRONMENT

IMI implements a clearly defined framework of 16 Internal Control Standards (ICS) aimed at maintaining an efficient and effective internal control system that corresponds to the organisation's strategic objectives and lifespan, its governance structure and resources, as well as to the degree of maturity, risk and change across its operational and support systems and processes. IMI has appointed an Internal Control Coordinator (ICC) to supervise and coordinate the development of the ICS structure and systems on a day-to-day basis in close liaison with the Executive Director and the Head of Administration and Finance. Internal control systems are monitored on a continuous basis through a number of supervisory controls and internal checks. Internal control issues and actions are also systematically discussed and reviewed on a regular basis through weekly management meetings. In addition, the ICS Action Plan is reviewed twice a year and a comprehensive self-assessment exercise is carried out annually by the ICC to monitor and report on compliance with the minimum requirements of the ICS, assess the effectiveness of the system as well as identify opportunities for action and improvement.

Risks that pose a threat to the achievement of IMI JU`s mission and objectives are also systematically identified, assessed and managed through an annual risk assessment exercise (RAE). The 2011 RAE identified fourteen corporate risk areas which were recorded in the IMI JU Strategic Risk Register together with a list of mitigating actions that have been taken or will be taken by the Executive Office to reduce the impact of risks to an acceptable level. Periodic reviews have also been scheduled to monitor progress and to keep the Strategic Risk Register updated.

In November 2011, sixty ex-post audits representing 40 per cent of the total costs claimed by beneficiaries and validated by the Executive Office by 30 June 2011 were also launched. In the sequence of controls, these on-the-spot financial audits are undertaken at the end of the payment cycle with the aim of providing reasonable assurance, on a multi-annual basis, on the legality and regularity of the underlying transactions. The first results are expected in April 2012 and on the basis of these findings follow-up actions may be taken to recover any amounts found to have been paid in excess. Moreover, in 2012, IMI JU will also review and update the ex-post audit strategy in order to better harmonise it with that of the European Commission and to also achieve a better balance between the costs and benefits of ex-post controls.

In parallel, during 2011, the roles of the IMI's Internal Audit Manager (IAC) and the Internal Audit Service of the European Commission (IAS) were clarified and formalised through the approval of the IAS and IAC Audit Charters in March 2011. A risk assessment and a coordinated strategic audit plan for the period 2012-2014 were also concluded and approved by the Governing Board in November 2011.

Collectively, these arrangements allow for an effective and timely implementation and tracking of the ICS implementation. They ensure proper accountability, adequate management of identified risks and greater staff awareness of ICS and related priorities.

During 2011, IMI has made significant progress in the implementation of its ICS Action Plan on the basis of priorities set by management for the year, lessons learned from implementing internal controls, the annual risk assessment exercise and the observations and recommendations resulting from audits. Although some actions still have to be completed before IMI attains full compliance with the ICS framework, these are adequately compensated through strong supervisory arrangements.

IMI's internal control system can be considered to be working as intended and to adequately mitigate the main risks for the achievement of IMI's objectives when taking into account the current

accountability and monitoring arrangements and requirements for internal control and the degree of development and the lifespan of the Joint Undertaking, as well as the results of the above-mentioned assessments on the level of efficiency and effectiveness of the internal control system against the ICS. Further details about ICS implementation are set out in Annexes C and D.

6. DECLARATION OF ASSURANCE BY THE EXECUTIVE DIRECTOR

6.1 BACKGROUND

As a European Union body, IMI is required to follow instructions from the European Commission regarding the reporting of its activities[1].

Under these requirements, the Annual Activity Report must include a Declaration of Assurance in which the Executive Director, in his role as Authorising Officer, provides assurance as regards the true and fair view given by the report and as regards the legality and regularity and the sound financial management of all financial transactions under his responsibility, as well as for the non-omission of significant information.

The Declaration of Assurance follows a structured assessment on IMI's management evaluation of resources based on pre-set building blocks. This assessment is based on the management's evaluation on the use of resources; adherence to the principles of sound financial management; as well as the effectiveness of the IMI JU internal controls processes put in place to ensure the regularity and legality of underlying transactions.

The following sources were used for this evaluation:

- Relevant internal briefings and reports that are prepared on a periodic basis for senior management and for the Governing Board;
- The Report on the Risk Assessment Exercise for 2011;
- The 2011 Annual Self-Assessment of the Effectiveness of the Internal Control System of IMI (January 2012);
- The results of the internal control monitoring of the Internal Control Coordinator (ICC), including the Action Plan for the Implementation of the ICS which is updated on a bi-annual basis;
- The Report on the Validation of the Accounting System (June 2011);
- The Panel Report on the "First Interim Evaluation of the Innovative Medicines Initiative Joint Undertaking" adopted by the EC according to Art. 11.2 of the Council Regulation 73/2008;
- The observations and recommendations of independent experts on the evaluation and selection of proposals;
- The coordinated risk assessment as well as the observations and recommendations of the Internal Audit Service of the European Commission (IAS) and IMI JU's Internal Audit Capability (IAC); and
- The observations and recommendations reported by the European Court of Auditors (ECA).

The building blocks towards the Declaration of Assurance are set out in sections 6.2.1 to 6.2.7 of this report.

[1] Final 2011 AAR instructions – SEC(2011)1331

6.2 DECLARATION OF ASSURANCE

STATEMENT OF REASONABLE ASSURANCE
2011

I, the undersigned, Michel GOLDMAN, Executive Director of the Innovative Medicines Joint Undertaking in my capacity as authorising officer,

- declare that the information contained in this report gives a true and fair view.

- state that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions;

- state that this reasonable assurance is based on my own judgement and on the information at my disposal, such as the information provided by Administration and Finance, the Internal Control Coordinator and internal audit, as well as the preliminary assessment of the Court of Auditors;

- confirm that I am not aware of anything not reported here which could harm the interests of the Joint Undertaking.

Signed in Brussels, 27 February 2012

Michel GOLDMAN

6.2.1 Building block 1: Assessment by management

Overall Control Strategy

IMI's overall control strategy includes a set of monitoring controls, as well as a combination of key ex-ante and ex-post controls that are embedded throughout the whole administrative processes and the grant management lifecycle.

In 2011, IMI has continued to consolidate the effective control and the sound financial management of its administrative and operational expenditure, apart from continuing to ensure the legality and regularity of the underlying transactions. In addition, the lessons learned from the first year of autonomy were used as a basis for continuous improvement. These included the following:

- Additional staff recruited on 2011 and the re-organisation of the Executive Office (including the strengthening of the management function).
- Shorter timeframes for the approval of core documents.
- Better implementation of the Call processes, as evidenced from the independent observers' reports and
- The introduction of key performance indicators and other management monitoring tools.

Nonetheless, challenges remained in achieving a 100% budget implementation as well as having the complete mechanisms in place for the reporting of in-kind contributions by EFPIA companies. Significant progress has been made regarding the implementation of the Internal Control Standards (ICS) framework, although a number of the internal processes need to be further enhanced. Furthermore, in 2011, key control measures such as the internal audit capability and the ex-post audit controls were still in the early stages of development with the first results of these actions expected in 2012.

Implementation of operational and administrative budgets

The budgets for 2011 were adopted by the Governing Board in April 2011 due to the delay in the adoption of the Annual Implementation Plan for that year. In line with Article 14 of the IMI Financial rules, this meant that in the interim IMI was limited to the use of the "provisional twelfths" for both commitments and payments. This had a direct negative consequence on the implementation of the budget in the first quarter of 2011 and resulted in longer timelines for the execution of commitments and payments. No amendments were made to the approved Budget in 2011.

Operational budget

At the end of 2011, 29 payments were made for a total of EUR 68,97 million. Budget execution was therefore 86,8% (compared to 35,5% in 2010). The average time to pay has been reduced compared to 2010 for both pre-financing payments (from 19 to 5 days) and for the payment of costs claims submitted by beneficiaries (from 66 to 54 days). There was one late payment (a delay of two days) during this year. The experience of the first interim payments will be used to further shorten and strengthen the related procedures.

Budget year	Nr of payments	Average time of report submission after the end of the reporting period*	Average suspension period	Average time to pay	Average of process time	% of payment on time	% beyond time limit
2010	1	84	87	66	237	100%	0%
2011	16	88.25	62.6	54.4	205	93.75%	6.25%

*including 60 contractual days for submission

Administrative Budget (Running Costs)

As at 31 December 2011, 955 payments were made for a total of EUR 5,32 million, resulting in a budget execution (including carry over) of 50,0 % (as compared to 34,6% in 2010).

Maximum payment time limit	Paid on time	Paid beyond time limit	Average time to pay (days)
30 days	50,9%	49,1%	39
45 days	59,6%	40,4%	44
60 days	71,4%	28,6%	47

Control Systems

Ex-ante controls have been put in place in the respective procedures, checklists and financial circuits for both the administrative and operational budgets. In the case of projects, the ex-ante controls cover the whole project lifecycle, from the initial validation and approval of the pre-financing payments to the initiation and verification of interim and eventually final payments. Grants are paid on the basis of the beneficiaries' declarations of eligible costs, the submitted Periodic Financial Management Reports (PFMR), and where applicable, the certificates on the financial statements. The operational and financial agents perform initiation and verification tasks. However, the moment the payment is authorised, IMI is not able to fully ensure that the amount paid is accurate and in compliance with the applicable legal and contractual provisions. This can only be achieved through ex-post audits carried out at the beneficiaries' premises, after the costs have been incurred and declared (see below).

Internal controls are also embedded in the Call and Grant Award process, including eligibility screening of the Expression of Interests and the Full Project Proposals; ethical reviews of the proposals performed by independent external experts; controls to ensure conformity with IMI JU rules, as well as procedures and checks carried out during the negotiation; grant preparation and signature processes. The reports of the independent observers in 2011 which reviewed the publication of the Calls, the selection of independent experts and the evaluations for Call 3 (Stages 1 and 2) and 4 (Stage 1) concluded that these were conducted with professionalism and according to the established procedures and regulations. According to the independent experts' opinion:

- There were no violations of the rules of the published evaluation guidelines.
- The evaluators generally possessed sufficient and relevant expertise and displayed the utmost professionalism.
- All evaluators fulfilled the stipulated criteria including not being involved in any of the applicant consortia and not being subject to any kind of conflict of interest.
- The evaluation of the proposals was fair and transparent.
- The consensus evaluation reports generated by all panels incorporated the opinions of all experts and truly represented the consensus opinions of the panels.

IMI also actively monitors the progress of the funded projects through the systematic review of technical reports and through interim reviews of each project. The first two interim reviews were held in 2011 and these had positive conclusions on the early achievements of the projects.

Ex-post audits

In December 2010, IMI adopted an ex-post audit strategy, harmonised with the EC's FP7 ex-post audit strategy that is intended to ensure the legality and regularity of the operational expenditure on a multiannual basis by systematically detecting and correcting errors. This strategy complements ex-ante controls embedded in management processes and will eventually include the recovery of any amounts found to have been paid in excess. Pre-financing payments are not subject to ex-post control as they carry a significantly lower risk of errors.

Due to its multiannual nature, the effectiveness of IMI's ex-post audit strategy can only be fully measured and assessed during the final stages of IMI, once the ex-post control strategy has been fully implemented and systematic errors have been detected, extrapolated and corrected.

The first sixty ex-post audit engagements covering the claims of final beneficiaries that were validated by 30 June 2011 were launched in November 2011, following the conclusion of a framework contract with three external audit contractors. These audits excluded those beneficiaries that are subject to planned, on-going or recently concluded audits by the European Commission and this impinged on the overall sampling approach as envisaged in the IMI Ex-Post Audit Strategy. The first results are expected in April 2012.

In-kind contributions from EFPIA Companies

EFPIA companies participate in the IMI projects by providing in-kind contributions as specified in the individual grant agreements. The first reports on the EFPIA companies' in-kind contributions are expected at the end of February 2012, following the approval of the revised model Grant Agreement in November 2011. Ex-ante and ex-post controls on the reported in-kind contributions of EFPIA companies can only be initiated after the first reports are received.

6.2.2 Building block 2: Results from audits during the reporting year

Risk Assessment by the IAS and IAC in 2011

There were no internal audits by the IAS or IAC in 2011 as the internal audit function was being formalised and developed during this period. The IAS and IAC Charters were adopted in March 2011 and a coordinated risk assessment for 2011 was carried out by the IAS and IAC in preparation for the internal audit strategy for 2012-2014 that was adopted in November 2011.

The IAS-IAC risk assessment exercise identified six key areas of high risk which management should give particular attention to, particularly the monitoring of activities through Key Performance Indicators; the establishment of an asset and inventory management system; the strengthening of IT development and management processes; the establishment of a comprehensive document management system; ensuring sufficient measures for business continuity; and the introduction of ex-post controls for grant management.

European Court of Auditors

The audit on the annual accounts for 2010 found no shortcomings, in all material respects, on the reliability of the IMI Accounts and on the legality and regularity of the transactions underlying the accounts.

Preliminary findings on the first audit carried out in November 2011 by the European Court of Auditors on the 2011 accounts have been received for comments. These covered issues related to budget implementation; progress in the implementation of internal control standards; a sample of administrative and operational commitment and payments; the call and grant award process; the recruitment procedures; the ex-post audit process and the reporting of in-kind contributions by EFPIA companies. IMI JU has provided comments to the Court on these preliminary findings.

Action plans have been devised by the Executive Office management team on how to adequately mitigate the risks and address the concerns raised by the internal and external auditors.

6.2.3 Building block 3: Audits from previous years

Follow-up of the previous years' reservations

No reservations were made in the Annual Activity Report and the Declaration of Assurance for 2010.

Follow-up of the European Court of Auditors' recommendations

In the report of the Court on the 2010 Accounts five key recommendations were made. Two of the recommendations related to the clarification on the role of Internal Audit Function and the Commission's Internal Audit Service and the signature of the Host State Agreement have been fully implemented. Significant progress was made on the other three recommendations related to the implementation of the budget in terms of both commitment and payment appropriations (refer to the Financial Table on page 19), the implementation of the internal control and financial reporting system (as outlined in Section 5.2 and section 5.1.3 respectively), and the methodology for the evaluation of in-kind contributions by EFPIA companies (refer to item 13 in the Table on pages 5 and 6).

6.2.4 Building block 4: Assurance received from other Authorizing Officers

Not applicable.

6.2.5. Completeness and reliability of the information reported

The information reported in the building blocks is based on the systematic analysis of all available evidence and provides sufficient guarantees with regard to the completeness and reliability of the information reported.

6.2.6 Reservations

None.

6.2.7 Combined impact of the reservations on the Declaration as a whole

Not applicable.

ANNEX A – FINAL ANNUAL ACCOUNTS FOR 2011

ASSETS

Heading	Account Description	G/L acct	Note n°	Balance period 2011 EUR	Balance period 2010 EUR
I. NON-CURRENT ASSETS				**88.993.954,34**	**34.725.685,34**
Intangible fixed assets		21000000		**0,00**	**0,00**
Computer software			**3.1 a**	**256.674,08**	**0,00**
	Purchase price	21001001		342.232,11	0,00
	Depreciation	21008001		-85.558,03	0,00
Tangible fixed assets					
Computer hardware			**3.1 b**	**85.838,60**	**21.502,07**
	Purchase price	24101001		123.702,17	28.440,09
	Depreciation	24108001		-37.863,57	-6.938,02
Office furniture			**3.1 b**	**180.498,38**	**0,00**
	Purchase price	24001001		205.274,10	0,00
	Depreciation	24008001		-24.775,72	0,00
Long - term prefinancing		29911100	**3.1 c**	**88.470.943,28**	**34.704.183,27**
II. CURRENT ASSETS				**17.192.536,45**	**70.870.344,49**
Short - term receivables			**3.2 a**	**1.761.495,36**	**139.277,74**
	Receivable from EFPIA	40001000		1.660.162,00	
	Receivable from other JU	40005300		2.906,72	
	Bank interest to be received	49100000		94.579,09	**129.096,02**
	Advances on missions	45321000		3.133,70	5.243,70
	Advances on salaries	45311000		713,85	4.638,02
	Staff	40007000		0,00	300,00
Cash & Cash equivalents			**3.2 b**	**15.431.041,09**	**70.731.066,75**
Cash at banks				*15.431.041,09*	*70.731.612,03*
		55023000		15.431.041,09	70.731.612,03
Cash in transit		56023000		0,00	-545,28
TOTAL ASSETS				**106.186.490,79**	**105.596.029,83**
III. NET ASSETS				**-25.869.072,11**	**-80.368.941,68**
Members Contributions (EU + EFPIA Contribution)		14400000	**3.3**	**-128.879.681,75**	**-108.754.197,40**
Accumulated contributions used in previous years		14000000		**28.385.255,77**	**621.906,70**
(economic result of the year: surplus(-) / deficit (+))				**74.625.353,87**	**27.763.349,02**
TOTAL NET ASSETS				**-25.869.072,11**	**-80.368.941,68**

LIABILITIES

Heading	Account Description	G/L acct	Note n°	Balance period 2011 EUR	Balance period 2010 EUR
IV. NON-CURRENT LIABILITIES				**0,00**	**0,00**
Long term provision		16320000		**0,00**	**0,00**
V. CURRENT LIABILITIES				**-80.317.418,68**	**-25.227.088,15**
Accounts Payables			**3,4**	**-99.373,76**	**-4.230.528,96**
	Accounts payables with consolidate entities	44005100		0,00	-1.785,00
	Grant beneficiaries			*0,00*	*-4.226.564,10*
		44001000		0,00	-502.081,15
		44002000		0,00	-1.142.465,38
		44004000		0,00	-2.582.017,57
	Suppliers			*-99.373,76*	*-2.179,86*
		44001000		-102.315,29	-6.049,12
		44002000		-638,59	-228,00
	Eligibility to be confirmed	49030000		3.580,12	0,00
	Verification - invoices	49040000		0,00	4.097,26
Other accounts payables			**3,4**	**-80.218.044,92**	**-20.996.559,19**
	Taxes, salaries and social security			*-15,70*	*-49.577,93*
	Contribution for pension costs	45491000		0,00	-18.362,62
	Contribution for sicknesscosts	45492000		0,00	-8.287,72
	Contribution for taxes	45493000		0,00	-18.371,53
	Contribution for accident costs	45622000		0,00	-1.316,47
	Contribution for unemployment	45800000		0,00	-3.239,59
	Contribution for nurserycosts	46207000		-15,70	0,00
	Net salary to be paid	47530100		0,00	0,00
	Accrued charges:		**3,4**	*-80.218.029,22*	*-20.946.981,26*
	Estimated "in-kind" contribution of EFPIA members	44520000		-51.026.268,00	-14.160.447,00
	Cost claims received after the year end	49030000		0,00	-6.399.720,90
	Accrued administrative charges	49055000	**3,4**	-386.812,95	-386.813,36
	Accrued operational cost claims	49055000		-28.804.948,27	
TOTAL LIABILITIES				**-80.317.418,68**	**-25.227.088,15**

Economic Outturn Account

Heading	Account Description	G/L acct	Note N°	Balance period 2011 EUR	Balance period 2010 EUR
I. OPERATING REVENUES				**289.966,27**	**44.164,01**
Miscellaneous income from other JU		74025000	**3.5**	**85.065,89**	**44.164,01**
Other Income (Fixes assets)		74000700		**204.900,38**	
II. OPERATING EXPENSES				**-75.459.258,22**	**-28.404.492,41**
Administrative Expenses				**-5.201.608,12**	**-3.083.378,38**
	Experts & Related Expenses	61085000	**3.5**	-596.303,73	-341.077,98
	Fixed Assets related expenses (Depreciation of Assets)	63020000		-141.259,30	-6.938,02
	Other administrative expenses		**3.5**	*-1.402.533,72*	*-589.763,95*
	Office supplies	61010000		-64.124,75	-5.313,29
	Communications& publications	61020000		-159.000,99	-168.762,39
	Miscelleneous insurances	61040000		-20,00	-3.725,70
	Transport expenses	61050000		-4.478,45	-3.372,00
	Recruitment costs	61060000		-708,84	-73.789,08
	Training costs	61070000		-12.908,19	
	Missions costs	61080000		-114.443,85	-54.458,42
	Other goods&services	61090000		0,00	376,36
	IT-development costs	61094020		-104.627,71	0,00
	IT-operational costs	61094030		-502.187,27	-31.660,61
	Other external services non IT	61095000		-339.976,13	-188.404,14
	Other administrative expenses with Consolidated entities	61100000		-100.057,54	-60.654,68
	Rent expenses		**3.5**	*-331.907,60*	*-302.819,65*
	Rent of land & buildings	61001000		-278.176,93	-273.924,37
	Other rental expenses	61001500		-53.730,67	-28.895,28
	Staff expenses		**3.5**	*-2.729.603,77*	*-1.842.778,78*
	Staff costs	62000000		-2.174.824,57	-1.515.593,51
	Employer's contribution to unemployment costs	62020000		-25.298,20	-18.296,55
	Employer's contribution to Social Security	62030000		-78.690,16	-55.933,72
	Social activities	62040000		-23.050,30	-28.005,04
	Staff allowances	62050000		-427.740,54	-224.949,96
Operational Expenses				**-70.257.650,10**	**-25.321.114,03**
	Cost Claims paid to beneficiairies	60810000		-33.391.829,10	-11.160.667,03
	Contribution in-kind	60820000		-36.865.821,00	-14.160.447,00
DEFICIT FROM OPERATING ACTIVITIES				**-75.169.291,95**	**-28.360.328,40**
III. FINANCIAL REVENUE				**546.603,88**	**601.515,31**
Interest Revenue			**3.5**	**546.603,88**	**601.515,31**
	Prefinancing Interest	74005000		19.285,68	
	Bank Interest	75016000		525.839,39	601.515,31
	Exchange Gain	74850000		1.478,81	
IV. FINANCIAL EXPENSES				**-2.665,80**	**-4.535,93**
Financial Expenses and others			**3.5**	**-2.650,80**	**-4.148,78**
	Exchange Loss	64850000		-1.979,17	
	Interest on late payment	65010000		-669,28	
	Extraordinary losses	69000000		-2,35	
Bank fees		65025000		**-15,00**	**-387,15**
SURPLUS FROM NON-OPERATING ACTIVITIES				**543.938,08**	**596.979,38**
CONTRIBUTION FROM MEMBERS USED DURING THE YEAR				**-74.625.353,87**	**-27.763.349,02**

ANNEX B – MATERIALITY CRITERIA

The Authorizing Officer assessed the significance of any weaknesses that could lead to a formal reservation. This exercise was limited by the fact that the first ex-post audits were launched in November 2011 and the preliminary results will be known in Q2 of 2012.

The assessment of weaknesses was done by identifying their potential impact and judging whether any weakness was material enough that its non-disclosure could influence the decisions or conclusions of the users of the declaration of assurance.

The materiality threshold adopted by IMI JU is established in application of the EC Standards after making both a qualitative and quantitative judgment in order to assess and quantify any significant weaknesses:

- *in qualitative terms*, the following factors are considered as part of the materiality criteria: nature, scope, duration, mitigating controls, existence of corrective actions; and

- *in quantitative terms*, the potential financial impact is taken into account and an acceptable limit of error is established for the percentage value of transactions of IMI's budget affected by the weakness.

In establishing the materiality threshold for ex-post audits, the guidance of the European Court of Auditors as well as the applicable EC standards will be taken in account for defining a materiality threshold of 2%.

ANNEX C – IMPLEMENTATION OF INTERNAL CONTROL STANDARDS

Internal Control Standard	Analysis
1. Mission	The mission and strategic priorities of IMI JU are clearly defined and communicated to stakeholders including staff. The job profiles of staff are being updated to reflect the recent organizational changes. Performance appraisals will also be aligned to the objectives and targets for the year.
2. Ethical and organisational values	IMI has in place its own rules on personal conduct and action against fraud, apart from the relevant guidelines issued by the EC. A third batch of implementing rules is in the process of being approved.
3. Staff allocation and flexibility	IMI has in place the necessary procedures for the allocation and recruitment of staff, including the general implementing provisions on the procedure governing the engagement and use of temporary and contact staff, and on the approval of the multi-annual staff policy planning. Additional measures are being taken to strengthen the internal recruitment procedures.
4. Staff evaluation and development	A performance appraisal exercise is carried out each year. This process is being enhanced by linking individual objectives to IMI JU's strategic goals as well as giving greater attention to staff development.
5. Objectives and performance indicators	A significant improvement has been made in the annual planning cycle with the timely approval of the Annual Implementation Plan for 2012. Key Performance Indicators have also been established during 2011 for the measurement of performance against targets.
6. Risk management process	Risk management has been fully integrated in the management's planning and monitoring processes. A detailed annual risk assessment is performed by the third quarter of each year. In addition, corporate and functional risk registers have been developed outlining actions and responsibilities. Risks that are considered critical are communicated to the Governing Board and reported in the Annual Implementation Plan.
7. Operational structure	Responsibilities and delegation of authority have been clearly defined, assigned and communicated in writing. Risks related to sensitive functions have identified and mitigation controls have been put in place. Action is being taken to update the manual of financial procedures as well as the budget/accounting procedures in order to consolidate this aspect following re-organization of the Executive Office. In 2011, there was further consolidation of the key elements essential for effective IT governance. This process is ongoing and is expected to be completed in 2012.
8. Processes and procedures	There are appropriate segregation of duties to ensure effective governance and control. Ex-post controls for operational expenditure were launched in November 2011. A procedure is also in place to ensure that all instances of overriding of controls or deviation from established processes and processes are documented in exception reports, justified and duly approved. Efforts have continued in 2011 to document and update all procedures and practices and consolidate these in manuals and guidelines. This is an organizational challenge, particularly as the Executive Office is also making changes to further simplify and streamline its systems. Updated financial guidelines for participants were published in January 2012.

Internal Control Standard	Analysis
9. Management supervision	Effective and efficient management and supervisory mechanisms have been integrated at all levels in the day-to-day operation of the Executive Office. Potentially significant issues are raised at Governing Board level and reported in the Building Blocks for the Declaration of Assurance of the Authorising Officer.
10. Business continuity	A Business Continuity Plan has been developed and will be tested and integrated with a disaster recovery plan for IT infrastructure in the first quarter of 2012.
11. Document management	Opportunities for improvement in the current internal document management system are being identified and will be followed up in 2012.
12. Information and communication	In 2011 a new external communication strategy has been adopted by the Governing Board and is being implemented. There are also established channels for internal communication (e.g. staff meetings, internal newsletters). Further improvements are envisaged, such as the development of scoreboards for the reporting on organizational performance. Policies and procedures for IT security have also been concluded and are in the process of being adopted. Moreover, the IT platform for interaction and exchange of information within the Executive Office and with stakeholders is also being enhanced. The strategic IT planning process is also being formalized. A system is in place to ensure that there is adequate implementation of data protection rules and the proper notification to the European Data Protection Supervisor (EDPS).
13. Accounting and financial reporting	Adequate procedures and controls are in place to ensure that accounting data and related information are used for preparing the annual accounts and financial reports. A validation exercise of the underlying systems was carried out by the accounting officer in 2011. Follow-up action is being taken to implement recommendations.
14. Evaluation of activities	An independent interim review by an external expert panel commissioned by the EC on IMI JU's performance and achievements was published in 2011. Action has been taken to implement the recommendations of the expert panel. Each stage of the call evaluation process is systematically assessed by independent observers and reports are reviewed and published on the IMI website.
15. Assessment of internal control systems	IMI JU applies its own methodology on the self-assessment of the compliance and effectiveness of the ICS and the management of risks. The first self-assessment by management for the year under review (2011) was concluded in January 2012. The first results of ex-post audits will also provide an indication on the effectiveness of ex-ante controls for operational expenditure.
16. Internal Audit Capability	The roles of the Internal Audit Service of the European Commission and the Internal Audit Capability were formalized in March 2011 and a coordinated internal audit strategy was approved by the Governing Board in November 2011. In 2012 the first internal audits will be carried out.

ANNEX D - INTERNAL CONTROL FOR BUDGET IMPLEMENTATION

Management mode Key figures	Direct centralised for administrative and operational expenditure. *For administrative expenses*, 955 payments were made for a total of € 5.324.401 million. These represented 80 payments per month in average, with peaks in the number of payments in July and December (169 and 155 payments respectively). *For operational expenditure*, 29 payments were made for a total of € 68.979.926 million, with peaks in May and December due to the pre-financing payments linked to Call 2 and Call 3 projects, apart from interim payments for Call 1.
Management and control systems: stages and main actors The IMI JU applies the simple financial circuit model in ABAC system, but the respective role of Operational Initiating Agent and Operational Verifying Agent are taken into account - where relevant - during the process (as defined in the routing sheet).This financial circuit, together with the management and accounting systems, segregation of duties and procedures, internal controls, reporting structures and control functions were established in line with the requirements of the IMI JU Financial Rules. The internal manual for financial procedures is currently being revised to reflect organisational and procedural changes. The Executive Director acts as Authorising Officer and in October 2011 powers were delegated to the newly created post of Head of Administration and Finance and, when necessary as back-up, to the Executive Officer. In accordance with the IMI Financial Rules, the Joint Undertaking uses the four-eye principle: all operational and financial aspects of an operation have to be verified by a second staff member before it is authorised. This verification is used to ensure compliance with rules and good financial management.	
Selection process	The selection process for *participants* in IMI JU is based on a two-stage evaluation process which includes a public call for proposal, official rules of participation, eligibility screening of the Expression of Interest and the Full Project Proposals; ethical reviews of the proposals performed by independent external experts; and controls to ensure conformity with IMI JU rules as well as procedures and checks carried out during the negotiation, grant preparation and signature processes. Each key stage includes a decision of the Governing Board. In the case of the selection of *experts*, individuals are chosen on the basis of a list of appropriate experts according to their specific expertise. The experts are appointed for the duration of each specific call process. A Scientific Officer ensures that the proposed experts have the necessary expertise and prepares a dossier with the required information to support the decision of the Executive Director. IMI also takes all necessary steps to ensure that the experts are not faced with a conflict of interest in relation to the expressions of interest and/or the full project proposals on which they are required to give an opinion. To this end, they are required to sign a declaration that no such conflict of interest exists at the time of their appointment and that they undertake to inform the IMI JU if one should arise in the course of their duties. When so informed, the IMI takes all necessary actions before and

	during the evaluation. In addition, all experts are required to re-confirm that they have no conflict of interest for each expression of interest or full project proposal that they are asked to examine at the moment of the evaluation. For the *procurement of services and supplies*, the preventive measures in place for each procurement activity include: a clear evaluation of needs, the volume and cost of the required services or supplies; the verification that the services or work cannot be executed in house or on the basis of any Framework Contracts of the European Commission to which IMI is associated or on the basis of Service Level Agreements; and a decision on the choice of procurement procedure. Standard procurement procedures apply depending on the established thresholds of the estimated value of the respective contract.
Communication and information	*Internally:* The main internal mechanisms for communication and the dissemination of information are the Governing Board teleconferences, Management Team meetings, Management of Scientific Activities meetings, Finance and Administration meetings, internal briefings and newsletters as well as horizontal and ad hoc meetings. These channels are important for ensuring effective communication and sharing of information between financial, administrative and scientific staff. *Externally:* Published information (such as the call text, guidelines for applicants and participants and information on the website); the organisation of special information days; meetings and workshops; and a wide range of communication tools are used to support the management processes and for the collection and reporting of information and data.
Detective and corrective controls	Projects are expected to submit periodic reports which include financial statements and an explanation on the use of resources. In addition, EFPIA companies are expected to submit an annual declaration of the in-kind contribution provided for each project they participate in. The first declarations on in-kind contributions related to Call 1 and 2 projects are expected in February 2012 following the revision of the model Grant Agreement in November 2011. The current cumulative threshold for the presentation of a certificate on the financial statements issued by an independent external auditor is €375.000. This requirement is waived (except at the end of the project) for those project participants that declare their costs according to certified accounting and reporting methodologies that are accepted by the EC and/or IMI JU. Before a payment is authorised, all relevant operational and financial aspects are verified by at least two independent members of staff. – Scientific officers verify that the work carried out by the beneficiary is in all respects in compliance with the grant agreement by evaluating the periodic reports and deliverables and by assessing the plausibility of declared spending in relation to reported progress. – Financial officers carry out checks to ensure financial statements

	and certificates of financial statement (CFS) have been submitted in accordance with the provisions of the grant agreement. – The authorising officer ascertains that these checks on the supporting documents have been done and validates the expenditure. Since 2011, interim reviews are also being used to complement the detective and corrective controls.
Corrective controls and audit	Ex-post audits are a key element of corrective controls. IMI JU follows the Joint Undertakings' ex-post audit strategy which was approved by the IMI JU Governing Board following harmonisation with the one for FP7. The control objectives of the ex-post audit activity are twofold: (1) to provide an adequate indication of the effectiveness of ex-ante controls; and (2) to ensure the accuracy of the expenditure and in-kind contributions, thereby, the legality and regularity of the underlying transactions on a multi-annual basis. At any time during the project implementation period the European Commission, the ECA and IMI JU can carry out on the spot checks and/or audits of beneficiaries. In addition, IMI JU can also carry out on the spot checks and/or audits of EFPIA companies providing in-kind contributions to the projects. The selected grant agreements to be audited are based on a sampling strategy that ensures comprehensive coverage of the audit population. This sampling includes representative sampling to estimate error rates in the total population, systematic coverage of "top beneficiaries" (with due consideration to any overlapping activity by the EC) as well as risk-based sampling to direct resources for controls and checks to those operations where the likelihood of errors is considered particularly high. The first ex-post audits among beneficiaries were launched in November 2011 and the results are expected in Q2 2012. The systematic errors detected on the audited contracts will be extrapolated to non-audited contracts. This will ensure that a substantial share of funding is largely free from systematic errors. All audit results will be implemented by the authorising officer and errors detected will be corrected by issuing recovery orders or deducting amounts wrongly paid from future payments to the same beneficiary. Ex-post audits on the reported in-kind contributions by EFPIA companies will be launched in 2012.

Feedback which enables control activities to be optimised	
Verification that processes are working as designed	Arrangements are in place to ensure adequate management supervision and proper segregation of duties. These measures prevent any control overrides or deviations from policies and procedures unless there is prior approval. Procedures are also in place for reporting and registering exceptions. Management at all levels supervise the activities they are responsible for and keep track of main issues identified. A system of checklists and routing sheets document the processes. Activities involving potentially critical risks (e.g. aspects of legality, regularity and operational performance) are also adequately documented. Weekly management meetings are also held, where relevant activities and their regularity, legality or operational performance are discussed among the services and with the Executive Director. The effectiveness and efficiency of management supervision is also systematically evaluated during each annual risk assessment exercise and by other checks carried out by the Internal Control Coordinator. An in-depth exercise was also carried out in 2011 by the Accounting Officer to validate the underlying processes supporting the accounting system.
Monitoring of performance	The European Court of Auditors audits the operations of the Joint Undertaking. In addition, from 2012, the IAS and IMI JU's IAC, will carry out internal audits and assessments on the efficiency and effectiveness of internal controls. IMI JU systematically monitors the implementation of audit recommendations through follow-up action plans and reporting on implementation.
High level management reporting	The Annual Implementation Plan includes specific objectives and, from 2012, KPI targets relative to the implementation of the budget. The latter facilitate the monitoring of performance against targets. Detailed briefings are submitted and discussed in monthly teleconferences with the Governing Board. The Executive Director also reports to the Board on progress and achievements during the three Governing Board meetings which are held every year. In addition, the Annual Activity Report outlines the progress made during the year, including issues related to budget implementation.

ANNEX E – EXECUTION OF COMMITMENT AND PAYMENT APPROPRIATIONS IN 2011

Budgetary Annual Account – Commitment appropriations execution IMI JU EUR		
Title 1 Staff Expenditures	**2010**	**2011**
11. Salaries & allowances	1.871.677	2.702.529
12. Expenditures to Staff recruitment	17.196	54.874
13. Mission expenses	56.260	141.567
14. Socio-medical infrastructure and other interventions	20.000	185.996
17. Receptions and Events	1.754	7.496
Title 2 Infrastructure and operating expenditures		
20. Rental of buildings and associated costs	504.715	365.748
21. Information and communication technology	561.964	508.798
22. Movable property and associated costs	6.917	11.207
23. Current administrative expenditure	84.733	75.764
24. Postage and telecommunication	53.818	29.160
25. Expenditures on formal and other meeting	54.536	55.723
26. Running costs in connection with operational activities	108.036	105.175
27. Information and publishing	306.126	198.737
28. Studies	30.000	370.790
29. Experts contracts and meeting	471.611	474.482
Sub-total title 1 & 2	**4.149.343**	**5.288.045**
Title 3 Operating expenditures		
30. Implementing the research agenda of the IMI JU	0	105.000.000
Carried over commitment appropriation following Art 10 of IMI's Financial Rules (C2)	2.096.872	112.250.000
TOTAL EXPENDITURE	**6.246.215**	**222.538.045**

Budgetary Annual Account – Payment appropriations execution IMI JU EUR		
Title 1 Staff Expenditures	**2010**	**2011**
11. Salaries & allowances	1.868.177	2.702.529
12. Expenditures to Staff recruitment	15.196	54.629
13. Mission expenses	35.227	99.619
14. Socio-medical infrastructure and other interventions	-	148.106
17. Receptions and Events	754	6.826
Payment of commitments carried forward from previous year (C8)	0	21,033
Title 2 Infrastructure and operating expenditures		
20. Rental of buildings and associated costs	112.281	344.783
21. Information and communication technology	42.133	342.223
22. Movable property and associated costs	1.957	5.052
23. Current administrative expenditure	5.883	48.934
24. Postage and telecommunication	422	869
25. Expenditures on formal and other meeting	45.951	39.966
26. Running costs in connection with operational activities	97.191	78.591
27. Information and publishing	246.786	122.888
28. Studies	24.000	-
29. Experts contracts and meeting	320.638	448.305
Payment of commitments carried forward from previous year (C8)	329,812	860,048
Sub-total title 1 & 2	**2.816.595**	**4.443.320**
Sub-total title 1 & 2 (C1-C8)	**3,146,408**	**5,324,401**
Title 3 Operating expenditures		
30. Implementing the research agenda of the IMI JU	20.504.000	14.972.613
Carried over payment appropriation following Art 10 of IMI's Financial Rules (C2)	14.738.038	54.007.313
TOTAL EXPENDITURE	**38,388,446**	**74,304,327**