Innovative Medicines Initiative

Annual Activity Report
2012

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EXECUTIVE DIRECTOR FOREWORD

The year 2012 was a landmark for the Innovative Medicines Initiative. With the launch of 4 new Calls for Proposals and the kick-off of 13 new projects, IMI committed almost half of its available budget in a single year. This unprecedented effort resulted in the successful mobilization of the different stakeholders, as reflected by the high quality funding applications that IMI received, involving 487 industrial and academic teams. Today, around 4500 scientists collaborate under the IMI public-private partnership umbrella. They have a common mission, namely to facilitate and accelerate the development of better and safer medicines for the benefit of patients and society across Europe. The strong interest elicited all over the world by the IMI programme to tackle anti-microbial resistance and the creation of the IMI European Lead Factory demonstrates that IMI effectively contributes to restoring European leadership and competitiveness in the pharmaceutical sector.

During 2012, IMI consortia developing new tools and methods to improve assessment of drug actions or implementing new education and training programmes reported striking results. While these first achievements are very encouraging, their effective translation into standards of care will require novel innovative approaches, taking advantage of the neutral platform represented by IMI. To help achieve this goal, in 2012 IMI launched new projects focusing on defining real effectiveness and risk/benefit evaluation of drugs and vaccines. This effort will be further amplified in 2013 with close attention paid to priorities defined by regulatory authorities and unmet needs expressed by patients and caregivers, thereby establishing a solid foundation for a renewed public-private partnership under Horizon 2020, the forthcoming framework programme for Research and Innovation of the European Commission.

Trust is the essential key for IMI's long-term success. It is the single most important element for ensuring fruitful collaboration between the many stakeholders inside IMI projects, and efficient governance of the partnership as a whole. I would like to express my appreciation for the support and constructive criticism received from IMI's Governing Board, IMI's Scientific Committee members and IMI's States Representative Group throughout the year. Last but not least, I express my deep gratitude to the staff of the Executive Office who was instrumental in making 2012 a memorable year for IMI.

Michel Goldman, MD, PhD
Executive Director
27 February 2013

1. OVERVIEW OF 2012 ACHIEVEMENTS

Objective AIP 2012	Action and outcome
Research Activities	
Monitoring of on-going projects (Call 1 and Call 2)	▪ 14 interim reviews (13 from Call 1 projects, 1 from Call 2) ▪ 3 Cross-projects meetings, 2 cross-projects brochures supported
Launch of Call 3 and Call 4 projects	▪ All seven Call 3 projects and six of seven Call 4 projects kicked off their activities in 2012 ▪ Preparation for kick off of EMIF project in early 2013
Launch of 4 new Calls for Proposals	▪ Calls 5, 6, 7 and 8 launched between March and December, incorporating the outcome of the simplification exercise (streamlined process supported by dedicated IT tool) ▪ First Call for Proposals to Explore New Scientific Opportunities (ENSO) launched in August 2012 : 5 applications submitted
Communication	
Promotion of IMI by enhancing stakeholders' outreach, taking advantage of success stories and testimonies of on-going projects	▪ IMI Communication strategy developed under the auspices of the Governing Board ▪ 16 events targeting policy makers and opinion and industry leaders ▪ Series of events to promote IMI to potential applicants and multipliers, including webinars, workshops and info sessions and active participation in 13 Member States national infodays ▪ 9 press releases and 11 public newsletters ▪ 320 publications from IMI projects ▪ Average of 8100 unique visitors per month on IMI website (up 20% from 2011)
Key performance Indicators	
Set of indicators critical for monitoring IMI's achievements in terms of: ▪ strategic relevance and added value of IMI in reinforcing pharma R&D in Europe by addressing bottlenecks and gaps in drug research. ▪ monitoring the operational performance of the Executive Office.	▪ Performance monitoring methodology developed (e.g. bibliometric data screening on IMI project publications) ▪ Project achievements analysis has been performed and is updated on a continued basis

Topics in AIP 2012	Action and outcome
Management of the Executive Office	
Staffing	▪ Staff ceiling of 36 reached in mid-2012 ▪ Staff Committee established
Finance	▪ Optimal budget execution: 95.7% in commitments and 96.7% in payments ▪ 1317 financial transactions made ▪ Improvement in payments time-lines, in particular reduction of late payments for running costs by a third compared to 2011 ▪ First joint IMI-EFPIA financial management workshops for IMI projects
Audits	▪ 55 ex-post audits of beneficiaries finalised ▪ Internal control environment strengthened ▪ Preparation and launch of first audits of in-kind (EFPIA companies) ▪ 4 visits by European Court of Auditors
Information and Communications Technology	▪ Core-business tool (SOFIA) subject to significant development improvements ▪ Technical consolidation of dedicated platforms for IMI Governance bodies as a vector of communication ▪ Several new tools set up for the internal environment, including an electronic document management system

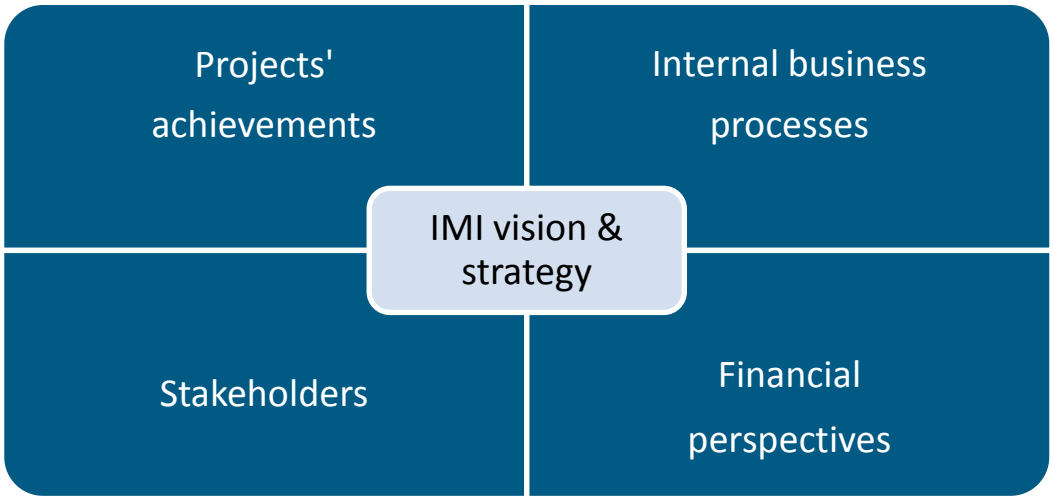
2. KEY PERFORMANCE INDICATORS

In 2012, IMI JU has further developed its set of Key Performance Indicators (KPIs) for the measurement of performance and results against two strategic overarching priorities identified as critical for overall success of IMI, namely:

- The strategic relevance and added value of IMI as a public-private partnership.
- The operational performance of the Executive Office.

IMI JU's KPIs are based on a 'Balanced Scorecard Framework' as a means to present the strategic performance of IMI according to 4 axes:

- Projects' achievements
- Stakeholders
- Internal business processes
- Financial perspectives



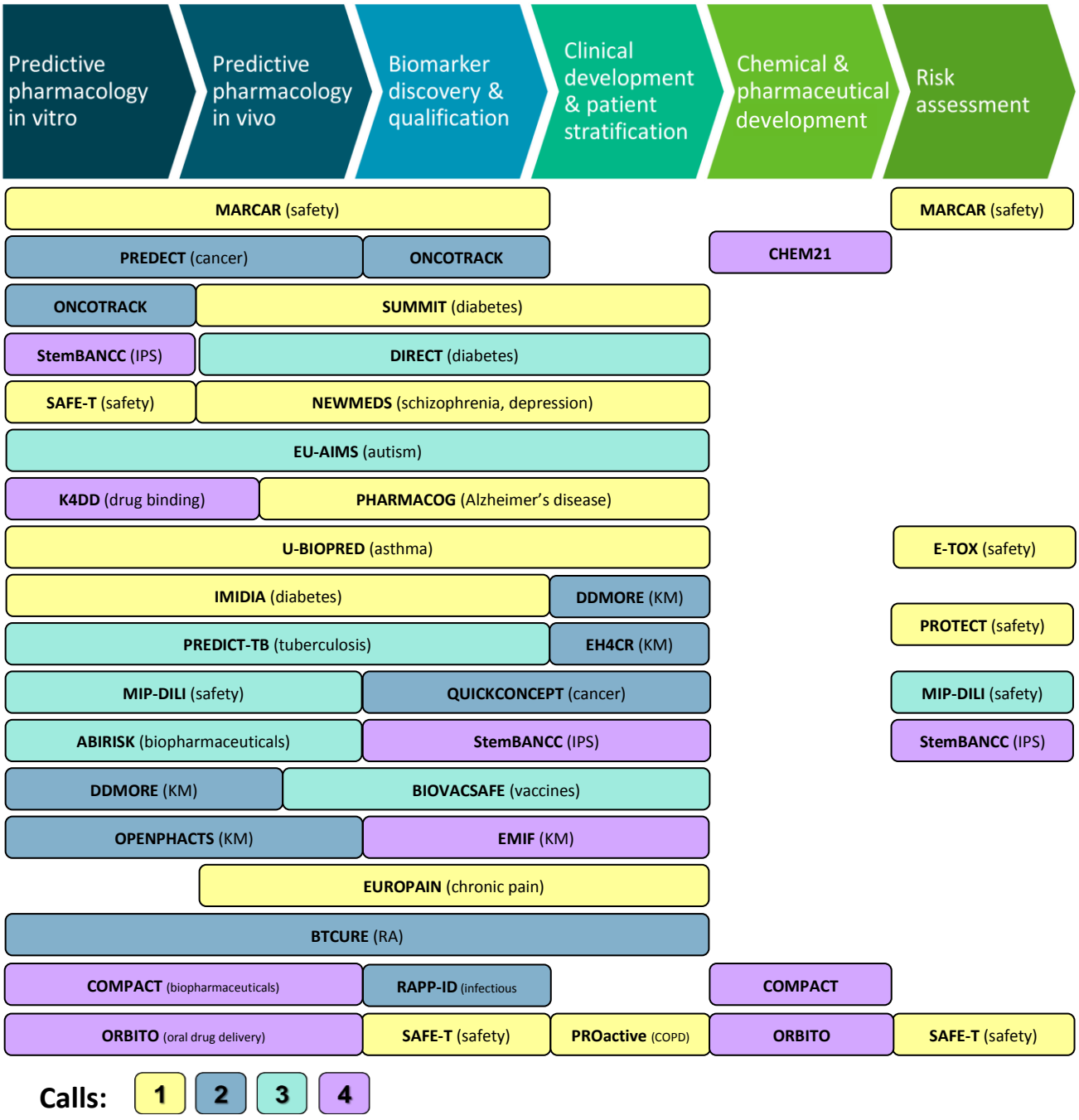
2.1 Projects' achievements

An extensive analysis of the IMI on-going projects has been performed by extracting project achievements from progress reports of the projects, interim reviews as well as the scientific publications resulting from the projects. These achievements support the following messages that have been and will be conveyed to the relevant audiences:

- IMI enhances EU competitiveness in the pharmaceutical sector by promoting a new ecosystem based on open innovation;
- IMI fosters European scientific leadership in medical sciences by creating collaborative intelligence networks;
- IMI accelerates the development of drugs for major unmet public health needs and the access of patients to innovative medicines;
- IMI offers new business opportunities to SMEs active in the pharmaceutical sector;
- IMI develops innovative tools and educates scientists and citizens to optimize data sharing and analysis of "big data" for the benefit of industry and patients.

The figure below represents the coverage of the value chain of the IMI on-going projects from Calls 1-4. As envisioned in the Strategic Research Agenda (SRA) of 2007, the projects from the early calls focus more on the early stages of the drug development process such as pre-clinical development and its translation, biomarkers and drug safety assessment. However the trend towards later phases of the value chain such as clinical as well as chemical development becomes visible with calls launched after the update of the SRA in 2011. In particular with the 5th and 6th Call there has been a shift towards "think big" projects such as European Lead Factory – ELF, and the antimicrobial resistance programme New Drugs for Bad Bugs - ND4BB.

Extent to which IMI JU project cover the value chain of drug development



The measurable outputs resulting from on-going projects and in some cases expected outcomes from recently launched "think big" projects have been divided into 6 categories:

- Establishment of robust validated models for drug development
- Development of biomarkers and tools predictive of clinical outcomes (efficacy and safety)
- Identification of new drug targets
- Clinical trials - improved design and process
- "Big Data" solutions to leverage knowledge
- Education and Training for new generation R&D scientists

Brief descriptions of the project outputs and objectives are set out as follows:

Project	Area	Results description
Establishment of robust validated models for drug development		
PHARMACOG	Alzheimer's disease	Developed a translatable sleep deprivation challenge model that performs well in 3 pre-clinical species as well as in human volunteers.
		3 transgenic mouse models of AD were longitudinally characterised using imaging, cognition, electrophysiological and a biochemical marker battery to assess their translational validity in efficacy prediction.
		Developed and pre-validated translatable rodent touchscreen technology for precisely measuring cognitive dysfunction (in collaboration with NEWMEDS).
EUROPAIN	chronic pain	New surrogate pre-clinical models of neuropathic pain and relevant outcome measures developed and pharmacologically validated across several laboratories: evoked pains (cold), neuronal activity (µENG), and quality of life (anxiety).
		Extensively evaluated multiple translational pain models and in progress of validation of several selected models, such as sleep deprivation model, menthol model, or UVB irradiation model.
NEWMEDS	schizophrenia, depression	Evaluated 14 animal models of schizophrenia in the proteomic biomarker panel developed by the consortium. Identified 4 preclinical models mimicking serum clinical biomarker signatures of first onset schizophrenia patients.
		Developed a circuit (hippocampal-prefrontal) model of schizophrenia and validated it against currently available agents.
		Developed new imaging techniques via new PET probes, and developed translatable animal-human imaging methodologies (fMRI).
		Developed and pre-validated translatable rodent touchscreen technology for precisely measuring cognitive dysfunction (together with PHARMACOG).
IMIDIA	diabetes	Developed the first fully functional human beta-cell line and completed successful validation of its secretory activity and functional properties by 3 pharmaceutical company partners – **patented.**
		Generated the SOFIA mouse – a new powerful tool for the functional imaging of insulin turnover in vivo.
SUMMIT	diabetes	Evaluated and characterized 9 existing pre-clinical models of diabetic vascular complications. Established new rat model of diabetic vascular complications – **patenting on-going**
		Developed new transgenic models by deletion of candidate diabetic nephropathy genes (GWAS).

U-BIOPRED	asthma	Identified 2 novel animal models (FCA/HDM, CT & MRI imaging of chronic HDM model).
		Evaluated and harmonized several animal models. Developed 2 reproducible and translatable animal models.
EU-AIMS	autism	Developed animal model that mimics nonsyndromic autism.
PREDECT	cancer	Developed ex-vivo tissue culture model for targeted drug discovery reproducing microenvironment contribution and intra-tumoural heterogeneity.
PREDICT-TB	tuberculosis	Is developing an integrated PK-PD/Disease modelling framework for tuberculosis which will facilitate prediction of optimal combinations and design of clinical studies.

Project	Area	Results description
Development of biomarkers and tools predictive of clinical outcomes (efficacy and safety)		
NEWMEDS	schizophrenia depression	Developed clinical imaging biomarkers - fMRI methods that can be applied in experimental drug development.
		Developed toolbox for the analysis of brain images for a better classification for drug development. **Publically available.**
		Developed robust surrogate proteomic biomarkers for drug efficacy prediction.
		Characterization and correlation of genotype-function-phenotype across species in carriers of CNVs linked to schizophrenia.
		Developed clinical meaningfulness calculator for assessment of biomarker candidates' utility in predicting antidepressant response: depressiontools.org – **publically available.**
		Identified neuropsychological and anthropometric phenotypes associated with schizophrenia CNVs.
PHARMACOG	Alzheimer's disease	Identified novel biomarkers sensitive to disease progression in transgenic mice.
		Demonstrated that cortical resting state EEG is sensitive to the cognitive decline in mild AD patients and might represent a cost-effective and non-invasive marker with which to enrich cohorts of AD patients that decline faster for clinical studies.
EUROPAIN	chronic pain	Developed translatable imaging biomarkers of brain activation related to chronic pain.
		Translational biomarkers (by transcriptomics, lipidomics, microneurography, imaging) developed and validated in pre-clinical species, experimental medicine pain models and pain patients.
U-BIOPRED	asthma	Developed various "omics" platforms based on genetic, proteomic, metabolomic, breathomic biomarkers – validation is on-going.
		Generated a preliminary phenotype 'handprint' by combining molecular, histological, clinical and patient-reported data – validation and refinement is on-going.
		Established a set of diagnostic criteria on severe asthma providing a stepwise algorithm for diagnosing the disease.
PROactive	COPD	Derived and statistically validated a conceptual model for physical activity.
		Developed patient reported outcome tools – validation is on-going.

SUMMIT	diabetes	Identified a biomarker of extracellular matrix degradation and vascular disease.
		Identified candidate biomarkers from the initial analysis of the lipodomic and metabolomic screening.
		Identified novel genetic markers to be further evaluated.
		Developed a new ultrasound-based method for non-invasive assessment of atherosclerotic plaque - **patenting on-going.**
		Generated phenotype definitions for diabetic complications.
EMIF-EMIF-AD	Alzheimer's disease	Will identify new AD biomarkers for the facilitation of drug development and trial design in predementia AD taking advantage of the largest single collection of data and samples yet assembled for biomarker analysis
EMIF-EMIF-Metabolic	Metabolic syndromes	Will identify new biomarkers predictors of metabolic complications in obesity, taking advantage of the largest single collection of data and samples yet assembled for biomarker analysis
SAFE-T	safety	Evaluated 153 potential biomarker candidates for drug-induced injury of the kidney, liver and vascular system.
		Established generic qualification strategy for new translational biomarkers.
e-TOX	knowledge management safety	Is building a toxicology information database utilising toxicology legacy reports from pharma partners to develop better in silico tools for toxicology prediction of new compounds (2087 reports extracted, 2904 cleared, 3643 planned in total).
		Assembled ChOX database using public data covering 175,000 compounds annotated to > 400 targets with > 700,000 activities extracted from 10,000 publications.
		Developed an in silico model for predicting cardiac toxicity.
		Developed 83 in silico models – internal pre-validation on-going.
		Developed toxicogenomics model for interpretation of transcriptomics and toxicogenomics data in order to predict inter-species toxicological profiles.
		Is building ontology for preclinical pathology, 3917 terms and 2535 synonyms have been mapped.
MARCAR	safety	Identified novel early non-genotoxic carcinogens (NGC) biomarkers and mechanisms via integrated genome-wide epigenomic and transcriptomic profiling of rodent livers and tumors.
		Exploited EFPIA in vivo toxicology studies, tissue archives, molecular profiling data for >30 reference compounds to study NGC, genotoxic carcinogens and non-hepatocarcinogen controls.
PROTECT	pharmacovigilance	Established the Drug Consumption Databases in Europe using data from European National sources and IMS data – **publically available.**
		Established the database of adverse drug reactions of centrally authorised medicinal products – **publically available.**
		Drafted a protocol for the review of graphical/visual representation of benefit risk scenarios.
RAPP-ID	infectious diseases	Developed a device and protocol related to breath-born aerosol sampling - **patenting on-going.**

STEMBANCC	stem cells	It will generate a large number of patient derived iPS cell lines, characterise them in terms of their genetic, protein, and metabolic profiles, and make them available to researchers. All cell lines will also undergo a rigorous quality check.

Project	Area	Results description
Identification of new drug targets		
EUROPAIN	chronic pain	Identified CXCL5 as novel translatable pain target.
NEWMEDS	schizophrenia depression	Completed de novo CNV analysis implicating specific abnormalities of postsynaptic signalling complexes in the pathogenesis of schizophrenia.
MARCAR	safety	Identified a sustained liver-specific epigenetic switch within non genotoxic carcinogens target genes.
		Gained novel insight into early mechanisms of non genotoxic carcinogens that might lead to novel target ide ntification.
EU-AIMS	autism	Uncovered NL1 isoform-specific cis-interactions with ionotropic glutamate receptors as a key mechanism for controlling synaptic properties.
BTCure	rheumatoid arthritis	Identified the association with rheumatoid arthritis of autotaxin, of the two microRNA-221/222 and microRNA-323-3p and of epigenetic changes.
ELF	drug discovery	Will combine a library of as many as 500,000 drug candidates from industry and academia with a high-throughput screening centre, providing to public partners an 'industry-like' discovery platform to translate cutting-edge academic research into high-quality candidate drug molecules on a scale and speed that was not possible previously.

Project	Area	Results description
Clinical trials- improved design & process		
NEWMEDS	schizophrenia depression	The analysis of the combined data from 23,401 schizophrenia patients has resulted in a proposal for reduction in the length of schizophrenia clinical trials as well as a reduction in the number of patients required to be enrolled.
		Initiated a clinical trial to develop new approach of combining medications with therapy.
PHARMACOG	Alzheimer	Optimized 4 clinical study designs based on literature reviews, protocols and data from EFPIA clinical studies.
EUROPAIN	chronic pain	Optimizing clinical trial design to reduce placebo response.
EU-AIMS	autism	Creation of pan-European network of clinical sites.
U-BIOPRED	asthma	Established network of excellence in bronchoscopy in severe asthma.
		Generated central registry of patients with severe asthma which can be utilised for future studies.
BTCure	rheumatoid arthritis	Provided recommendation for terminology to be used to define specific subgroups of RA patients during different phases of disease
EH4CR	knowledge management	Issued guidelines for writing the eligibility criteria for clinical research.

		Developing the protocol feasibility service/demonstrator.
		Identification and assessment of eligible patients through EHR.
ND4BB - COMBACTE	antibiotics	Will facilitate the creation of clinical investigator networks.
		Aims to develop new clinical study designs.
PREDICT-TB	tuberculosis	Aims to speed up the search and development for new, more effective combinations of treatments to tackle tuberculosis.
U-BIOPRED	asthma	Involving patients in clinical trial design and beyond.
PROactive	COPD	
EUPATI	E&T	

Project	Area	Results description
"Big Data" solutions to leverage knowledge		
OpenPHACTS	knowledge management	Integrated 7 pharmacological information sources into a modular platform to query and analyse the data (>450 M triples) and developed 4 example applications.
EMIF	knowledge management	Will build an integrated, efficient framework for consistent re-use and exploitation of currently available patient-level data to support novel research.
		Access to information on > 40 million patients.
eTRIKS	knowledge management	Building a Knowledge Management platform for collaborative KM for translational projects based on the open source TranSMART system.
		Development and adoption of translational information standards.
		Research & development of new analytics methods and tools.
DDMoRe	knowledge management	Developing various tools for model based drug discovery.
		Developing of clinical trial simulator tool – 2nd prototype delivered.

Project	Area	Results description
Education and Training for new generation R&D scientists		
EMTRAIN	E&T networking	Catalogued 4773 masters, PhD, CPD and short courses taught in 21 languages, from 39 countries, covering over 60 scientific, therapeutic and biomedical areas from about 1000 universities.
		Assembled extensive Continuing Professional Development (CPD) database of modules/courses recognised by professional bodies whose quality standards align with IMI's.
SafeSciMET	E&T in Safety Sciences	Successfully completed its first cycle of courses in 2012, with participants giving very positive feedback. More than 170 students participated (55% from EFPIA companies).
		Performed a gap analysis and identified and included new topics courses in particular 'Drug safety of stem cells and other novel therapeutics'.

Eu2P	E&T in pharmaco-vigilance and pharmaco-epidemiology	12 students are currently following the 2 year Master programme covering medicines risk identification and quantification, medicines and public health, medicine risk communication, assessing the benefits of medicines, and regulatory processes.
PHARMATRAIN	E&T in Pharmaceutical Medicine	Successfully launched the Cooperative European Medicines Development Course - a postgraduate qualification in medicines development that will provide students from Estonia, Hungary, Lithuania, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, and Turkey the very best teaching in the pharmaceutical field.
		317 students have been following various courses (49% from EFPIA companies).
		Signed Memoranda of Understanding (MoUs) with university of California and Peking.
EUPATI	E&T for patients in therapeutic innovation	Europe's first Patients' Academy on Therapeutic Innovation aiming to provide scientifically reliable information on medicines and R&D, as well as an online public library that will empower patients to engage more effectively in the development and approval of new treatments and become true partners in pharmaceutical R&D.

The above tables describes in detail many ground breaking results that are being delivered by IMI projects. Undoubtedly these will have an impact on the life of patients suffering from various diseases that are being studied. The advances that are made by IMI projects have a great potential to improve global healthcare and provide novel more effective treatments to patients faster.

- Already significant progress has been made to better understand the disease mechanisms in diabetes, lung disorders, autism, neuropsychiatric disorders, cancer and chronic pain.

- IMI researchers are developing tools that will accelerate the drug development process as well as reduce the time and cost of clinical trials to produce treatments that more precisely target each disease.

- Safety of medicines is another area of high importance and it is being tackled by multidisciplinary approaches such as:

  - development of safety markers that could be detected by a simple blood test;
  - computer modelling and predicting potential toxicity of compounds before considering them for drug candidates;
  - development of improved methods for monitoring of adverse effects of medicines that are already available to patients in order to catch problems early and prevent patients form suffering any serious complications.

Other benefits from IMI projects include tools that will result in replacement, reduction or refinement (3Rs) of animal use in drug development, as recognized by the Fund for the Replacement of Animal Research in Medical Experiments (Balls, M. (2012) ATLA 40: 295-300).

In addition, as underlined in a publication accepted for print in the journal of Nature Biotechnology by Susan Aldridge, the Chem21 IMI project is developing economical and environmentally friendly alternatives to traditional chemical synthesis.

As more IMI projects reach a mature phase, it becomes important to look at their relevance for regulators and at the business opportunities they are offering.

- Interactions with Regulators

Most IMI projects address questions in areas of emerging and innovative sciences and are intended to result in novel tools, methodologies and standards that can impact the R&D efficiency as well as the regulatory standards, guidance and practice for the benefit of public health.

The IMI JU is therefore taking initiatives to enhance interaction between Regulators and the consortia to ensure the translation of science into regulatory and clinical practice. In particular the Executive Office is raising awareness of how projects may interact with European Medicines Agency (EMA) and Food and Drug Administration (FDA). The Executive Office has identified projects of regulatory relevance to facilitate this on-going dialogue.

For instance, the project EU-AIMS has been instrumental in initiating the development of a guideline for the treatment of autism. In addition a number of projects have already taken steps to obtain advice on qualifying the tools, methodologies or standards resulting from the projects.

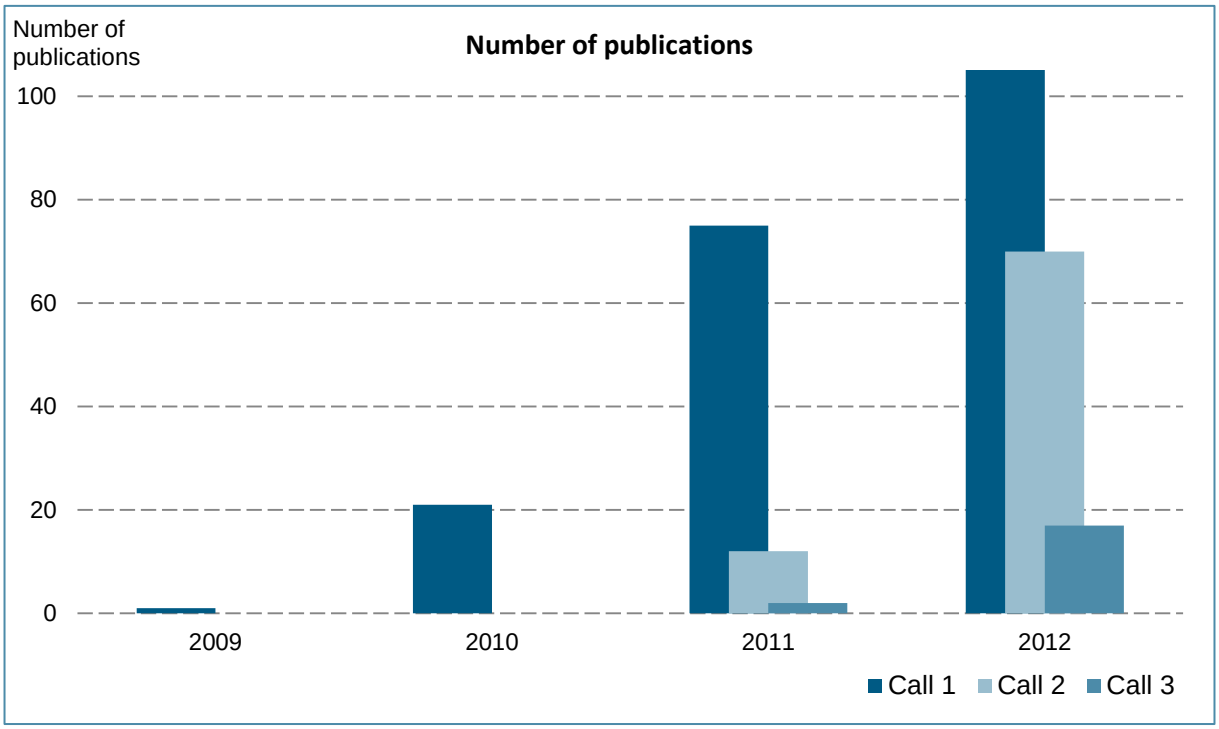
The value of IMI and the relevance of the outcomes from the projects are now well recognized by EMA. Representatives of the Agency participate in a number of IMI projects either as a participant (4 projects), coordinator (1 consortium - PROTECT), or as part of the Advisory Board (more than 10 projects). In addition, as referred in the EMA's Work Programme 2013, specific objectives concerning IMI have been included related to facilitating biomarker development, strengthening the research supporting safety monitoring as well as other novel approaches.

- Business opportunities

In order to identify potential opportunities for future commercial exploitation of the project results, a dedicated study has been launched in collaboration with the KU Leuven Research Centre for Pharmaceutical Care and Pharmaco-economics, including a value gap analysis.

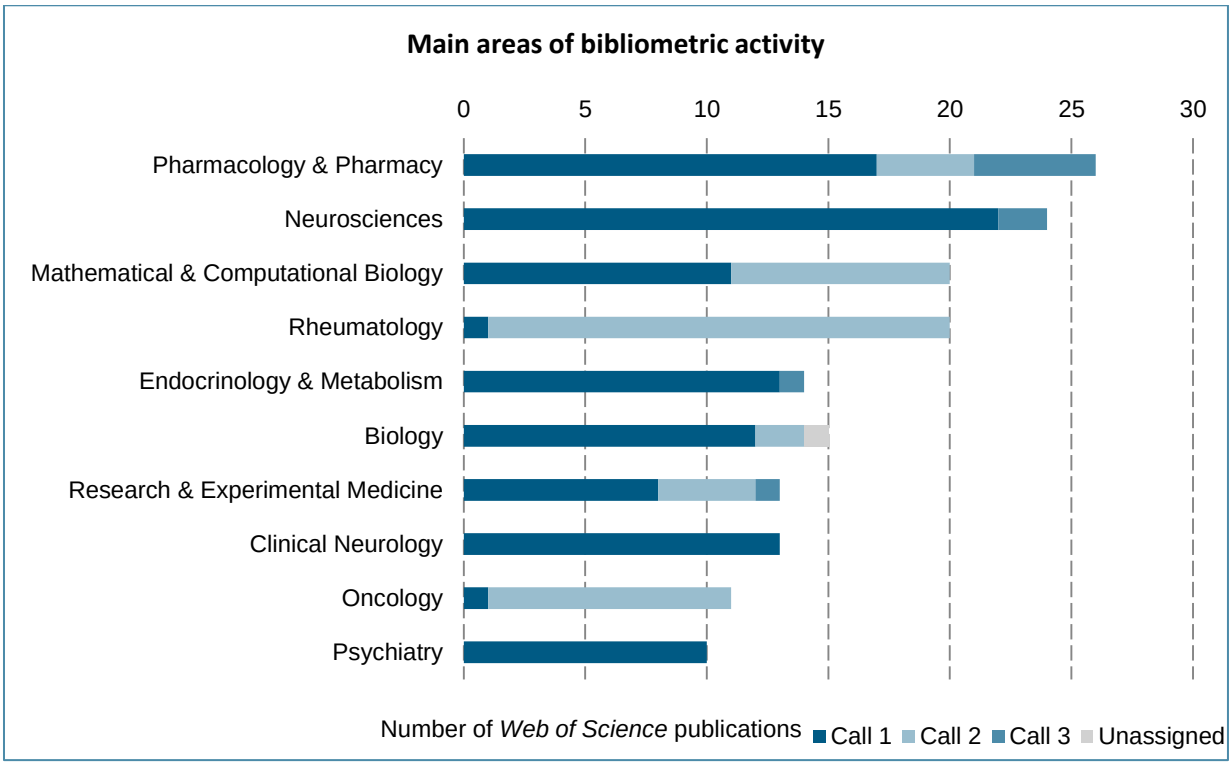
2.2 Bibliometric Analysis

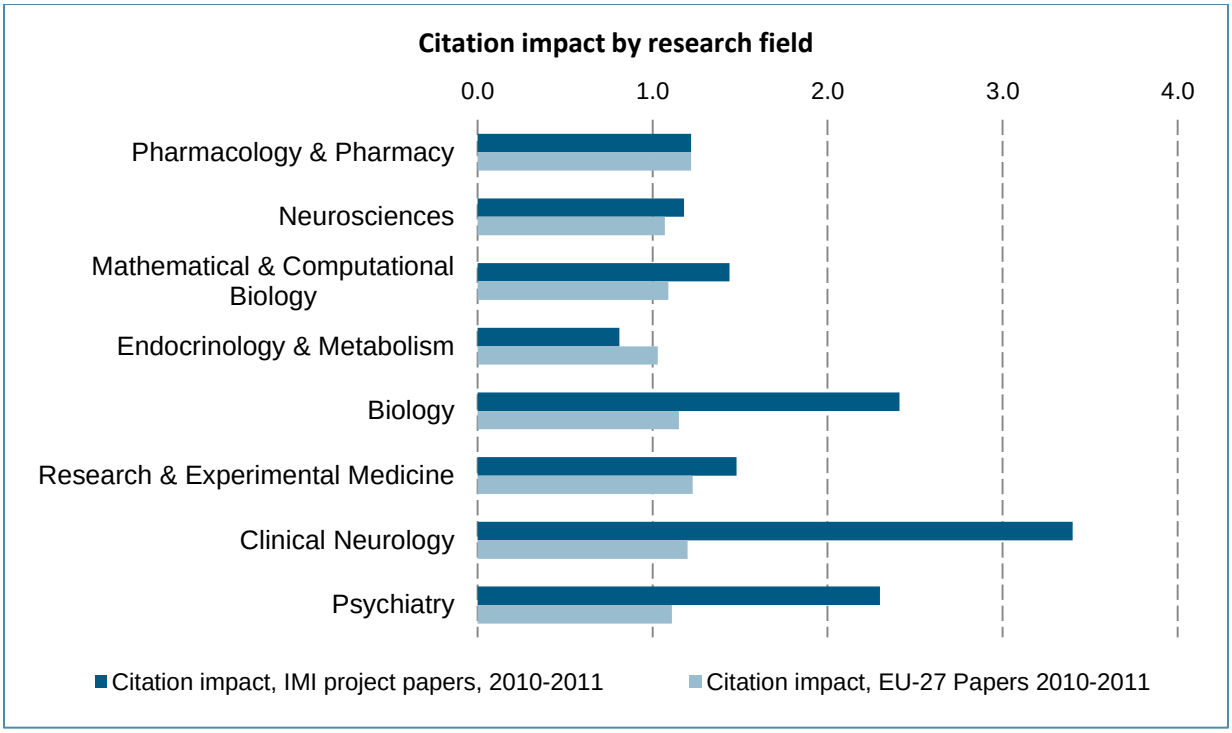
The bibliometric analysis of IMI projects was conducted with the assistance of a contractor and the first report delivered in October 2012. By the end of January 2013, a total of 320 publications resulting from IMI projects were identified. Publication output has increased each year since 2009 with a substantial increase between 2010 and 2011. In 2012, the publication output more than doubled the number identified for 2011. It is expected that publication output will continue to grow non-linearly as the number of funded projects increases and those projects yield results for publication.



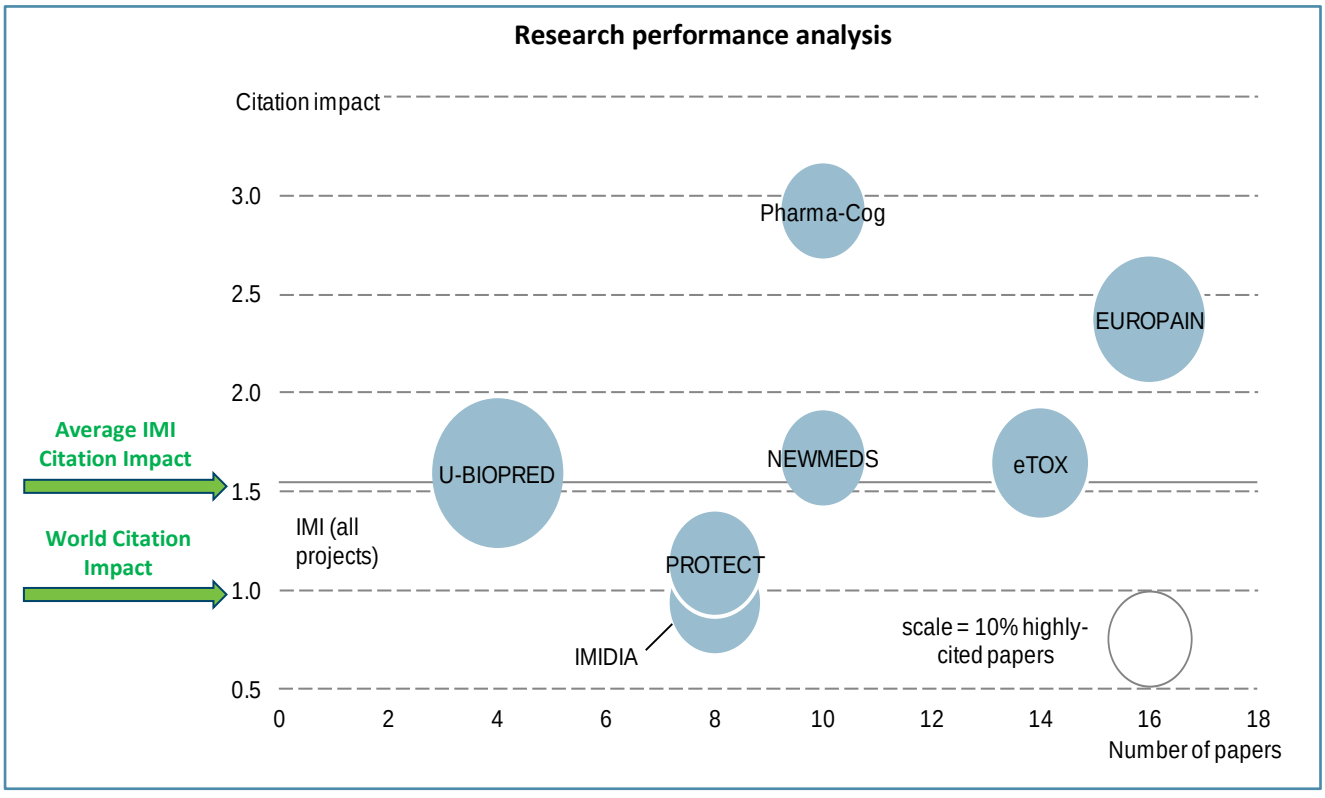
- IMI project publications have been published in a total of 119 journals to date, of which 95 are ranked in the top quartile of journals (by Journal Impact Factor) in their specific research fields. 82.7% of IMI project publications have been published in these well-regarded journals, including Nature, JAMA, PNAS and Nature Genetics. Almost one-tenth (9.5%) of IMI project research is assigned to the journal category of Pharmacology & Pharmacy which has overtaken Neurosciences (8.4%) as the most frequently used journal category in this dataset. Output in Mathematics & Computational Biology has expanded and is associated with eTOX and OpenPHACTS publications. Output in Rheumatology is mostly associated with BTCure project which has been quick to publish in scientific journals. Among the other journal categories, output is more evenly spread.

- The average citation impact for IMI project research is 1.55 for the 2-year period, 2010-2011, where world average is 1.0. For comparison, the EU's average citation impact relative to world baseline for the same 2-year period in similar research fields was 1.14. IMI project research published in Biology, Clinical Neurology and Psychiatry journals is exceptionally well-cited with average citation impact well above the European and world benchmarks. This performance is driven by multiple highly-cited papers, as well as publications identified as a 'hot papers' in the Thomson Reuters databases.


Main areas of bibliometric activity
0
5
10
15
20
25
30
Pharmacology & Pharmacy
Neurosciences
Mathematical & Computational Biology
Rheumatology
Endocrinology & Metabolism
Biology
Research & Experimental Medicine
Clinical Neurology
Oncology
Psychiatry
Number of Web of Science publications
Call 1
Call 2
Call 3
Unassigned

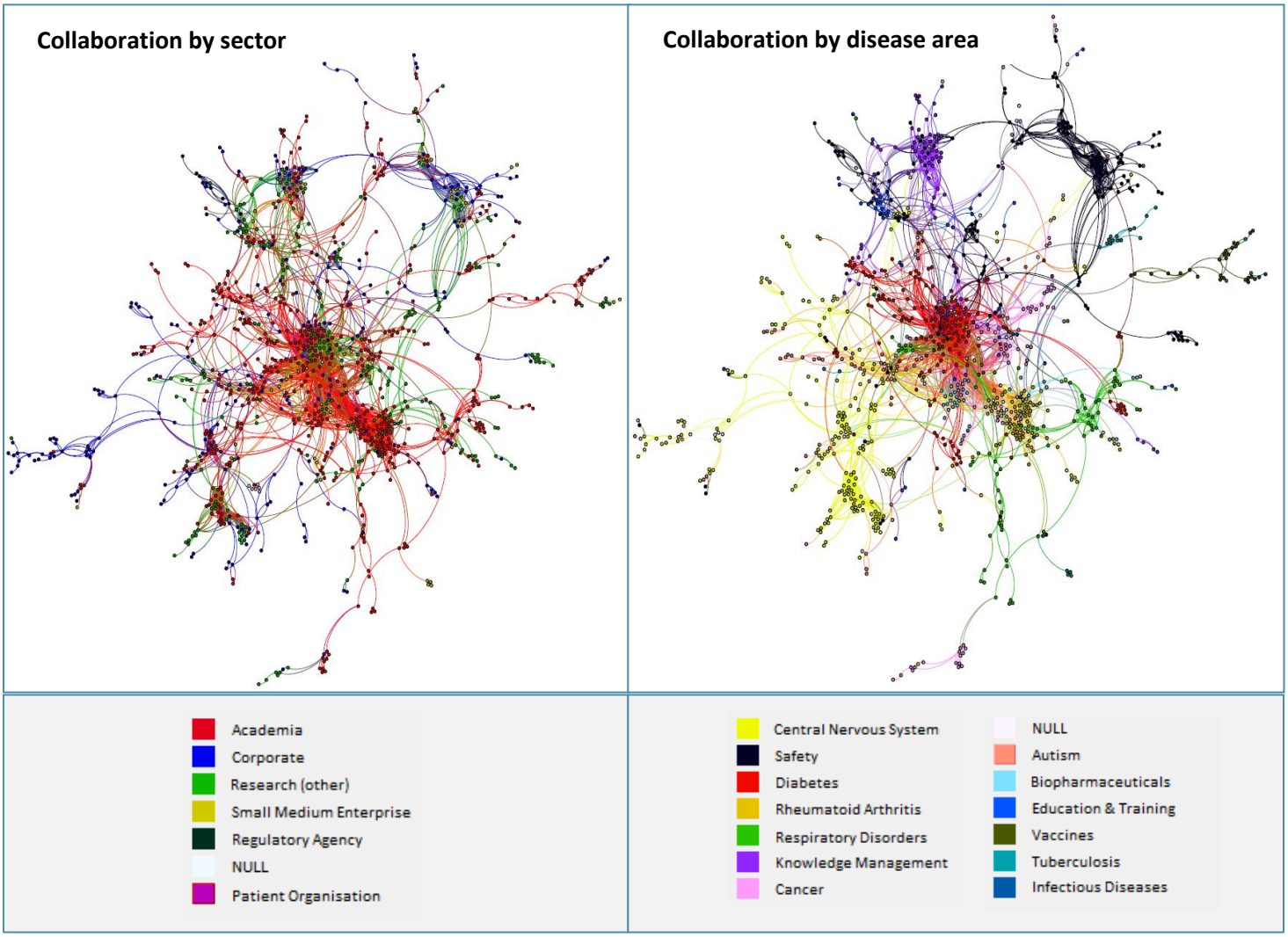

Citation impact by research field
0.0
1.0
2.0
3.0
4.0
Pharmacology & Pharmacy
Neurosciences
Mathematical & Computational Biology
Endocrinology & Metabolism
Biology
Research & Experimental Medicine
Clinical Neurology
Psychiatry
Citation impact, IMI project papers, 2010-2011
Citation impact, EU-27 Papers 2010-2011

- The productivity, research performance and collaboration of researchers funded by Call 1 IMI projects were assessed by analysing the total publication output of these individuals (not limited to publications acknowledging funding from IMI projects). 1470 researchers from Call 1 projects were included in the analysis and 9716 of their publications were identified for the period January 2007-August 2012.
- Analysis shows that publication output is, not surprisingly, higher for IMI-supported researchers based in academic institutions and research institutions compared to industry and SMEs. Researchers based in academic or in other research-active institutions also have the strongest research performance.
- Of the 385 publishing academic-based researchers, 23% of researchers have published at least one 'hot paper', 20% have an h-index of at least 10 and the majority have published most frequently in top quartile journals. The figure below presents a 'bubble-chart' visualisation of IMI project research for those call 1 projects with at least 4 papers over the time period (2010-2011).
- The number of papers, 2-year average citation impact and share of highly-cited papers are compared. The area of the 'bubble' is proportional to the share of highly-cited papers.
- The average citation impact of all but two of the projects is well above world citation impact (1.0) with the average citation impact of these projects (IMIDIA, PROTECT) approaching world average. Research associated with the Pharma-Cog and EUROPAIN projects is very well-cited with a mean citation impact almost twice the average for the dataset and well over twice world average. Two years after funding (in 2009) almost one-fifth (18.8%) of EUROPAIN papers are highly-cited.
- Though paper numbers are small, early indications are that eTox, NEWMEDS and U-BIOPRED are publishing well-cited research as they have already accumulated 2, 1 and 1 highly-cited papers respectively.



- Collaboration analysis was performed on the basis of co-authorship between IMI supported researchers as well as between co-authors. For this purpose 3477 individual researchers participating to the IMI projects from call 1-3 were identified. 1813 researchers have published documents that were indexed in the Web of Science and about three quarters of these researchers collaborated (co-authored) with at least one other IMI researcher during the period January 2007-January 2013.
- The patterns and the frequency of those collaborative activities are shown in the following figures where each individual is represented as a single node coloured with respect to the sector of their organization (left pane) or according to the disease in which their project is active (right pane). Lines between researchers are instances where the co-authorship has occurred in a published work. The distance between the nodes correlates to the frequency of co-authorship.

- As expected, co-authorship is more common among researchers in the same sector than among researchers in different sectors.
- However, there are also substantial co-authorship activities among researchers from different sectors, accounting for 36% of all co-authorship activities during the IMI lifetime so far.

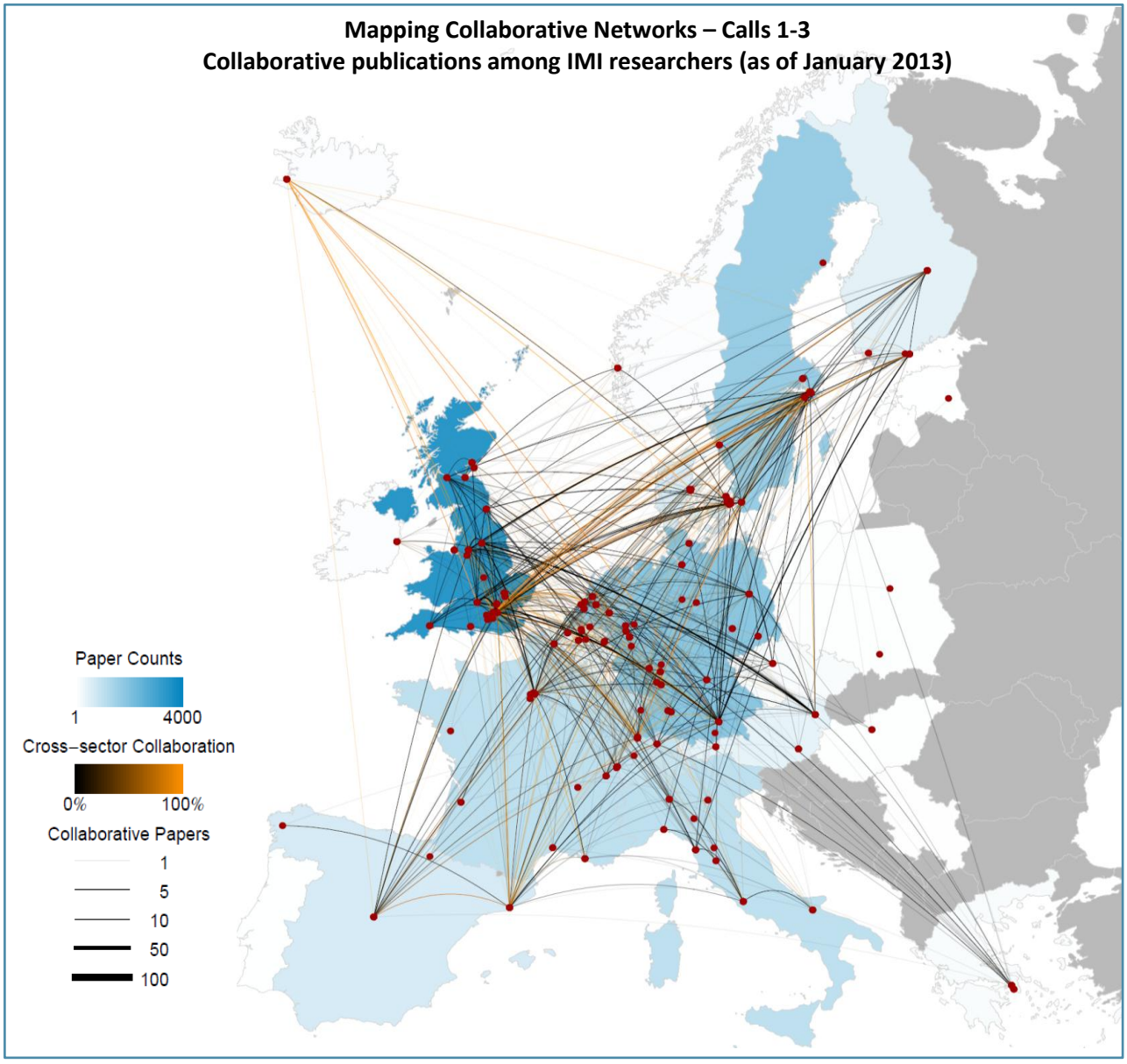


IMI facilitates widespread collaborations between researchers involved in IMI projects. This could be illustrated by mapping collaborative networks in the figure below where collaborative publications among IMI researchers have been mapped across Europe. The data covers all IMI participants in Europe from calls 1-3 and includes more than 17,000 publications published since 2008 by those researchers.

The map visualises:

- The total number of publications from each partner country. Maps are shaded from white to dark blue according to the output. Countries with no contributing output are shaded in grey.
- The frequency of collaboration between affiliations. Lines connecting countries or cities indicate co-authorship with thicker lines indicating a higher number of co-authored papers.
- Visualization of cross-sector nature of the collaborations. If both collaborating partners are from the same sector, the line is black; if they are from different sectors, the line is orange. As the data are aggregated, either by country or by city, the proportion of cross-sector collaborations will therefore vary between these two extremes.

It should be noted that this map focuses on within-Europe collaboration and that some papers may also have authors based outside this region, e.g. USA or China.



2.3 Stakeholders

The involvement of Small and Medium Enterprises (SMEs) in IMI projects is one of the priorities of IMI. Therefore efforts are being made to enhance their participation.

These efforts have focused on increasing the profile of IMI within the sector and communicating the benefits of project participation to SMEs. This has taken the form of direct engagement with SMEs by IMI staff presenting at SME-orientated meeting such as BioFocus Lille 2012; face-to-face meetings with umbrella organisations such as European biotechnology network (EBN) and European Biopharmaceutical Enterprises (EBE) and promoting SME involvement by highlighting the success of SMEs in on-going IMI projects.

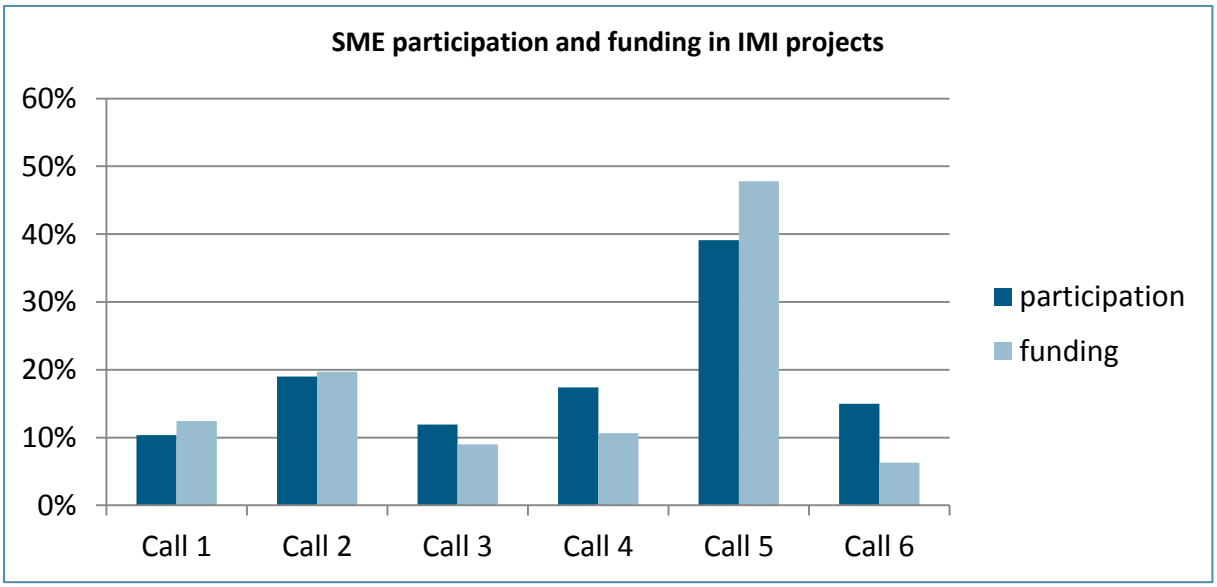
The table and figures below details SME involvement in IMI projects for which grant agreements were signed up to the end of 2012.

In summary, SMEs receive a total of 18.9% of IMI funding (13% in 2011) and represent 16.1% of total IMI participation (13% in 2011).

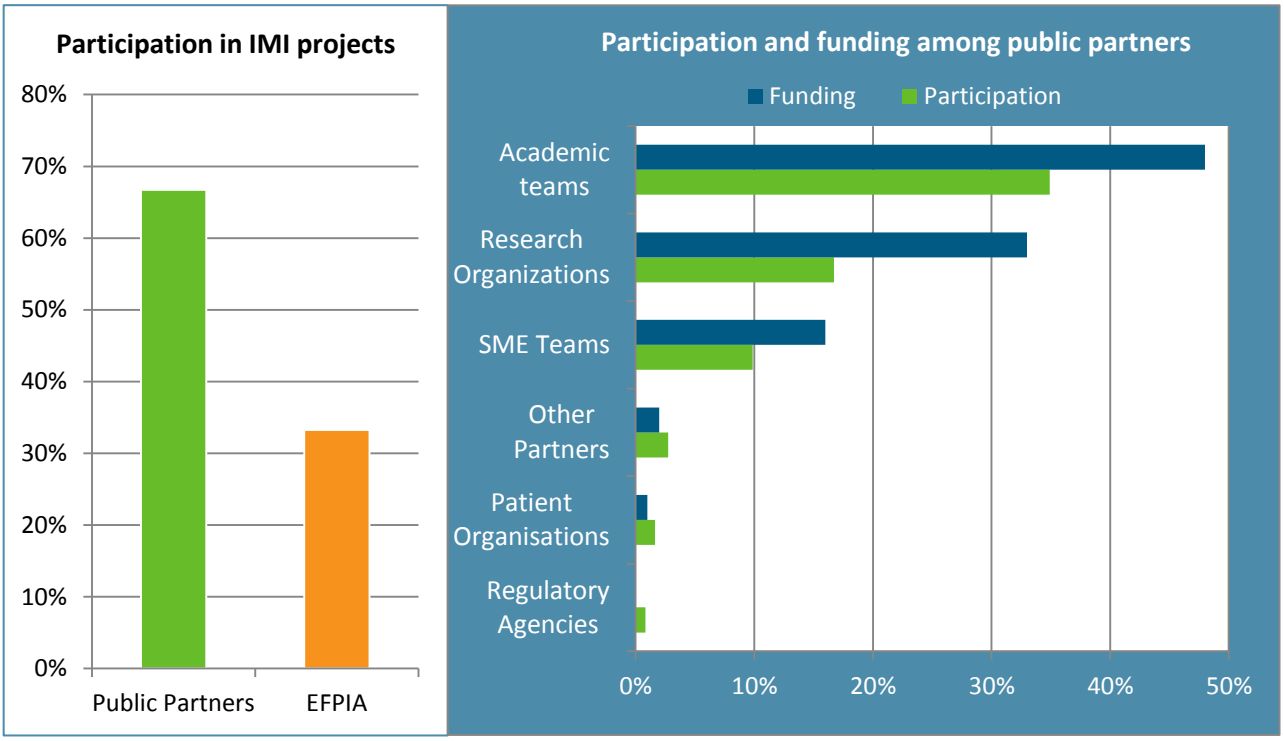
IMI Grant Agreements signed

Total IMI contribution	€496,851,540
Total SME funding	€93,711,345
% SME	18.9%
Total SME participation	112
% SME	16.1%
Unique SMEs	98
% unique SME	14.1%

The following graph sets out SME participation per Call:



The status of participation in IMI's 39 running projects at the end of December 2012 is set out in the table below:



The IMI JU contribution in projects from Calls 1 to 6 is distributed as follows:

Budget beneficiaries in IMI projects – per Call

Budget IMI beneficiaries (million EUR)	Call 1	Call 2	Call 3	Call 4	Call 5	Call 6	Total
Number of Projects	15	8	7	7	1	2	40
Academic	57.5	41.0	70.6	70.2	19.0	19.4	277.7
Research Organisations	32.3	22.2	24.2	16.8	5.6	72.9	174.0
SMEs	13.9	15.9	10.1	10.4	55.4	6.2	111.9
Patient's Organisations	1.1	0	2.6	0.3	0	0	4.0
Regulatory Agencies	2.3	0	0	0	0	0	2.3
Other Partners	3.3	1.6	4.3	0.2	0	0.5	9.9

IMI JU and EFPIA in-kind contribution – per Call

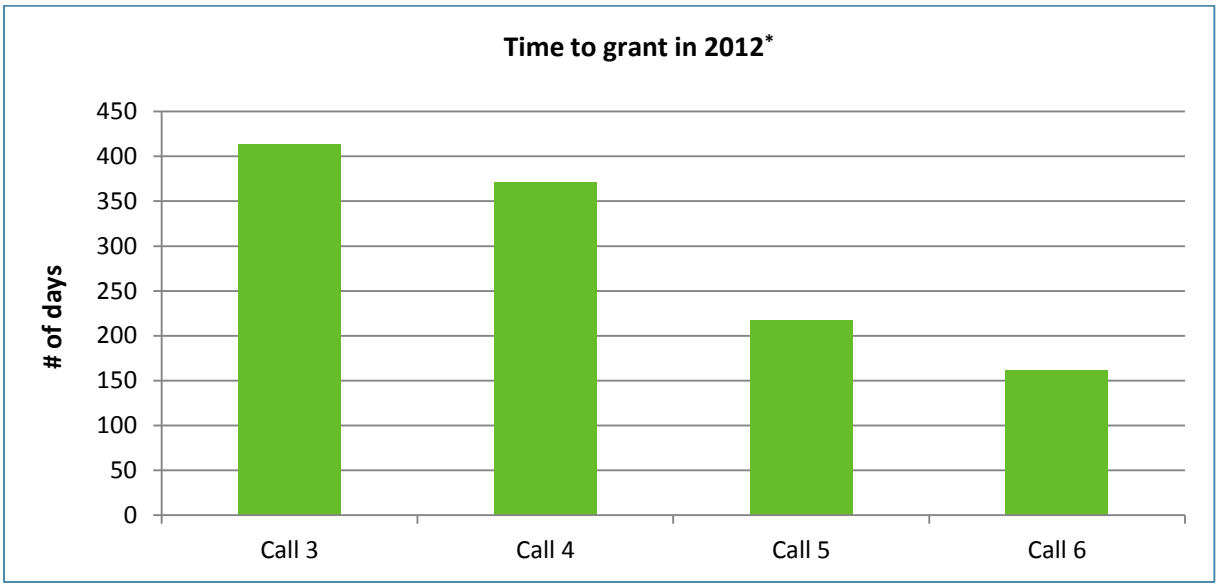
The following table shows the IMI JU contribution and the EFPIA in-kind contribution per Call. For Call 7 and Call 8, the amounts are estimates for the time being, and will be finalized once the evaluation process is completed.

million EUR	Call 1	Call 2	Call 3	Call 4	Call 5	Call 6	Call 7*	Call 8*	Total
IMI JU Contribution	110.4	80.7	111.8	97.9	80.0	99.0	13.0	143.3	736.1
EFPIA in-Kind Contribution	138.8	68.1	69.6	106.9	91.3	112.5	14.0	99.4	700.6

*estimated amounts

2.4 Internal business processes

As a result of the simplification exercise and the associated process streamlining, IMI's time to grant record has improved. The following table shows 2012 achievements per Call. Time line calculation goes from the deadline for submission of Expressions of Interest (EoIs) until Grant Agreement signature.



*includes two Call 3 projects with Grant Agreements signed in 2012; the seven Call 4 projects, Call 5 project and one Call 6 project.

The following figure sets out the break down per transaction type and enables a comparison with the two previous years. Details about Time to pay are set out in the following graphs:

Operational costs

Budget year	Number of payments	Average time of report submission after the end of the reporting period* (days)	Average suspension period** (days)	Average time to pay (days)	Average processing time (days)	Payment on time %	Late payment %
2010	1	84	87	66	237	100	0
2011	16	88	62	54	205	94	6
2012	26	76	65	60	201	96	4

*including 60 contractual days for submission

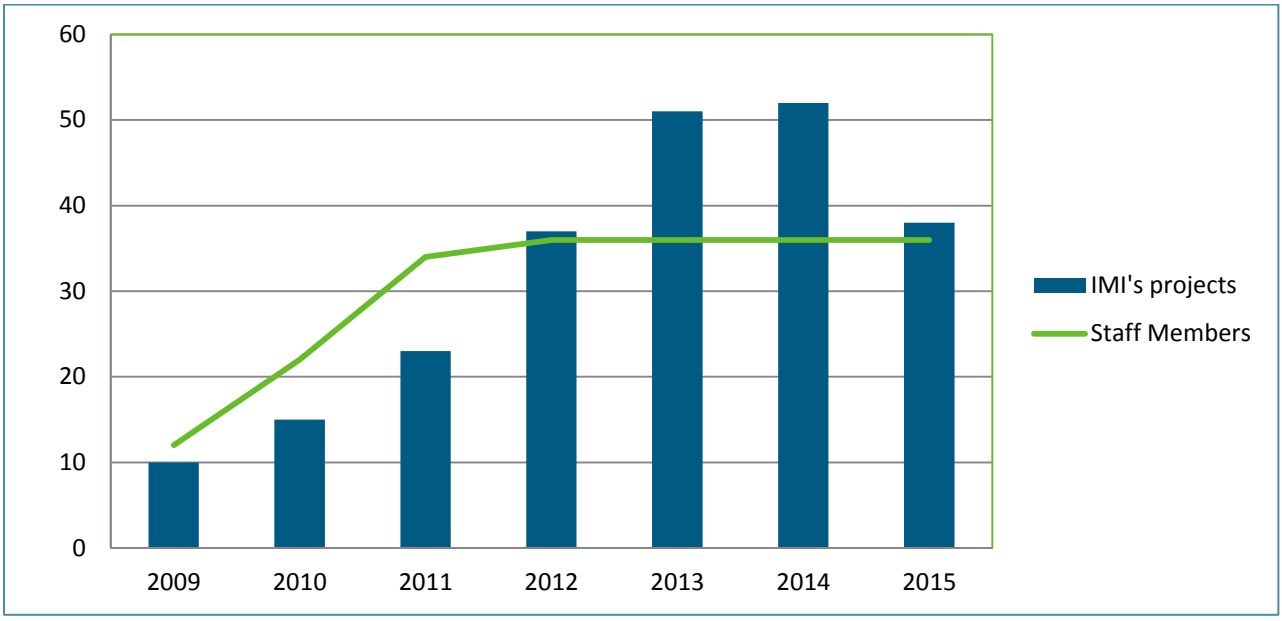
** Suspension time refers to those periods when one or more of the reports or appropriate deliverables have not been supplied, or are not complete or if some clarifications or additional information is needed or there are doubts concerning the eligibility of costs claimed in the financial statement and/or additional checks are being conducted. The suspension is lifted from the date when the last report, deliverable or the additional information requested is received by the IMI JU, or where the IMI JU decides to proceed with an interim payment in part in accordance with Article II.5.4 of the Grant Agreement.

Running costs

Maximum payment time limit	Payment on time %		Late payment %		Average time to pay (days)	
Year	2011	2012	2011	2012	2011	2012
30 days	51	85	49	15	39	17
45 days	60	90	40	10	44	23
60 days	71	84	29	16	47	25

The analysis of these data can be found in sections 6.1 and 7.2.

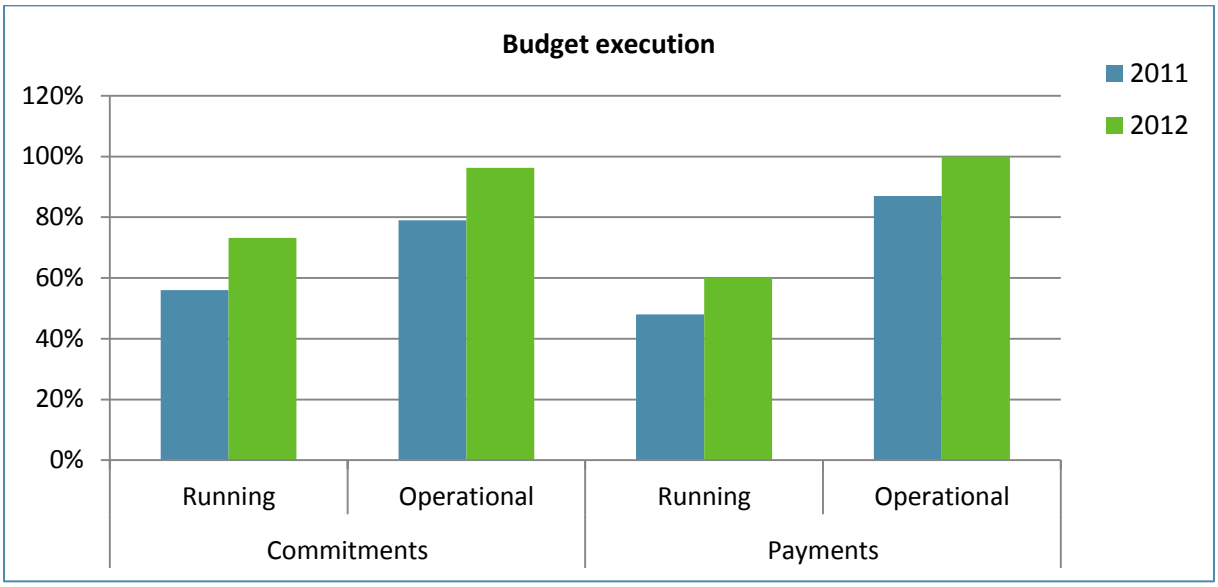
IMI Executive is now fully staffed, enabling it to carry out its activities and tasks and be prepared for a forthcoming fast growing workload. The graph below shows IMI's staffing level and workload evolution between 2009 and 2015.



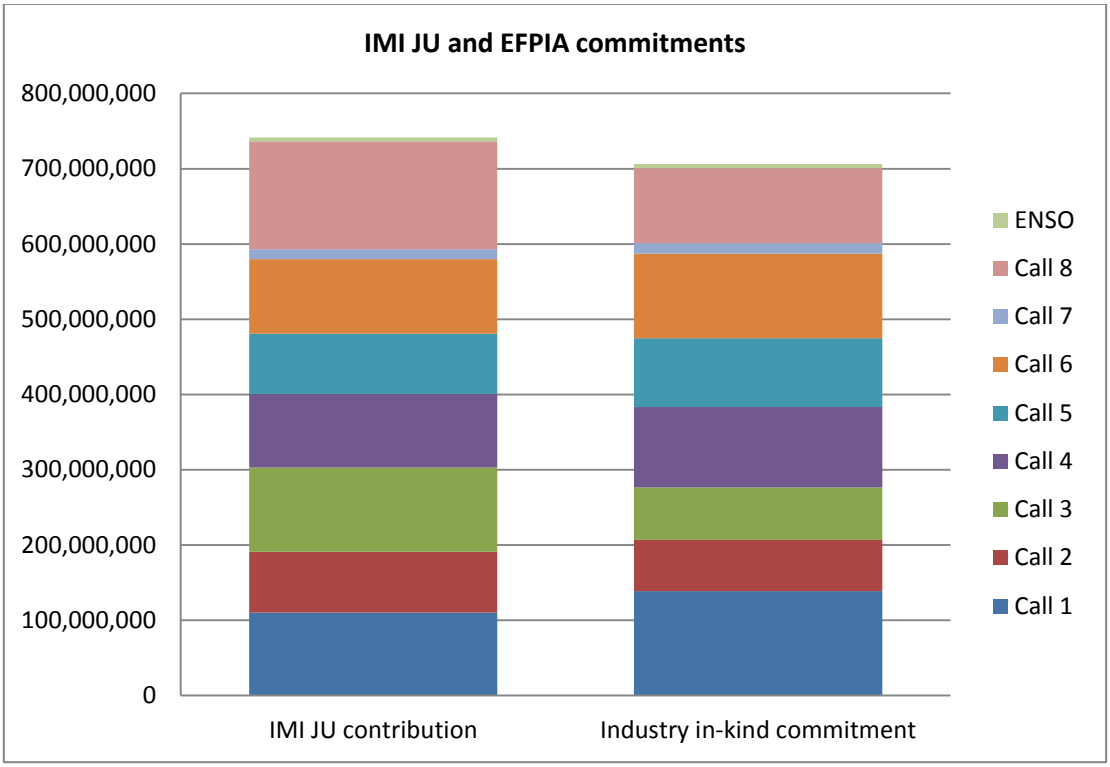
2.5 Financial perspectives

2012 marked a significant progress in the execution of the programme, with almost half of the total envelope committed.

The table below summarises the results of 2012 compared to 2011. Details can be found in sections 6.1 and 7.2.



The total financial commitment of IMI founding members is set out on a 'per Call' basis, below:



3. MANAGEMENT OF ON-GOING PROJECTS

3.1 Interim Reviews for Call 1 and Call 2 projects

In 2012, IMI JU conducted 14 project interim reviews: 13 projects from Call 1, and 1 project from Call 2 as shown in the table below.

	IMI Project Acronym	Project full name Interim Review	Interim Review date
Call 1	MARCAR	Biomarkers and molecular tumour classification for non-genotoxic carcinogenesis	21/11/2011
	SAFE-T	Safer and Faster Evidence-based Translation	29/11/2011
	PROTECT	Pharmacoepidemiological research on outcomes of therapeutics by a European consortium	12/03/2012
	PROactive	Physical Activity as a Crucial Patient Reported Outcome in COPD	15/03/2012
	U-BIOPRED	Unbiased biomarkers for the prediction of respiratory disease outcomes	16/03/2012
	Pharmatrain	Pharmaceutical Medicine Training Programme	05/04/2012
	EMTRAIN	European Medicines Research Training Network	25/04/2012
	EUROPAIN	Understanding chronic pain and improving its treatment	03/05/2012
	Pharma-Cog	Prediction of cognitive properties of new drug candidates For neurodegenerative diseases in early clinical development	11/05/2012
	Eu2P	European programme in Pharmacovigilance and Pharmacoepidemiology	22/05/2012
	SUMMIT	Surrogate markers for micro- and macro-vascular hard endpoints for innovative diabetes tools	24/05/2012
	NEWMEDS	Novel methods leading to new medications in depression and schizophrenia	29/05/2012
	SafeSciMET	European Modular Education and Training Programme in Safety Sciences for Medicines	13/06/2012
	eTOX	Integrating bioinformatics and chemoinformatics approaches for the development of Expert systems allowing the in silico prediction of toxicities	15/06/2012
	IMIDIA	Improving beta-cell function and identification of diagnostic biomarkers For treatment monitoring in diabetes	18/06/2012
Call 2	Open PHACTS	The Open Pharmacological Concepts Triple Store	23/11/2012

- The expert reviewer panel consisted of 3 experts: one from Scientific Committee, one from the original full project proposal evaluation panel, and one selected from the suggestions provided by the consortium. The reviewers were satisfied with the progress achieved. The consortia have completed the majority of the set milestones and are now in progress for the final, critical steps of the projects such as clinical studies and validation studies. In most cases the reviewers had some recommendations aimed at ensuring progress towards tangible achievements delivery by the end of the funding period.

- Those recommendations were shared with the consortia and they are in the process of responding to them by proposing necessary action and/or amending the work planned for the remainder of the project lifetime.

3.2 Cross projects meetings and collaborations

In 2012 IMI initiated important cross projects interactions and collaborations in 3 key IMI activity areas: Diabetes, Oncology and Education & Training.

Diabetes

IMI portfolio includes three projects working on diabetes: Call 1 SUMMIT and IMIDIA started respectively in late 2009 and beginning of 2010, and Call 3 DIRECT started at the very beginning of 2012. The three projects have a combined budget of over €100 million. IMIDIA focuses on studying the pancreatic beta cells to develop new therapeutic strategies while SUMMIT's work addresses the vascular, renal and ocular complications of diabetes. Finally, DIRECT takes a personalised medicine approach to diabetes. The projects already worked together on an informal basis, and in 2012 took their collaboration to a new level with the signature of a Memorandum of Understanding (MoU) that covers the transfer of knowledge and materials and the handling of intellectual property. It is planned that the collaboration agreement will also be extended to DIRECT.

- With the support of the IMI Executive Office the three projects have produced a joint leaflet on the IMI diabetes platform.

Oncology

- The IMI portfolio includes three projects focusing on Oncology, generated from the 2010 IMI Call 2 and started during 2011:

  - PREDECT: New Models for Preclinical Evaluation of Drug Efficacy in Common Solid Tumours.
  - ONCOTRACK: Methods for systematic next generation oncology biomarker development.
  - QuIC-ConCePT: Quantitative Imaging in Cancer: Connecting Cellular processes with Therapy.

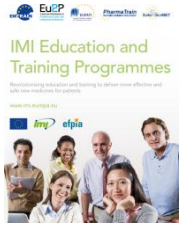
- On 19 September 2012, IMI's oncology projects gathered in Brussels for their first cross-project meeting. The consortia discussed project achievements, addressed major challenges, and explored synergies. Possible cross-project activities identified at the meeting included:

  - whether a combination molecular analysis and imaging biomarkers can predict colorectal cancer;
  - exploiting the outcomes of the projects to create a prototype European patients screening platform - to investigate with the IMI project EMIF and EMA;
  - a meta-analysis of trial data from failed drugs with a common pharmacological mode of action;
  - better engagement with patients – to explore with the IMI project EUPATI.

- It was agreed among the projects that at least some of these issues might be relevant to a cross project ENSO application.

- In addition, on 5 November IMI organised a teleconference at the request of the EFPIA Research Directors Group where the 3 Oncology projects presented an update of results obtained.

Education and Training



A cross project meeting of the 5 IMI Education & Training projects was organised in June at the IMI's office in Brussels. The aim of the meeting was to help the five E&T projects to identify additional synergies and common issues and to explore possible solutions. Important aspects like cross-project communication, cross-project quality standards, and best practices were addressed as well as identifying potential gaps. A major common concern remains the sustainability of the schemes after the lifetime of the projects. In this context, the option was discussed to apply jointly to the 'Explore New Scientific Opportunities' (ENSO) Call. The Chair of the Scientific Committee as well as one of the expert reviewers of the E&T project for the mid-term review attended the meeting and made recommendations following the IMI joint working meeting.

- In addition on 23 November IMI organised a teleconference at the request of the EFPIA Research Directors Group where the four Call 1 E&T consortia presented an update of results obtained focusing mainly on results of relevance to pharmaceutical companies.

- With IMI's support, the E&T Cross Project Communication Task force has produced a joint video introducing the four Call 1 E&T projects. A new cross project flyer has also been produced.

3.3 Knowledge Management

IMI portfolio of knowledge management projects

- The IMI portfolio includes five knowledge management projects, three Call 2 projects DDMORE, Open Phacts and EHR4CR were initiated in the first quarter of 2011, while the last two Call 4 EMIF and eTRIKS signed their grant agreement at the end of 2012.

- DDMORE had important achievements in the area of Model Based Drug Development by setting up a drug and disease model library now including 52 drug/disease models in the area of diabetes and oncology and developing a framework for Modeling & Simulation facilitating software to software interoperability of models and data.

- Open PHACTS addressed the difficulty in drug discovery research to accurately link data on bioactive molecules to their targets. Both projects have started informal interactions with other IMI projects (e.g. Call 4 K4DD) to provide support in their areas of expertise.

- Many IMI projects involve the integration of data from different sources, and until now every project has had to devise its own solutions to the problems raised by data sharing.

- eTRIKS aims to create and run an open, sustainable research informatics and analytics platform for use by IMI (and other) projects with knowledge management needs. In addition, the project partners will provide associated support, expertise and services to ensure users gain the maximum benefit from the platform. The project coordinator has invited several potential 'customer' projects to take part. U-BIOPRED was selected as the first project to be served by eTRIKS, and will act as a pilot for other IMI and non-IMI projects.

Knowledge Management workshop on CDISC standards

- Representatives of 14 IMI projects were given an overview of the 'latest in clinical data standards' during a workshop on CDISC (Clinical Data Interchange Standards Consortium) organised on 2 October 2012. On the basis of IMI's Memorandum of Understanding with CDISC, IMI project teams can benefit from CDISC's expertise and assistance in the development of new standards. During the workshop, participants were introduced to CDISC's many standards, designed to facilitate the harmonisation of clinical data and streamline research processes from the study plan, through analysis, to reporting. The standards also cover the use of electronic health records. In addition, CDISC has specific standards for certain therapeutic areas, such as pain and tuberculosis. Feedback indicated that the participants found the course useful and many are keen to have additional training on both the basic 'foundational' standards and the therapeutic area standards.

- Furthermore IMI participated on 24 October in the CDISC International Interchange (Baltimore, USA) stressing the importance of using Data Standards from the perspective of collaborative research.

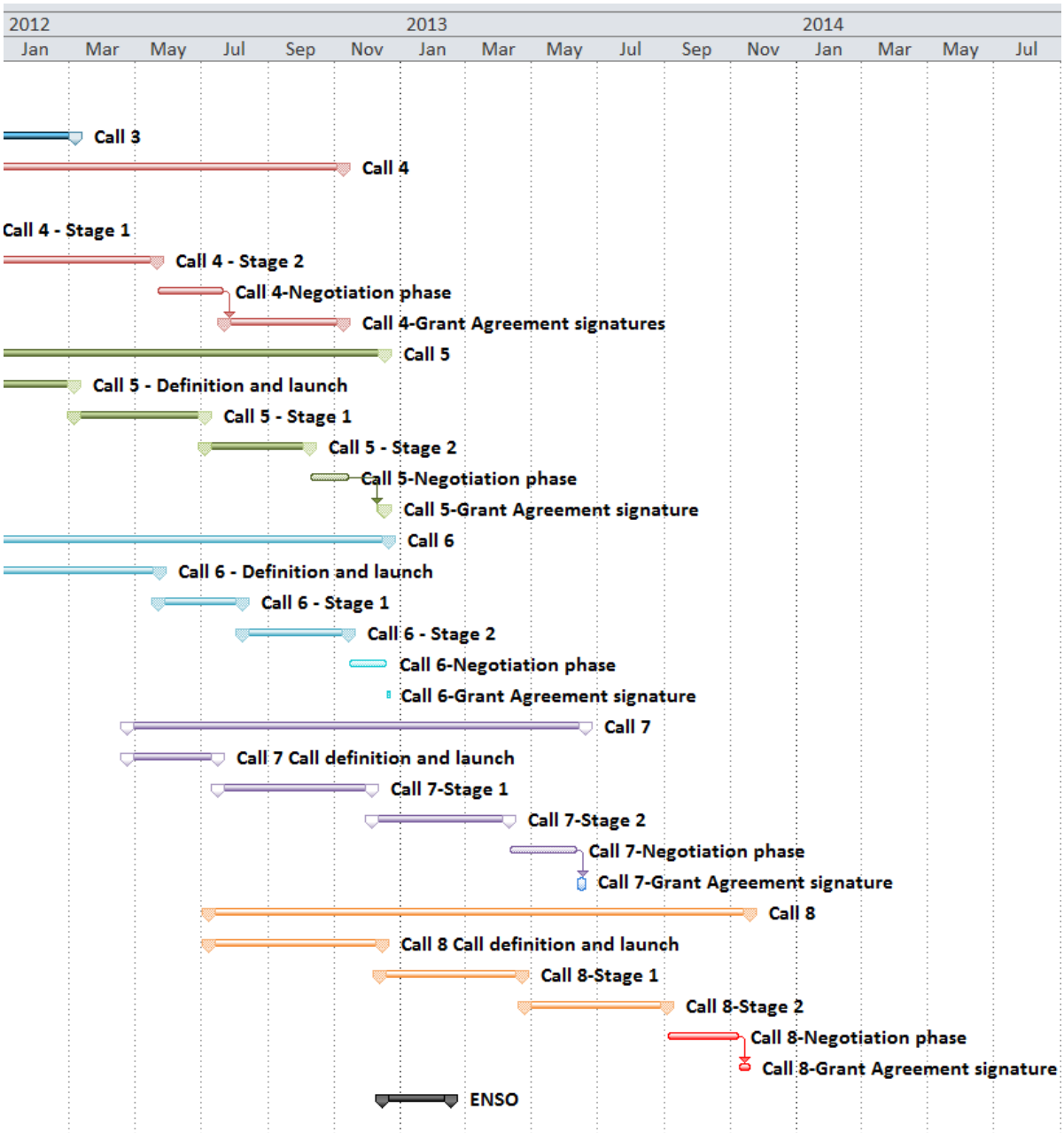
4. IMPLEMENTATION FROM 3rd CALL TO 6th CALL FOR PROPOSALS

- 2012 marked the full implementation of the new process of continuous Call launch, which is one of the key outcomes agreed by the Simplification Task Force created between IMI Executive Office, EFPIA and the European Commission (EC).

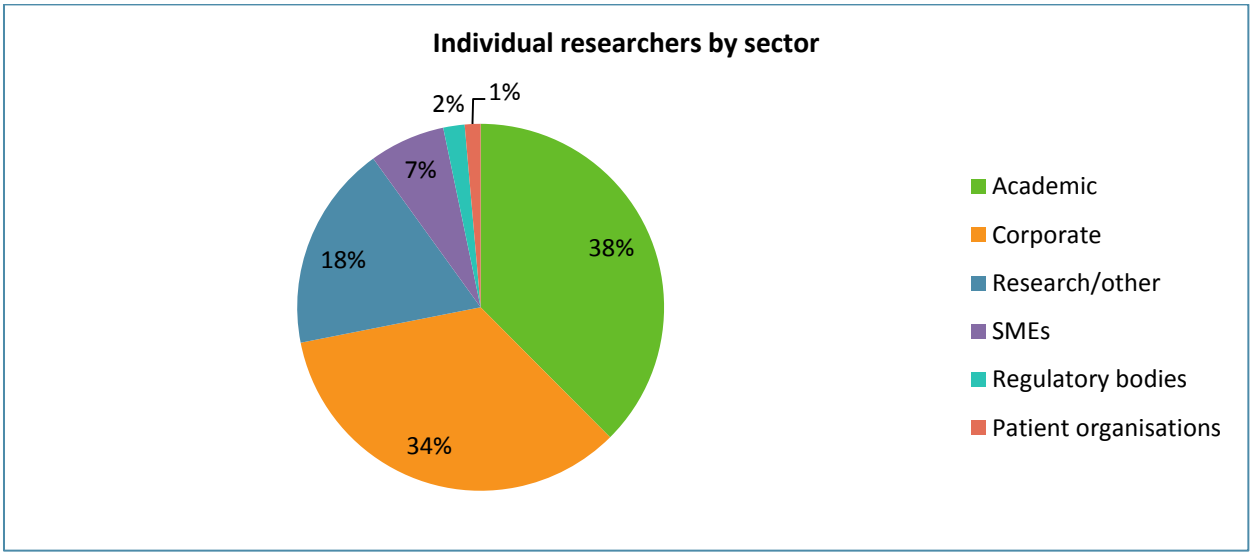
- In addition to the implementation of the final stages of Calls 3 and 4, five new Calls (Calls 5 to 8 and the ENSO Call) were launched in 2012.

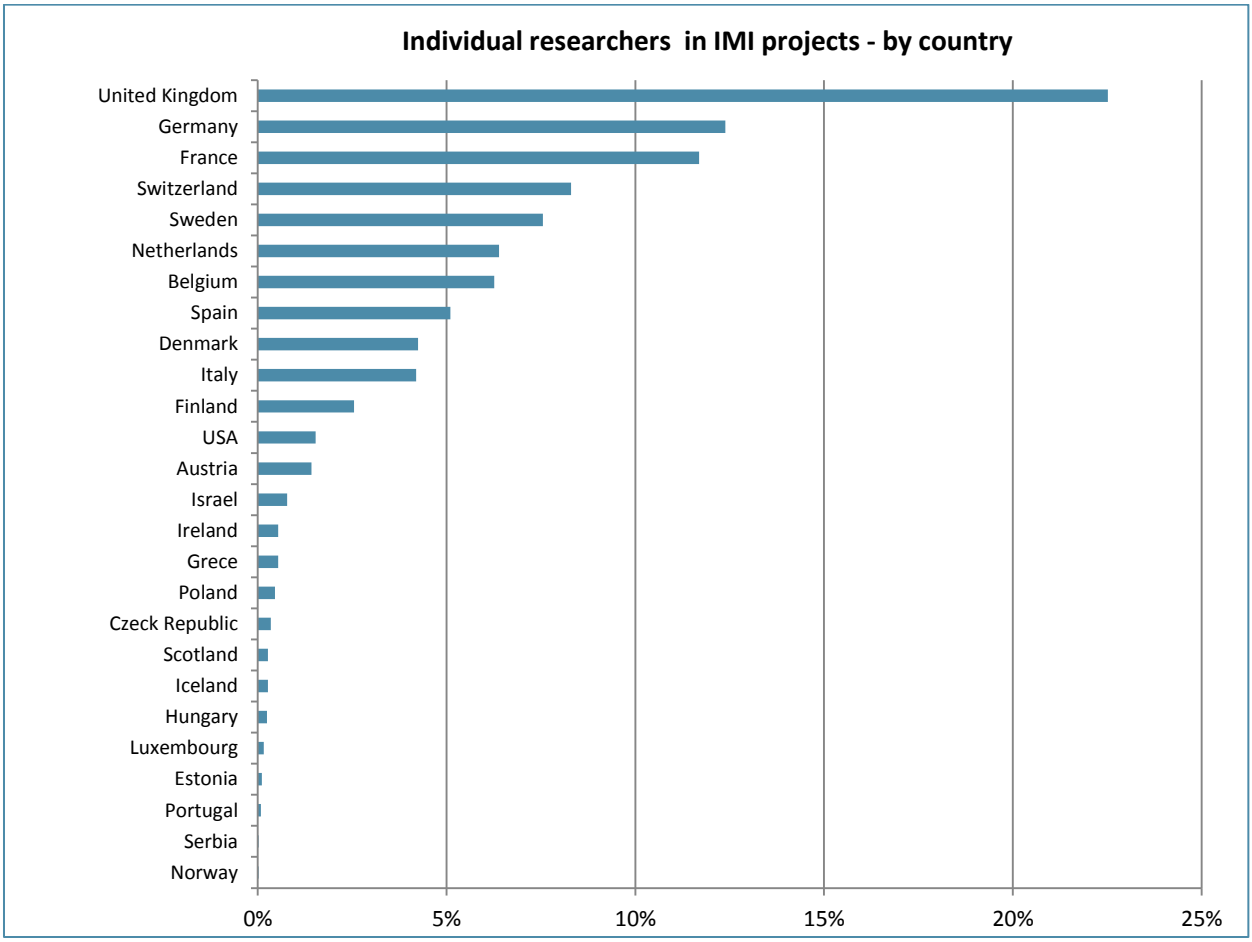
- The new streamlined Call process, including simplified forms and the improved SOFIA submission tool, was fully implemented from the 5th Call.

- These changes shortened the time needed from Call launch to project funding, and therefore allowed the full implementation (including Grant Agreement signature) of both Calls 5 and 6 within one year. An overview of these activities is displayed in the chart below (2012 – 2013).

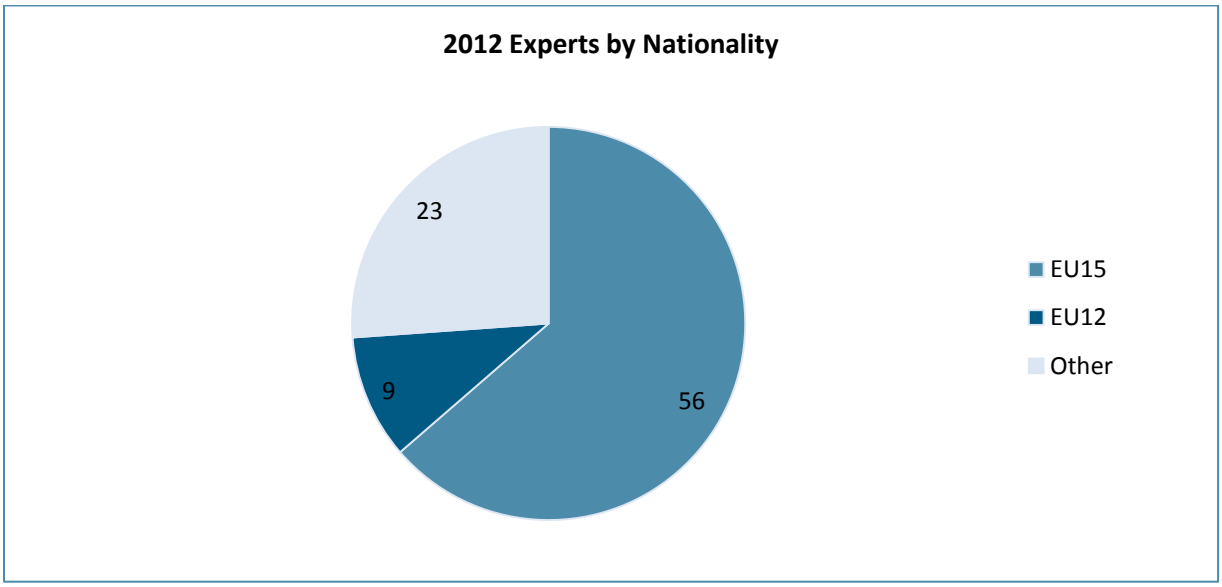


- The increase in work volume enables to provide a snapshot of number and type of scientists and experts involved in IMI.
- Based on the latest analysis the estimated number of scientists participating in IMI projects is approximately 4500, among which 34% are with EFPIA companies. The breakdown of individual researchers by the sector they belong to is shown in figure below. In addition the distribution of the researchers by country is shown in the following figure.
- The data for this analysis was collected from project coordinators when possible, alternatively from Description of Work documents, project web sites, presentations or progress reports.





With respect to experts involved in the review of proposals submitted in response to Call 4, 5 and 6 the majority originated from Europe[1].



4.1 Implementation of 3rd Call for Proposals

The final two grant agreements for Call 3 were signed in early 2012. This enabled the IMI to proceed with pre-financing payments of EUR 10.5 million.

The 3rd Call projects in 2012 – Budget in Euro

IMI Project	EFPIA + IMI Funding	EFPIA Funding	IMI Funding	SME	Academic	Research	Patient Org.	Other
EU-AIMS	29,005,838	9,538,634	19,467,204	2,024,304	13,910,567	3,532,333		
ABIRISK	27,528,310	9,358,093	18,170,217	891,852	7,177,058	9,552,317	283,670	265,320
BioVacSafe	25,005,599	7,579,933	17,425,666	2,377,372	11,802,276	2,725,215		520,803
DIRECT	37,861,388	16,472,745	21,388,643		17,098,122	4,290,521		
EUPATI	10,006.112	4,756,112	5,250,000		1,152,303	56,245	2,352,097	1,689,355
MIP-DILI	27,894,003	12,558,465	15,335,538	3,857,938	9,892,493	1,585,107		
PreDiCT-TB	24,075,012	9,296,156	14,778,856	915,860	9,895,999	2,167,534		1,799,463
TOTAL	181,376,262	69,560,138	111,816,124	10,067,326	70,928,818	23,909,272	2,635,767	4,274,941

All seven Call 3 projects kicked-off their research activities in early 2012.

[1] EU15: Belgium, Greece, Luxembourg, Denmark, Spain, The Netherlands, Germany, France, Portugal, Ireland, Italy, United Kingdom, Austria, Finland, Sweden.
EU12: Poland, Czech Republic, Cyprus, Latvia, Lithuania, Slovenia, Estonia, Slovakia, Hungary, Malta, Bulgaria, Romania.

4.2 Implementation of 4th Call for Proposals

The 4th Call for proposals, published on 18 July 2011, consisted of the following 7 topics:

Knowledge management

- Building a European Medical Information Framework (EMIF) of patient-level data to support a wide range of medical research. This Call theme consisted of 3 "sub-topics" to be merged into one final project.
  - 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 optimizing binding kinetics in drug discovery.
- Following the approval of the recommendations of the consensus panels by the Governing Board in 2011, the first-ranked EoIs were invited to prepare a Full Project Proposal with the pre-established EFPIA consortia. For EMIF the first-ranked EoIs of the three subtopics were invited to merge and prepare with a single FPP the pre-established EFPIA consortium.
- The evaluation of the resulting FPPs was conducted by the external experts; initially working remotely and then at a consensus panel meeting. All 7 Full Project Proposals were recommended for funding by IMI and approved by the Governing Board. Grant agreements were signed during 2012 for all 7 projects.

The seven 4th Call projects pre-financed in 2012 – in Euro

IMI Project	EFPIA + IMI Funding	EFPIA Funding	IMI Funding	SME	Academic	Research	Patient Org.	Other
CHEM21	23,387,655	13,558,017	9,829,638	988,039	7,324,932	1,516,667		
Compact	26,746,491	16,561,578	10,184,913	559,740	8,586,999	1,038,174		
K4DD	18,118,249	9,831,318	8,286,931	1,213,764	5,927,524	1,145,643		
OrBiTo	20,432,255	11,456,863	8,975,392	840,000	7,697,392	438,000		
EMIF	48,481,352	24,124,503	24,356,849	3,226,698	15,086,664	5,779,387	264,100	
StemBANCC	47,023,330	21,023,330	26,000,000	2,225,351	20,162,420	3.438,373		173,856
eTRIKS	20,645,996	10,336,178	10,309,818	1,385,280	5,440,264	3,484,274		
TOTAL	204,835,328	106,891,787	97,943,541	10,438,872	70,226,195	16,840,518	264,100	173,856

Six Call 4 projects kicked-off their research activities in 2012, with EMIF due to begin in early 2013 (Grant Agreement signed on 11 December 2012).

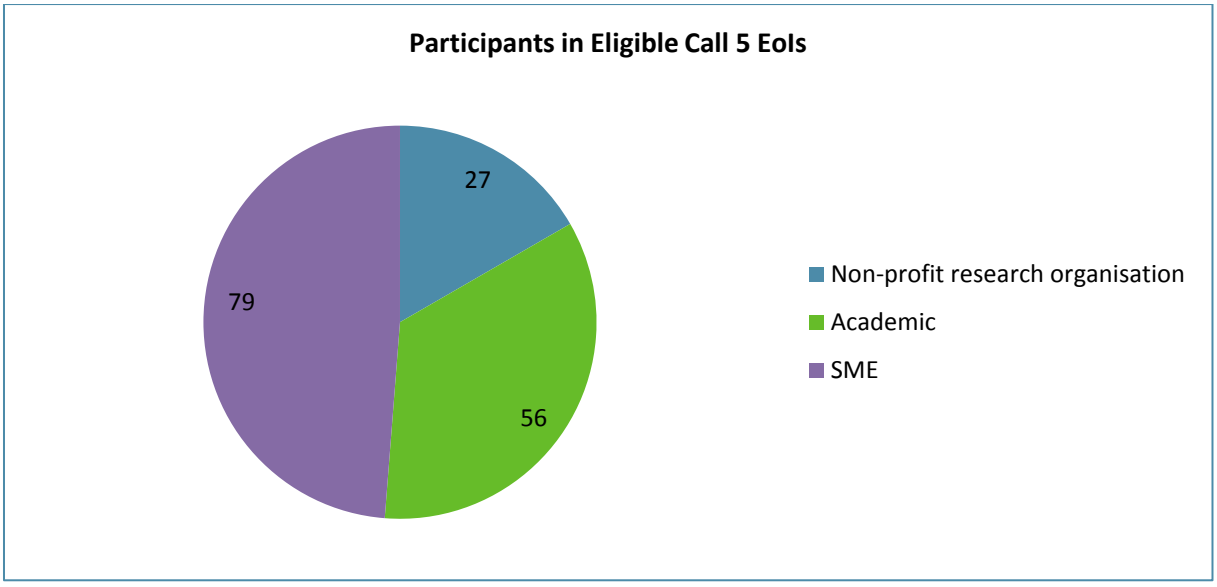
4.3 Implementation of 5th Call for Proposals

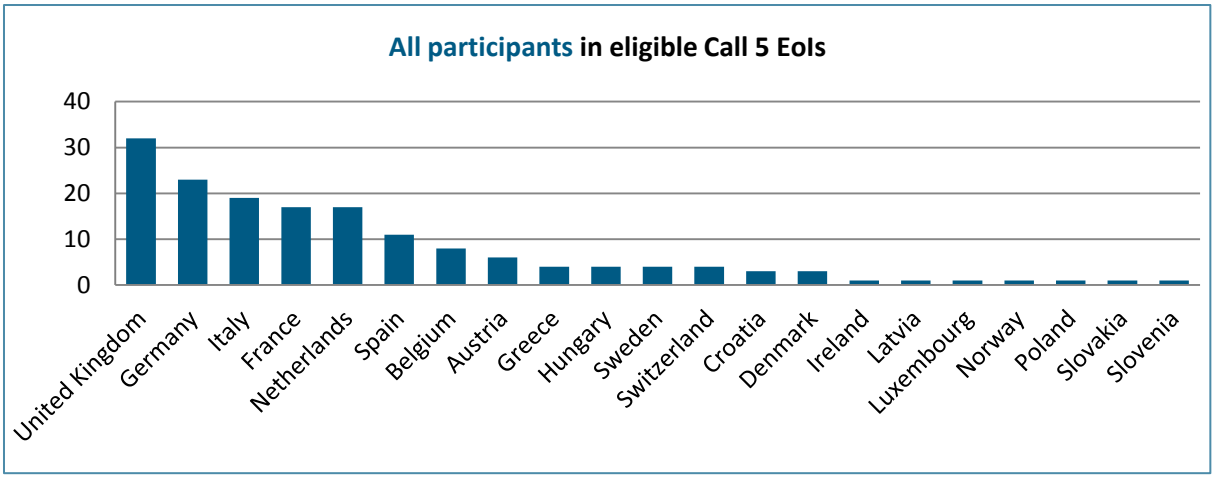
IMI's 5th Call theme, the creation of a European Lead Factory for drug discovery, comprised 2 topics:

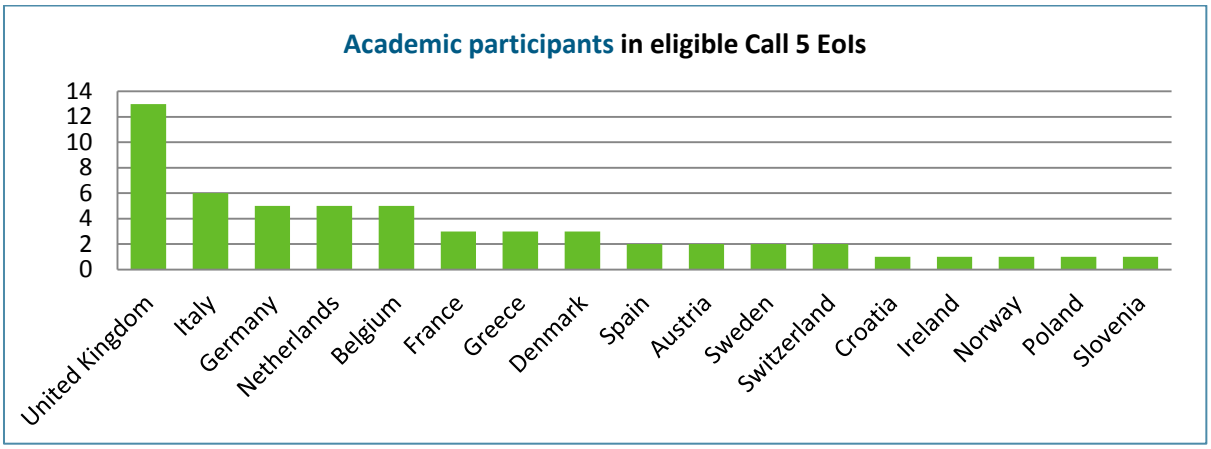
- European Lead Factory - Screening Centre.
- European Lead Factory - Compound Collection.
- The EFPIA in-kind contribution committed to the 5th Call was EUR 91,3 million, with the IMI JU contribution fixed to, EUR 80,0 million (90% of in-kind contribution).
- The Call was launched on 6 March 2012. The Call launch was supported with large-scale promotion through IMI Newsletter, website, targeted and general emails, network organisations and IMI ambassadors at various events. A webinar, covering the main topics presented and discussed at the Open Information Day, was also held to allow those who could not attend the opportunity to interact with the EFPIA topic writer and address any questions that they had.
- 14 expressions of Interest (EoIs) had been received by the submission deadline of which 12 were eligible, as follows.

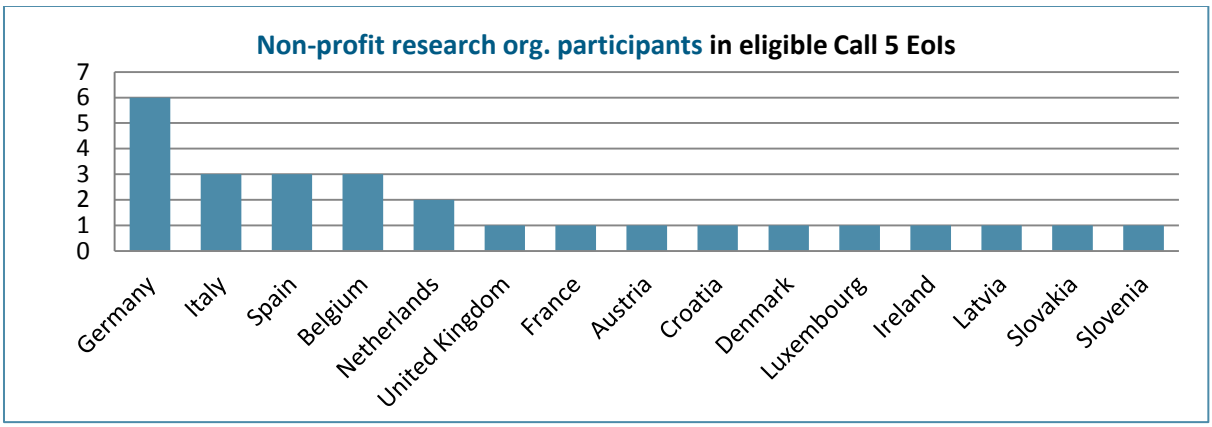
Call 5 Topic	Nr of Eligible EoIs Call 5
European Screening Centre	6
Joint European Compound Collection	6
Total	12

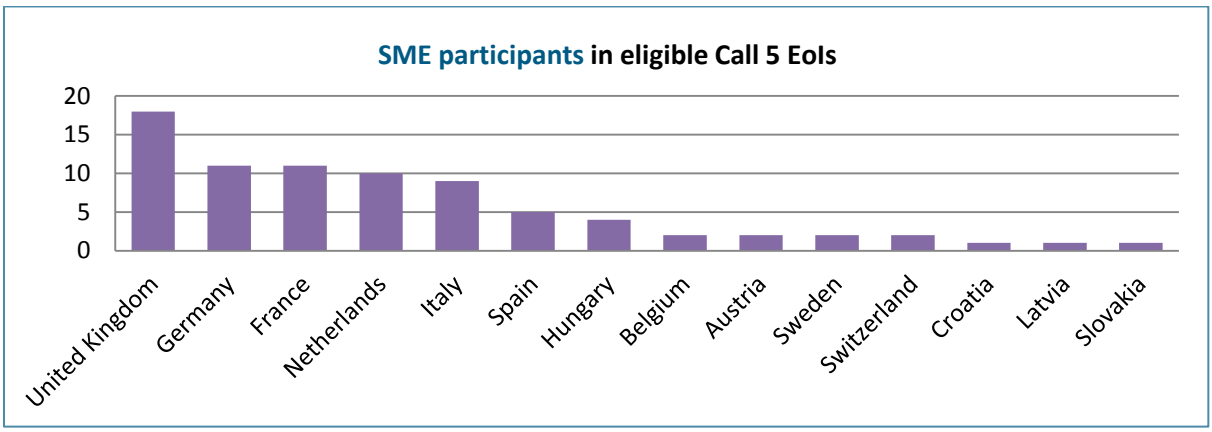
Analysis of the applicants revealed that 162 legal entities took part; 83 (51%) were academic and non-profit organisations and 79 (49%) were small and medium-sized enterprises (SMEs). On average, there were 13.5 entities per EoI (range 5-32). Key figures regarding submitted EoIs are presented below.




All participants in eligible Call 5 EoIs
40
30
20
10
0
United Kingdom
Germany
Italy
France
Netherlands
Spain
Belgium
Austria
Greece
Hungary
Sweden
Switzerland
Croatia
Denmark
Ireland
Latvia
Luxembourg
Norway
Poland
Slovakia
Slovenia

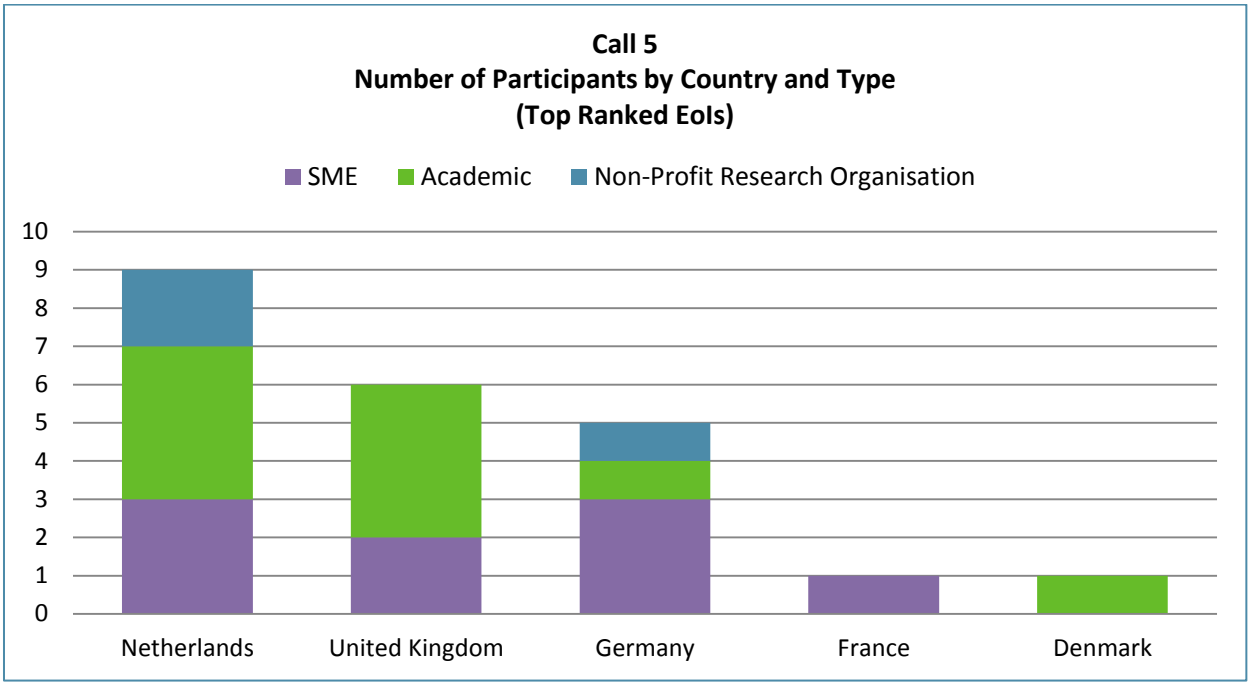

Academic participants in eligible Call 5 EoIs
14
12
10
8
6
4
2
0
United Kingdom
Italy
Germany
Netherlands
Belgium
France
Greece
Denmark
Spain
Austria
Sweden
Switzerland
Croatia
Ireland
Norway
Poland
Slovenia


Non-profit research org. participants in eligible Call 5 EoIs
7
6
5
4
3
2
1
0
Germany
Italy
Spain
Belgium
Netherlands
United Kingdom
France
Austria
Croatia
Denmark
Luxembourg
Ireland
Latvia
Slovakia
Slovenia


SME participants in eligible Call 5 EoIs
20
15
10
5
0
United Kingdom
Germany
France
Netherlands
Italy
Spain
Hungary
Belgium
Austria
Sweden
Switzerland
Croatia
Latvia
Slovakia

- The in-house evaluation - Stage 1 of the EoIs was conducted by a single panel of six independent experts mainly from Europe. The ELEGENCE consortium was ranked first for the Screening Centre Topic, while the SYNTARA consortium was ranked first for the Compound Collection topic. The first-ranked applications were found to comprise 22 legal entities of which 9 (41%) were SMEs.

- Key figures of the first-ranked EoIs are presented below.



- The two subtopics were combined at the second stage, therefore the two successful applicant consortia and the EFPIA consortium merged to form a single consortium to produce and submit their Full Project Proposal (FPP).

- Evaluation of the FPP at Stage 2 (project name: European Lead Factory; acronym EUC^{2}LID: European Centre for Chemistry and Lead Identification) was successfully completed with the Expert Panel recommending to the Board that the EUC^{2}LID consortium progress to the negotiation stage.

- Despite the project involving complex legal and Intellectual Property issues, the negotiation of the Call 5 proposal European Centre for Chemistry and Lead Identification (EUC^{2}LID) was concluded on 3 December 2012. The negotiation involved several changes to the status of partners to ensure that the SMEs were eligible to receive IMI funding. One major change was the change of Managing Entity. The Grant Agreement signature took place on the 19th December 2012 with pre-financing released on the 21 December 2012. The project could then start on 1 January 2013.

Final budget figures for the EUC^{2}LID project – in Euro

IMI Project	EFPIA + IMI Funding	EFPIA Funding	IMI Funding	SME	Academic	Research
EUC^{2}LID	171,336,227	91,337,070	79,999,157	55,422,940	18,946,178	5,630,039

4.4 Implementation of 6th Call for Proposals

The 6th Call consisted of 2 topics:

- Topic 1 - Innovative Trial Design & Clinical Drug Development:
  - Subtopic 1A: Workpackage 1-4
  - Subtopic 1B: Workpackage 5
- Topic 2 - Learning from success and failure & Getting Drugs into Bad Bugs

- Topic 1 focused on building and training networks of researchers, facilitating and increasing the exchange of research data, improving the efficiency of clinical trials on new antibiotics through better laboratory tests and better trial design, and conducting clinical trials to test a new antibiotic targeting infections caused by methicillin-resistant Staphylococcus aureus (MRSA).

- Topic 2 focused on exploring new methods to improve antibiotic uptake in Gram-negative resistant bacterial pathogens.

- The Topic text was finalized during the first months of 2012 and was sent for consultation with the States Representatives Group and the Scientific Committee in April and May 2012.

- Upon Governing Board approval, the 6th Call for Proposals was launched on 24th May 2012, initiating an ambitious programme (NewDrug4BadBugs, ND4BB) which addresses the major public health issue of antimicrobial resistance. The programme aims at creating a new research environment in Europe which will favor speeding up the delivery of much-needed new antibiotics to patients, in particular targeting Gram-negative and multiresistant bacteria.

- The EFPIA in-kind contribution committed to the 6th Call projects was EUR 112.5 million, while the committed IMI JU contribution was EUR 99.0 million.

- 14 Expressions of Interests (EoIs) were submitted for the 6th Call for Proposals, among which 13 were found eligible.

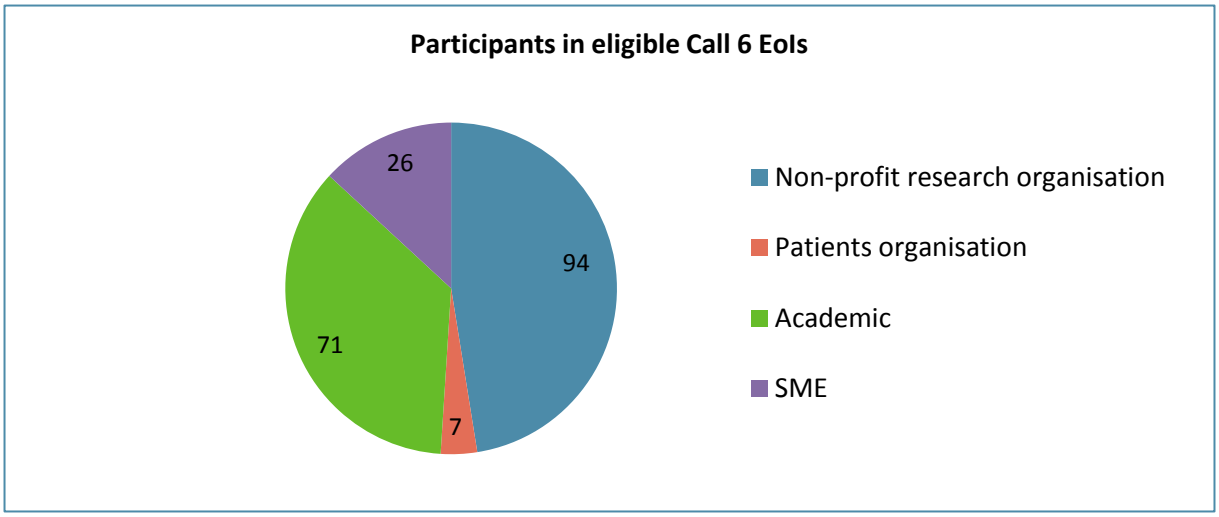
- Key figures regarding submitted EoIs are presented here below.

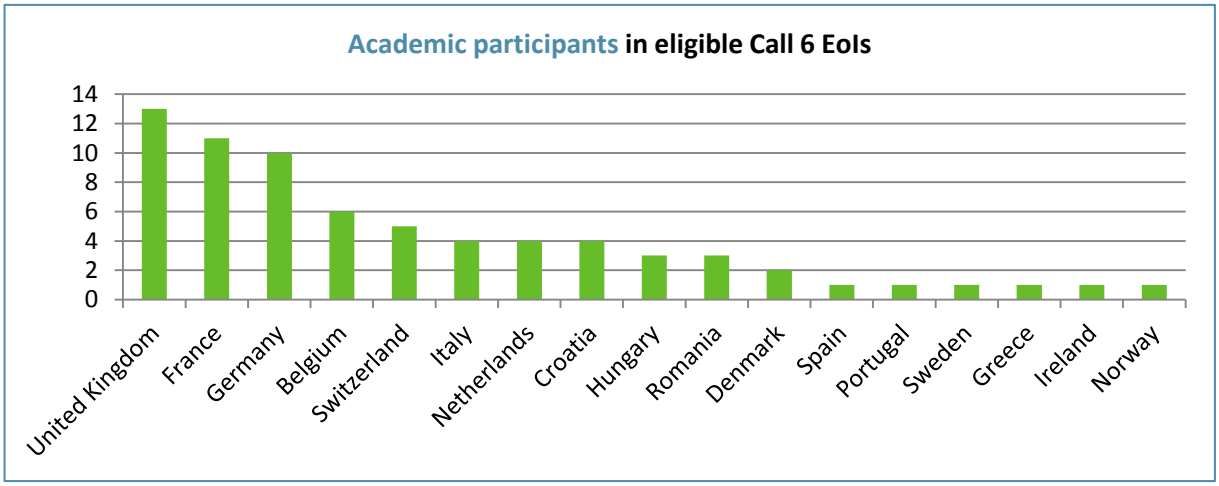
Number of EoIs per topic in Call 6

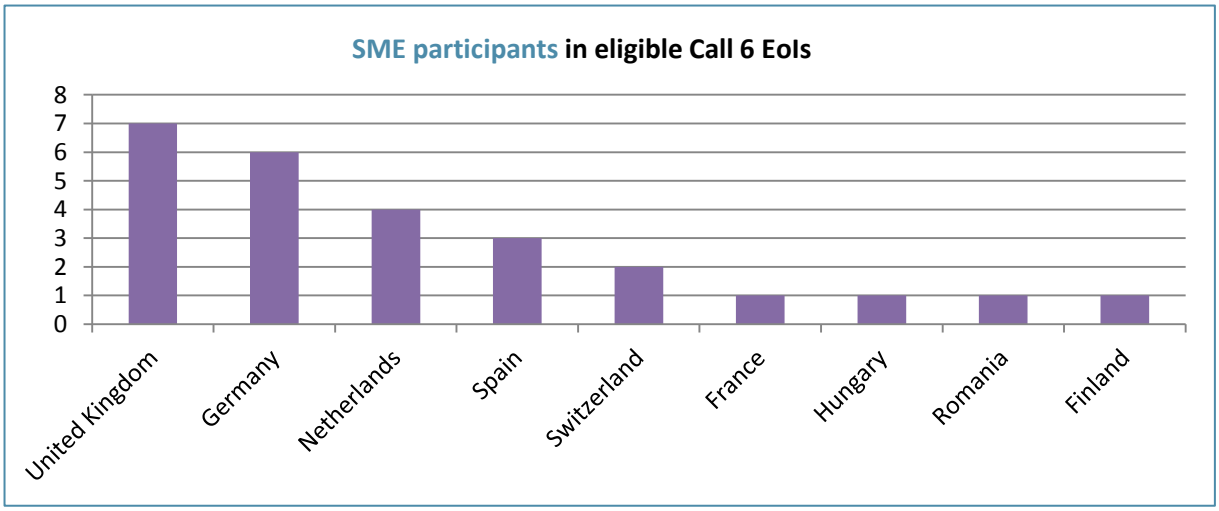
Call 6 Topic	Nr of Eligible EoIs Call 6
Innovative Trial Design & Clinical Drug Development Subtopic A	4
Innovative Trial Design & Clinical Drug Development Subtopic B	4
Learning from success and failure & Getting Drugs into Bad Bugs	5
Total	13

Final budget figures for the 6th Call projects – in Euro

IMI Project	EFPIA + IMI Funding	EFPIA Funding	IMI Funding	SME	Academic	Research	Other
COMBACTE	187,431,199	104,398,189	83,033,010	3,178,500	10,717,398	68,672,112	465,000
Translocation	24,120,036	8,135,833	15,984,203	3,046,137	8,680,449	4,257,617	
TOTAL	211,551,235	112,534,022	99,017,213	6,224,637	19,397,847	72,929,729	465,000

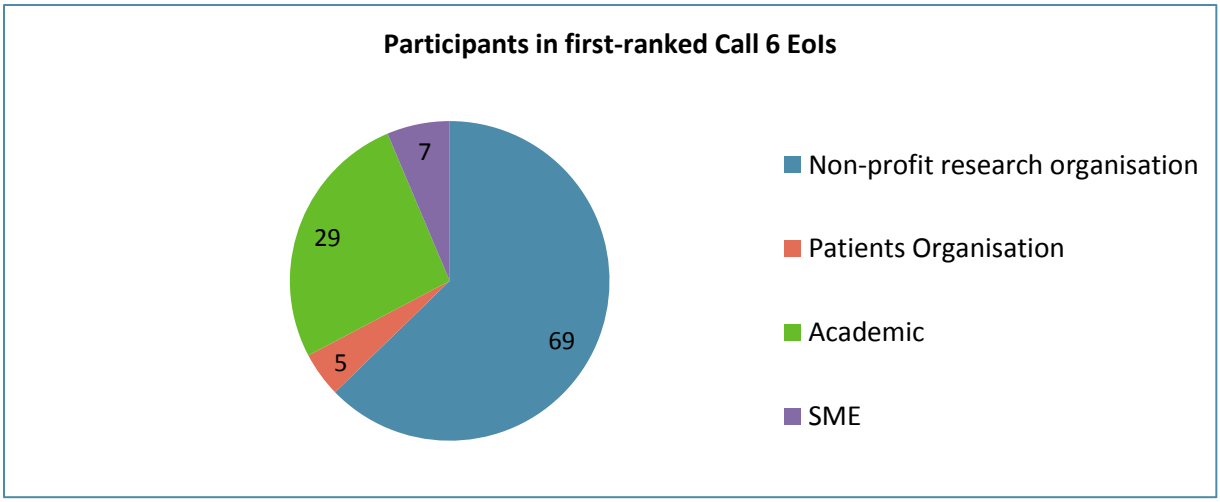


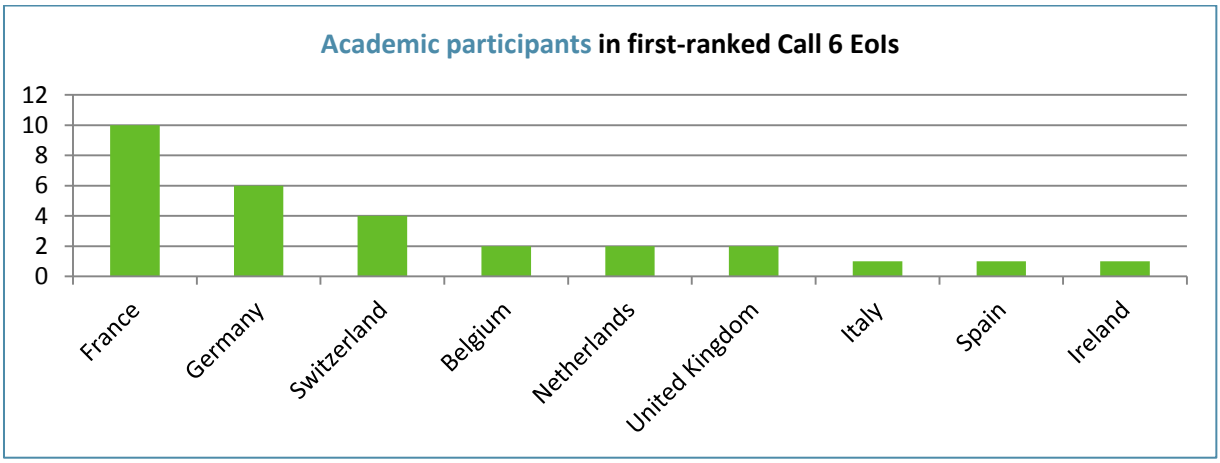




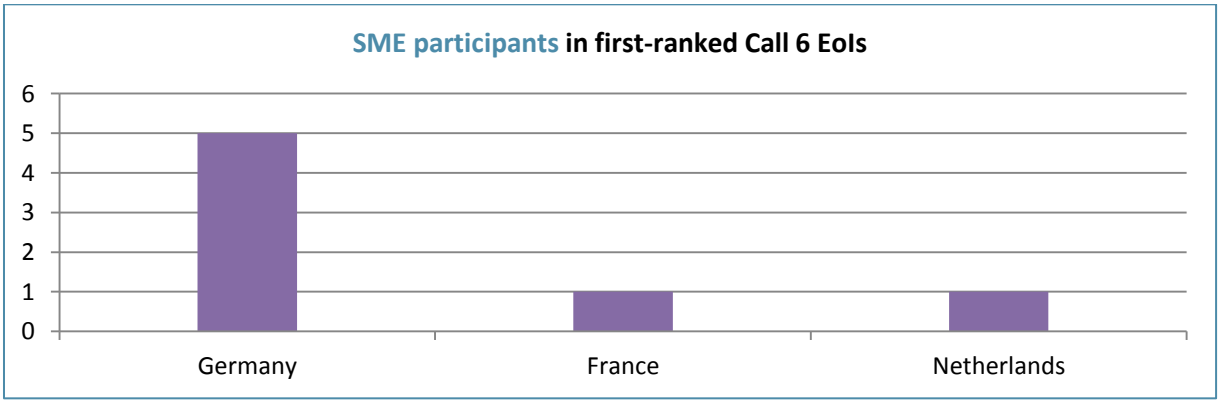
- The evaluation of the EoIs was conducted by panels of independent experts from Europe, (including EU 12), Canada, and the USA working initially remotely and then at a consensus meeting. Thirteen external experts worked in 2 panels (1 panel per topic) moderated by IMI's Scientific Officers, in accordance with the IMI Rules for submission, evaluation and selection of Expressions of Interests and proposals'.

- Key figures of the first-ranked EoIs are presented as follows.


Participants in first-ranked Call 6 EoIs
7
29
5
69
Non-profit research organisation
Patients Organisation
Academic
SME


Academic participants in first-ranked Call 6 EoIs
12
10
8
6
4
2
0
France
Germany
Switzerland
Belgium
Netherlands
United Kingdom
Italy
Spain
Ireland


Non-profit research org. participants in first-ranked Call 6 EoIs
40
30
20
10
0
France
Italy
Germany
Spain
Belgium
United Kingdom


SME participants in first-ranked Call 6 EoIs
6
5
4
3
2
1
0
Germany
France
Netherlands

- Following the approval of the recommendations of the evaluation panels by the Governing Board, the two first-ranked EoIs for Topic 1 were invited to merge, and prepare a Full Project Proposal (FPP) together with the pre-established EFPIA consortium.
The first-ranked EoI for Topic 2 was also invited to prepare an FPP with the pre-established EFPIA consortium. The evaluation of the resulting two FPPs was conducted by the external experts working initially remotely and then at a consensus panel meeting. Full Project Proposals, COMBACTE and Translocation were recommended for funding by IMI and approved by the Governing Board.

- In light of the urgency in the implementation of the topics the timelines of the 6th Call were kept very short with the 2-stages evaluation process and the negotiation finalized within 2012.

- The Grant Agreement was signed in December 2012 for Translocation. The IMI proceeded with pre-financing payments of EUR 5.1 million for Translocation. The remaining project, COMBACTE will receive pre-financing in early 2013.

4.5 New Calls for Proposals

Call 7

4.5.1 Launch of 7th Call for Proposals

The 7th Call for proposals included 2 topics.

- Topic 1: Developing a framework for rapid assessment of vaccination benefit/risk in Europe
- Topic 2: Incorporating real-life clinical data into drug development

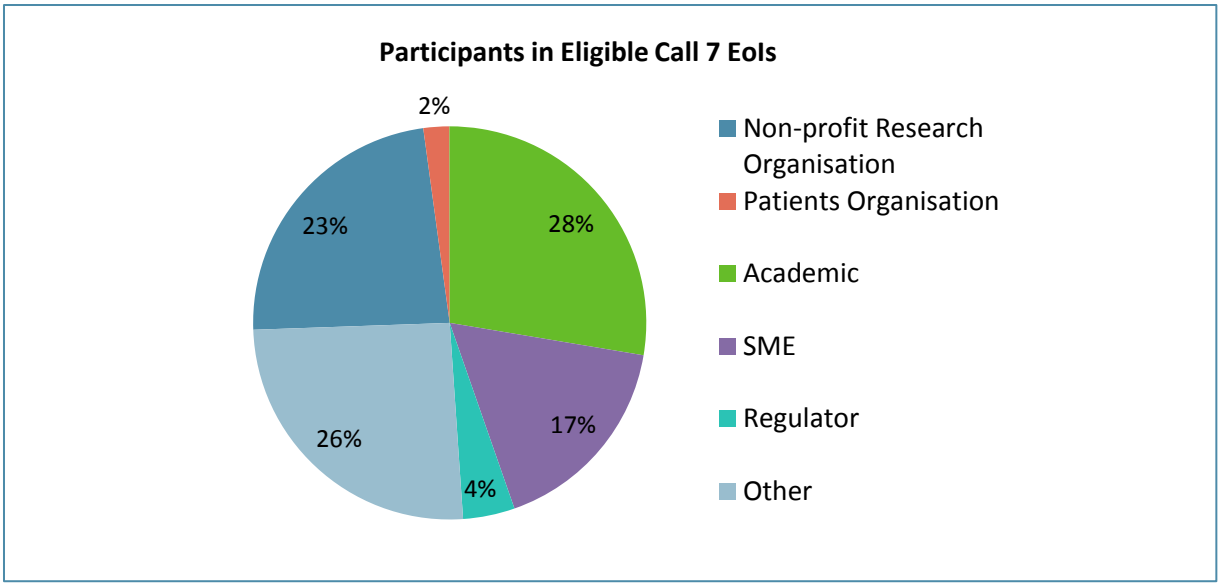
- As a first consultation of the Scientific Community, a workshop on effectiveness research and the impact of vaccines was held on 24 April 2012. The EFPIA coordinator for each topic presented the topic followed by a discussion with a panel of invited experts. Experts were selected based on recommendations from Scientific Committee members, members of the SRG, and also the EFPIA project teams. This workshop, moderated by the Scientific Committee Chair and co-Chair, resulted in a series of recommendations that were used for the preparation of draft topic texts to be submitted for a final consultation of the SRG and Scientific Committee during early June 2012.

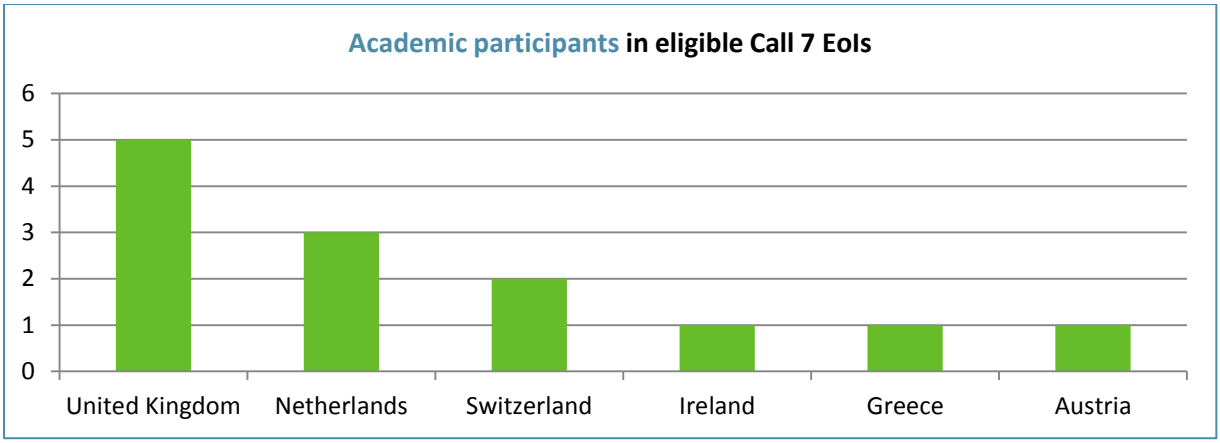
- On 17 July 2012, IMI launched its 7th Call for proposals with the deadline for submission of Expressions of Interest on 9 October 2012.

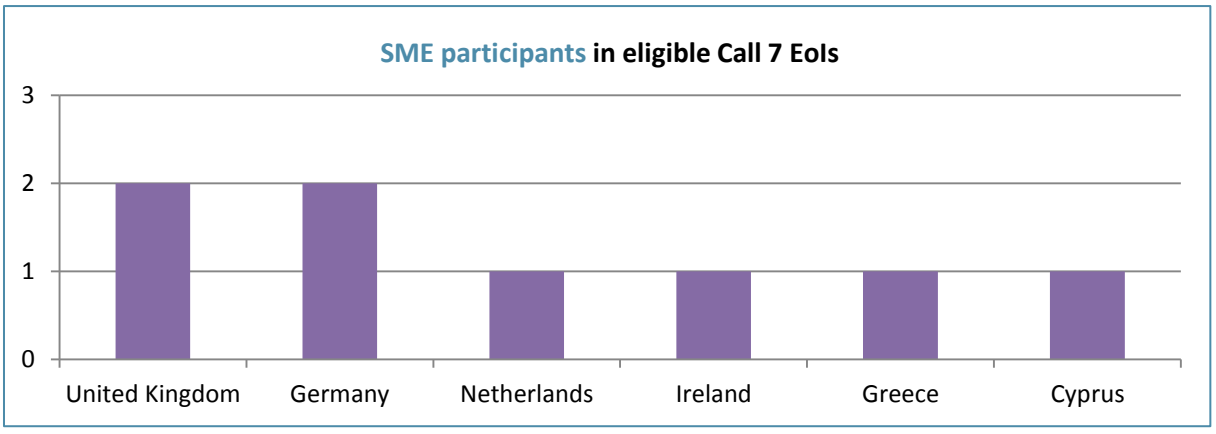
- The launch of the 7th Call was announced to the media with a press release “IMI builds collaborations to monitor vaccine safety and drug effectiveness”, while webinars were used to present the two topics to potential applicants. The EFPIA in-kind contribution committed to the 7th Call projects was EUR 14.0 million and IMI JU contribution of EUR 13.0 million.

- The high degree of specialization of these Call topics resulted in 9 Expressions of Interests (EoIs) among which 8 were eligible. Key figures regarding submitted EoIs are presented here below.

Call 7 Topic	Nr of Eligible EoIs Call 7
Developing a framework for rapid assessment of vaccination benefit/risk in Europe	5
Incorporating real-life clinical data into drug development	3
Total	8

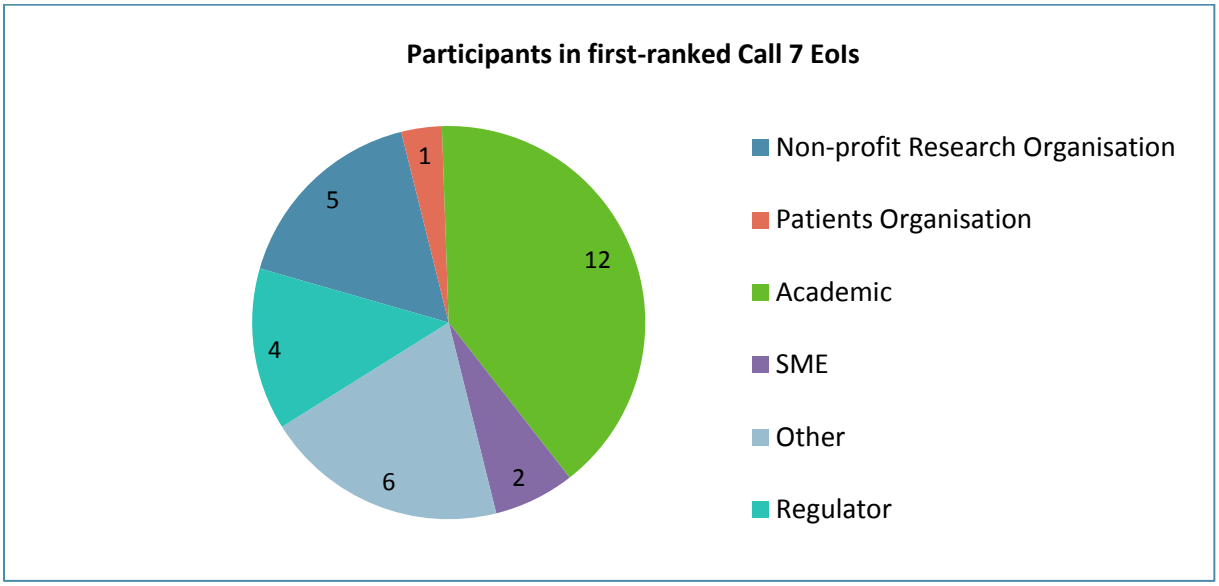


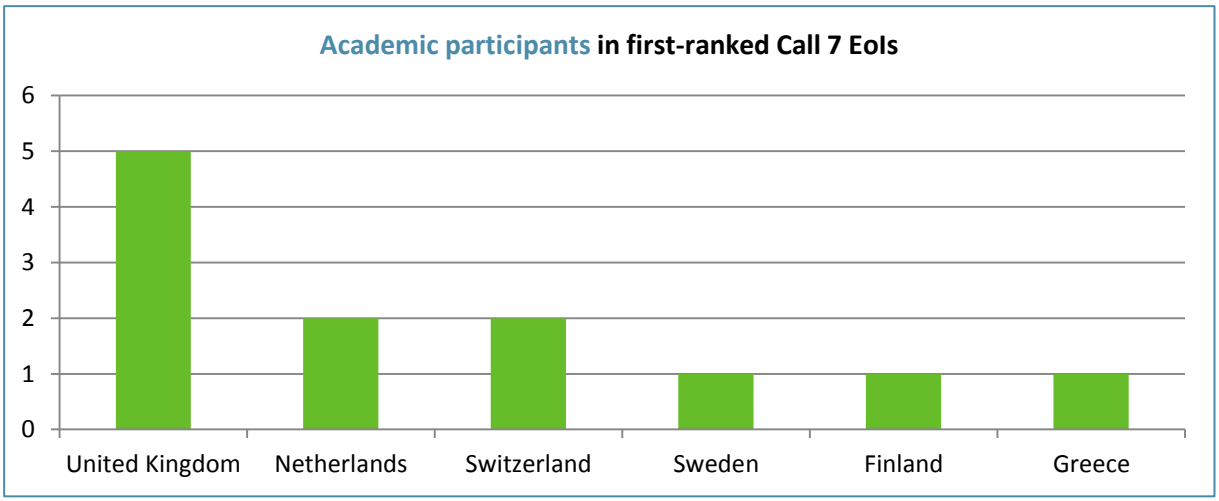




- The evaluation of the EoIs was conducted by panels of independent experts from Europe and the USA working initially remotely and then at a consensus meeting. 14 external experts worked in 2 panels (1 panel per topic) moderated by IMI's Scientific Officers.

Key figures of the first-ranked EoIs are presented here below:





- The two SME partners in the first ranked consortium were from Belgium and Spain.

- Following the approval of the recommendations of the evaluation panels by the Governing Board, the two first-ranked EoIs were invited to prepare a Full Project Proposal (FPP) together with the pre-established EFPIA consortium. The deadline for submission of the FPP is 7 March 2013. The evaluation of the resulting two FPPs will be conducted in 2013.

4.5.2 Launch of 8th Call for Proposals

Call 8 includes the following topics:

1. ND4BB Subtopic 1C: Conduct of clinical studies supporting the development of MEDI4893, a monoclonal antibody targeting Staphylococcus aureus alpha toxin.
2. ND4BB Topic 3: Discovery and development of new drugs combating Gram-negative infections.
3. Developing an aetiology-based taxonomy of human disease: A new classification for systemic lupus erythematosus (SLE) and related connective tissue disorders and rheumatoid arthritis (RA).
4. Developing an aetiology-based taxonomy of human disease: A new classification for neurodegenerative disorders with a focus on Alzheimer's disease and Parkinson's disease.
5. European induced pluripotent stem cell bank.

- ND4BB Subtopic 1C in Call 8 is part of Topic 1 of IMI Call 6 and aims at reinforcing the clinical investigator network in Europe. The resulting project will run under the same Grant Agreement as the Topic 1 projects of Call 6 (Subtopics 1A and 1B).

- A workshop was held by the IMI Executive Office on 12-13 September 2012 in Brussels to discuss the proposed topics. The 4 topics discussed were:

  – Leveraging emerging technology for Pharmacovigilance.
  – European human induced pluripotent Stem Cell Banking.
  – Development of drug-drug combinations

- Developing an aetiological based taxonomy of human disease.

As with previous workshops, members of the Scientific Committee chaired the sessions, the EFPIA coordinator for each topic presented the topic followed by a discussion with a panel of invited experts. Experts were selected based on recommendations from Scientific Committee members, members of the SRG, and also the EFPIA project teams. The output from the workshop was a report detailing advice and recommendations to be incorporated into the topic text prior the start of consultation.

- The IMI antimicrobial resistance programme had been the subject of a workshop dedicated to this program in 2011. Therefore the two additional topics for Call 8 that run under the ND4BB programme were not on the agenda of the September workshop.

- During the further maturation of the Call 8 topics following the workshop, it became apparent that EFPIA companies needed an extended period for the maturation of the topics on 'Leveraging emerging technology for Pharmacovigilance' and on 'Development of drug-drug combinations' and it was decided to delay these two topics to a future Call.

- The final text of the Call 8 Topics was sent for consultation on 30 October 2012, and following Governing Board approval the 8th Call for Proposals was launched on 17 December 2012.

- The EFPIA in-kind contribution committed to the 8th Call projects was EUR 99.4 million while the committed IMI JU contribution was EUR 143.3 million.

- The Call is open for submission of Expressions of Interest until 19 March 2013, with evaluations taking place from April 2013.

4.5.3 Implementation of ENSO Call for Proposals

- The first Call for Proposals to Explore New Scientific Opportunities (ENSO) was launched in August 2012. On-going IMI projects were offered the opportunity to submit applications to explore new scientific opportunities.

- To promote the ENSO Call among IMI project participants and clarify the key points a Q&A on the ENSO Call was published on the IMI web page (http://www.imi.europa.eu/content/new-opportunities), informational presentations were given to the projects, notably through a webinar.

- No applications were received by the first cut-off date of 30 September 2012. The unspent budget earmarked for this cut-off date became part of the total available IMI budget of EUR 5.4 million for the next cut-off date on 15 December 2012.

- 5 applications were submitted by the 15 December deadline. The evaluations were scheduled for January 2013.

5. COMMUNICATION AND NETWORKING

- In 2012, the IMI communication strategy and key messages focused on communicating the success of IMI. As the overview below shows, IMI has generated a wide visibility through various events, publications and other communication actions. In addition, IMI communication continued to promote the new Calls for proposals, as well as the ongoing projects. Day-to-day interactions with stakeholders reveal that IMI has become more visible and is increasingly perceived as a successful example of public-private collaboration in health research.

As participation in central- and eastern European countries is still low, the communication strategy of 2013 will further target these audiences. Participation by SMEs has been good in recent Calls, but continues to require special attention.

- The contribution from founding members in all activities set out below is hereby acknowledged. In addition, such activities are without prejudice to initiatives undertaken directly by founding members.

5.1 Strategy and key messages

In 2012, the communication strategy focused on the strategic goals defined in the Annual Implementation Plan for 2012 and later updated in function of the discussions on Horizon 2020:

1. Enhance IMI visibility to EU policy makers based on achievements
2. Mobilise applicants for IMI Calls across Europe
3. Enhance wider visibility of IMI and its success
4. Secure continued support of industry top managers in the light of competing initiatives worldwide
5. Provide communication support to project coordinators
6. Maximise efficiency and effectiveness of IMI communication efforts

5.2 Improving IMI outreach

Key events targeting policy makers, opinion leaders and industry leaders

Events	Date & Place	Outcome / Report
European Voice Debate on Healthcare ▪ Presentation on IMI	19 March 2012 Brussels	▪ Article in European Voice ▪ Visibility towards EU journalists and opinion/decision makers
DIA Euromeeting ▪ Session + Exhibition stand	26-28 March 2012 Copenhagen	Visibility towards industry/opinion leaders.
Innovation in Healthcare without Borders, European Commission ▪ Exhibition stand	16 April 2012 Brussels	Visibility towards SMEs
Hearing at the European Economic and Social Committee	4 May 2012 Brussels	Visibility to national EU opinion makers

Events	Date & Place	Outcome / Report
European Parliament Lunch Debate (The Parliament Magazine), hosted by Lambert Van nistelrooij, MEP ▪ Presentations on IMI	8 May 2012 Brussels	Visibility towards MEPs.
IMI Stakeholder Forum ▪ on IMI's impact on pharma R&D	30 May 2012 Brussels	Over 150 people attended
European Partnership for Action Against Cancer (EPAAC) Research Forum ▪ Presentations on IMI on patient involvement	2 July 2012 Brussels	Outreach to patients' organisations
EuroScience Open Forum (ESOF) ▪ Presentations on IMI	13 July 2012 Dublin	Visibility towards media.
Innovation Days – a Pharma & Biotech event ▪ Presentation on IMI	1 October 2012 Poland	Visibility towards SMEs and industry
European Health Forum Gastein ▪ EPFIA lunch debate: Dialogue, transparency, trust ▪ IMI/EFPIA session : Connecting new science, research healthcare needs	4 October 2012 Austria	Strong visibility towards policy makers / industry decision makers
Innova Health Cyprus Presidency event ▪ IMI satellite event 'IMI – Putting Policy Into Practice' ▪ IMI involvement in main event & resulting report	11 October 2012 Cyprus	Strong visibility and positive recognition by policy makers / industry decision makers.
German Pharmaceutical Industry Association (BPI) Parliamentary Evening ▪ Key note speech on IMI	17 October 2012 Brussels	Exposure to industry and EU policy makers
Regulatory aspects in Innovative Medicines Initiative Projects (EMA) ▪ IMI chairs session	7 November 2012 London	Encouraging involvement of regulators
IMI European Parliament Event, hosted by Amalia Sartori, MEP Health Research at a Crossroads – Are Public-Private Partnerships the Way Forward?	13 November 2012 Brussels	▪ ~140 attendees ▪ Personal contacts with MEPs and high-level opinion makers
IMI participation in InnovaHealth event in the European Parliament (by European Alliance for Personalised Medicine), hosted by Petru Luhan, MEP	29 November 2012 Brussels	Personal contacts with MEPs
Launch of 4th Call projects ▪ Press release + through other communication channels	5 December 2012	
ENSO Call promotion ▪ Webinar for coordinators of on-going projects	25 October 2012	

Key events to promote IMI's Calls to potential applicants and multipliers key actions

Events	Date & Place
IMI support and/or staff presenting IMI at national info days	Throughout 2012 Austria, Cyprus, Czech Republic, France, Germany, Lithuania, Malta, Poland, Portugal, Romania, Spain, Sweden, Switzerland
5th Call promotion ▪ Open Info Day ▪ Webinars ▪ Web + email campaign	 27 February 2012, Brussels 5 and 20 February 2012
6th Call promotion ▪ presentation at FP7 Health Info Day ▪ workshop at IMI Stakeholder Forum ▪ presentation at FP7 Health NCP meeting ▪ webinars	 29 May 2012, Brussels 30 May 2012, Brussels 31 May 2012, Brussels 24, 25 May and 12 June 2012
7th Call promotion ▪ Webinars ▪ Info session during IMI Stakeholder Forum	 12, 17, 20 July, 2 August 2012 30 May 2012
Health NCP webinar (Health NCP Net) ▪ On IMI Calls, rules, procedures, communication This was highly successful and will be repeated in the future	 17 September 2012
BioPartnering Future Europe (focus on SMEs) ▪ Presentation on IMI Calls	8 October 2012, Brussels
8th Call promotion ▪ Webinars on AMR topics for SRC & SC ▪ Webinars for applicants (+ for NCPs & SRG) on all topics	15 October 2012 6,11,12,13,17 December 2012
ENSO Call promotion ▪ Webinar	 25 October 2012

Other key actions

Actions	Objective	Target audience
Promotion of 4 open Calls for proposals launched in 2012, through info days, webinars, Newsletters, email campaign, social media, and multipliers. In addition, the ENSO Call was promoted to its specific target audience	Attract applicants to IMI's Calls for proposals	Potential applicants Multipliers
Publication of 9 press releases	Promote IMI success, gain wider visibility of IMI	Media Ultimate target: EU opinion leaders / decision makers
Invitation of journalists to selected IMI events	Promote IMI success, gain wider visibility of IMI	Media Ultimate target: EU opinion leaders / decision makers
Conclusion of a contract with a PR-agency (Media Consulta), including the following services ▪ Continuous communication support ▪ Event-based communications support ▪ Media training of selected IMI staff ▪ Media monitoring and analysis	Strengthen and increase relations with the press	Media Ultimate target: EU opinion leaders / policy makers
Delivering material and services to project coordinators ▪ 1-page guide on communication (use of logos etc). ▪ Guide on how to build a project website ▪ Guide on how to build a project communication strategy ▪ General slide set on IMI ▪ Review and improvement of draft press releases, websites and other project communication material ▪ Recommendations, feedback and discussion on communication aspects during (joint) projects meeting ▪ Promotion of project actions and achievements through IMI communication channels (events, website, Newsletter, social media, publications in journals and magazines)	Provide communication support to project coordinators	Policy makers, opinion leaders, potential applicants
Concluding four framework contracts for communication services ▪ Graphic Design ▪ Digital printing ▪ Offset printing ▪ Conference material	Enhance the efficiency and effectiveness of the communication activities	

5.3 Key publications

- **New IMI brochure** (October 2012)
  - to support IMI's events and direct networking towards policy makers,
  - highlighting project achievements and stakeholder's testimonies
- **Leaflets** on EP event, 8th Call for proposals and 4th Call projects

Media highlights

- ***MedNous,*** November/December 2012
  As Big Pharma pulls back, IMI steps in
- ***Speech by José Manuel Barroso*** at the European Parliament, 21 November 2012,
  underlined the importance of dedicating sufficient funds to the Horizon 2020 programme to develop jobs and growth in SMEs, to support top researchers and their teams, and for the continuation of IMI in the health sector.
- ***European Voice,*** November 2012
  'Public-private partnerships are the way forward to improve drug safety – the example of the Innovative Medicines Initiative'
- ***Deutschland Radio Kultur,*** 8 November 2012
  Interview with Michel Goldman about antimicrobial resistance
- ***Deutsche Welle***, 20 October 2012
  New future with pre-competitive science
- ***Nature Biotechnology,*** 7 August 2012
  Incentives aim to boost antibiotic development
- ***The Lancet,*** 15 June 2012
  Europe to boost development of new antimicrobial drugs
- ***Biocentury,*** 4 June 2012
  Innovating Antibiotics
- ***The Parliament Magazine,*** 28 May 2012
  Joint Action
- ***Financial Times,*** 27 May 2012
  Public health: Raised resistance
- ***The Wall Street Journal,*** 24 May 2012
  EU joins widening push to find new antibiotics
- ***The Guardian,*** 24 May 2012
  GlaxoSmithKline and AstraZeneca invest in biotech research
- ***The Times,*** 24 May 2012
  Drugs giants put rivalries aside to tackle the scourge of the superbug
- ***Nature News,*** 24 May 2012
  Europe targets superbugs with public-private effort
- ***Scrip,*** 24 May 2012
  IMI launches €224m R&D programme to tackle antibiotics resistance
- ***The Parliament Magazine,*** 10 May 2012
  Public private partnerships key to growth of EU pharma research
- ***Science-Business eXchange,*** 10 May 2012
  A mind for precompetitive collaboration
- ***Science-Business eXchange,*** 19 April 2012
  Building tools against autism
- ***Nature Medicine,*** 5 April 2012
  Europe plans molecular screening center for translational research
- ***Science-Business eXchange,*** Kai-Jye Lou, 29 March 2012
  IMI's leadoff hitter (on 5th Call for proposals)
- ***Nature***, 27 March 2012
  Chemistry's web of data expands
- ***InPharm,*** 12 March 2012
  UCB chief executive to chair IMI
- ***SCRIP Intelligence,*** 8 March 2012
  Seven pharma fuel €170m EU-wide screening honeypot
- ***Pharma Times,*** 8 March 2012
  IMI to set up European Lead Factory for new drug opportunities
- **Pharma Times,** 8 March 2012
  UCB chief Doliveux to head IMI
- ***PharmaNews***, 8 March 2012
  IMI funds platform to discover new medicines
- ***PMLiVE,*** 7 March 2012
  Europe's IMI plans compound library and screening centre
- ***Microbiology Today***, February 2012, p 55.
  'IMI to launch major antimicrobial resistance project'

IMI in scientific journals & reports

- ***Expert Review of Pharmoeconomics & Outcomes Research,*** Laverty, H. et al., Vol.12(5), pp. 545-548 (November 2012)
  Improving R&D productivity of pharmaceutical companies through public-private partnership: experiences from the Innovative Medicines Initiative
- ***Nature Reviews Drug Discovery***, Denee, T.R. et al., online 30 March 2012
  'Measuring the value of public–private partnerships in the pharmaceutical sciences'
- ***Nature Medicine***, Goldman, M., Vol. 18, p. 341, 6 March 2012
  'Public-private partnerships need honest brokering'
- ***Clinical Pharmacology and Therapeutics***, Goldman, M., Vol. 91 (3), pp. 418-125, March 2012
  'The Innovative Medicines Initiative: A European Response to the Innovation Challenge'
- ***Science Translational Medicines***, February 2012
  Recalibrating Intellectual Property Rights to Enhance Translational Research Collaborations
- ***Innovation Excellence***, Paul Hobcraft, 6 January 2012
  Open Innovation, Technology Platforms and a New Business Model- All-in-One Biggie!

Video coverage

- ***RTBF***, 25 May 2012
  Les bactéries, Le Point avec l'invité Dr. Michel Goldman
- ***SkyNews,*** 24 May 2012
  Drug Companies Unite in Battle Against Bugs
- ***YouTube,*** Roch Doliveux, 17 April 2012
  'Innovation in Healthcare'

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

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

5.4 Support to Governance and Consultative bodies

IMI provided continuous support to the its governance and consultative bodies. Efforts were made in improving communication and feedback on IMI existing and planned scientific activities, notably through the development of dedicated platforms and periodic newsletters. In addition, the consultation process of the Scientific Committee and the States Representatives Group on future Call topics was streamlined.

Governing Board

The Governing Board oversees the implementation of IMI's activities. As from April 2012, Mr Roch Doliveux (EFPIA) became Chairman and Dr Rudolf Strohmeier (EC) Vice-Chairman for a one year mandate. The Governing Board met three times (March, June, October), adopting various decisions and reports that include the Annual Activity Report 2011, the Annual Implementation Plan for 2013, Call texts and budgets and the outcome of evaluations, as well as modifications to IMI model Grant Agreement. In addition, monthly teleconferences between the Chair, Vice-Chair and the Executive Director were held for information purposes.

Scientific Committee

The Scientific Committee held three meetings in 2012 (March, June, October), Chaired by Professor C. Noë. Key activities included update on IMI projects achievements, notably on the occasion of interim reviews of Call 1 projects, and consultation on future and new call topics.

States Representatives Group

The IMI States Representatives Group held three meetings (February, May, October), including one in Larnaca around EU Cypriot Presidency events, chaired by Dr G. Sandberg. Detailed updates on IMI activities in terms of on-going projects' achievements were provided and consultation on future Calls and topics organised.

Joint SC-SRG workshop on Horizon 2020

In September a joint SC-SRG workshop on Horizon 2020 and perspectives for a future public private partnership in life sciences was held. This was a useful opportunity for IMI Founding Members to seek initial feedback from these bodies on their approach and views as to the future.

Stakeholder Forum

Through its annual Stakeholder Forum, IMI engages key stakeholders in discussions about its activities. IMI held its 2012 Stakeholder Forum on 30 May. Updates on IMI project achievements and future calls topics were presented and discussed.

5.5 Support to SMEs

As part of its commitment to communicating better with all stakeholders, the Executive Office pursued its efforts towards SMEs. Staff attended many meetings with SME organisations, ensured that the voice of SMEs is heard at its stakeholder meetings and presented at relevant meetings explaining the mission of IMI and the opportunities that being involved in an IMI project can bring.

Consultation Workshop for SMEs on a future PPP under Horizon 2020

- A Stakeholder Workshop Addressing 'Public-Private Partnership in Innovative Health Research under Horizon 2020' was held in Brussels, on 19 September 2012. This workshop addressed the experience of SMEs in Public-Private Partnerships (PPPs), particularly IMI, and gathered important lessons learnt for inclusion in any future PPP under Horizon 2020. SMEs, both those involved in IMI projects and those not involved, were invited to attend and contribute. The IMI Executive Office, the European Commission and EFPIA presented the current status of SME participation in IMI and future perspectives under Horizon 2020.
- There was strong support for IMI and the benefits that working in a PPP can bring, however, based upon experience, areas of improvement were suggested. These included the need to speed up decision making and the Call process and recruitments into consortia.

There was general support for a future PPP under Horizon 2020 and the societal benefits that such an initiative could bring. It was clearly felt that a future PPP should have a broader range of partners and be easier to access for SMEs in order for it to be truly successful.

To further improve communication and support for SMEs the following actions were implemented:

- Inclusion of a page dedicated to SMEs on the IMI website with information useful to SMEs
- The IMI Executive Office was represented and presented on IMI activities at the following meetings addressing specifically the issues and challenges faced by SMEs and how IMI can help SMEs be more successful:

Europharm SMC – 10th International Meeting 'New Business Opportunities for SMEs'
Incremental Research, New Markets, Emerging Markets ' Barcelona 8 & 9 March 2012
Biopartnering Future Europe SME workshop, Brussels, 7-9 October 2012
BioFit workshop 'SME feedback on the pros and cons of the Innovative Medicines Initiative', Lille, 4 December 2012

5.6 Cooperation with external bodies

European Medicines Agency

- On 7 November 2012 The European Medicines Agency (EMA) hosted the second IMI regulatory summit meeting. The objective of these annual meetings is to review IMI project outputs with regulatory relevance, identify questions which the regulatory authorities would like to see addressed in the context of on-going projects, and identify areas that would benefit from collaborative research projects in order to align research and regulatory agendas. The output of the meeting was a series of recommendations to enhance the communication and involvement of regulators in current and future IMI activities, and plans for Horizon 2020.

NIHF Biomarkers Consortium

- IMI participated to the NIHF Biomarkers Consortium Autism Initiative Meeting on 28 March 2012 in Washington DC. The meeting was organized by the NIH Foundation (NIHF) in order to kick start the plans for their Biomarker Autism Initiative by gathering input from all the stakeholders. IMI and its autism-focused project EU Aims were invited as they represent the only active PPP initiative in this area.

Interaction with other PPPs working on kidney safety biomarkers

- IMI, together with the Critical Path Institute and the Foundation for the National Institutes of Health held a special symposium at the ERA-EDTA (European Renal Association – European Dialysis and Transplant Association) Congress in Paris, on 24 May 2012. The session, entitled 'Drug-induced renal injury: the quest for sensitive biomarkers', focused on efforts to improve the detection of kidney damage caused by drugs. To address this issue, three public-private partnerships have been formed: the Predictive Safety Testing Consortium Nephrotoxicity Working Group, the Drug Induced Kidney Injury (DIKI) working group of the IMI SAFE-T consortium and the Biomarkers Consortium Kidney Safety Project Team. All three partnerships conduct research designed to define thresholds and characterize the performance of the new DIKI biomarkers in order to enhance decision making in drug development. During this session, achievements and on-going projects of the three partnerships were presented and the complementarity of their approaches was discussed. The panel discussion was led by a representative of EMA. The ERA-EDTA congress attracts thousands of kidney experts

from Europe and beyond with a major focus on the potential of translating research results into novel therapies and diagnostic tools. The IMI session was introduced by a keynote lecture of the current EDTA'chair, Raymond Vanholder, and was attended by more than 140 delegates. http://www.eraedta2012.org/

C-Path Institute

- In addition to the area of Safety kidney markers, IMI and the C-Path Institute have complementary activities in the areas of tuberculosis (C-Path CPTR consortium and IMI PreDiCT-TB project) and Alzheimer's disease (C-Path CAMD consortium and IMI PharmaCog and EMIF-AD projects). Under the umbrella of the IMI-C-Path MoU interactions among these initiatives have started with the facilitation of IMI. The CPTR and PreDiCT-TB consortia are working on a MoU between the two initiatives which will allow for formal sharing of workplans and data to enhance synergy, particularly in the area of data standards. The PharmaCog and CAMD project have started informal discussion on an interaction between the two initiatives in the field of regulatory approval of imaging data.
- In the last quarter of 2012 the IMI and C-Path Office have started planning for a joint meeting in March 2013 where these interactions will be further explored and consolidated.

CDISC

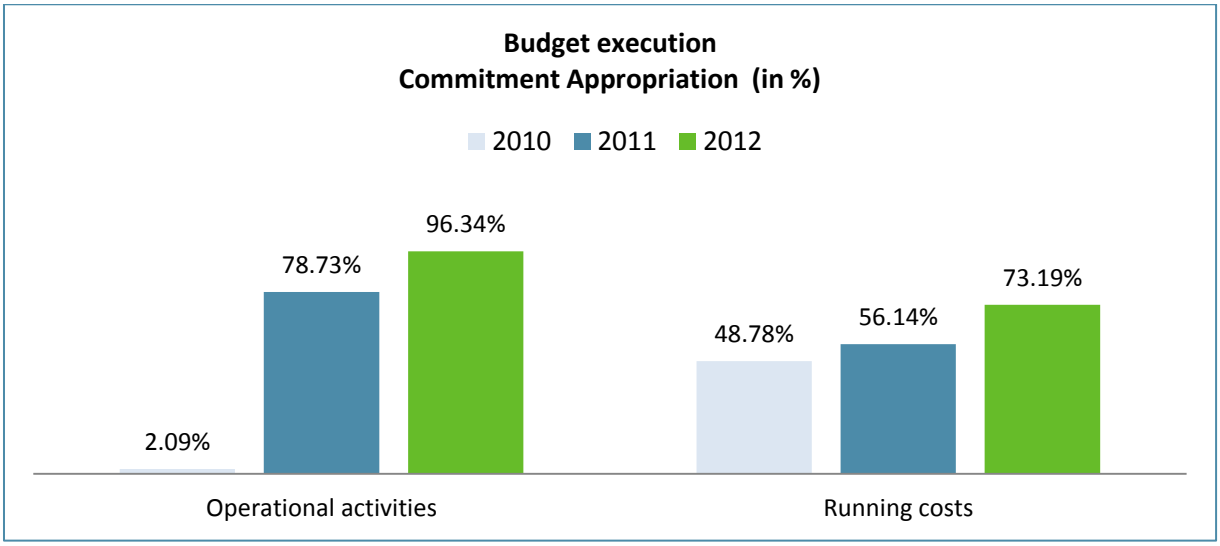
Please refer to the knowledge management section of the Management of Running Projects chapter.

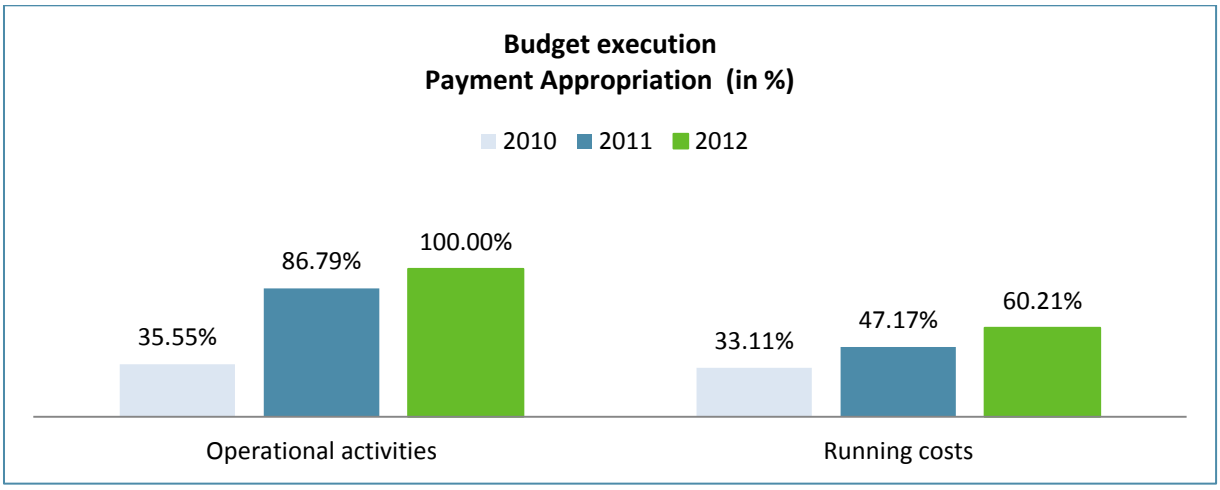
6. EXECUTIVE OFFICE MANAGEMENT

6.1 Budget and Finance

Budget execution

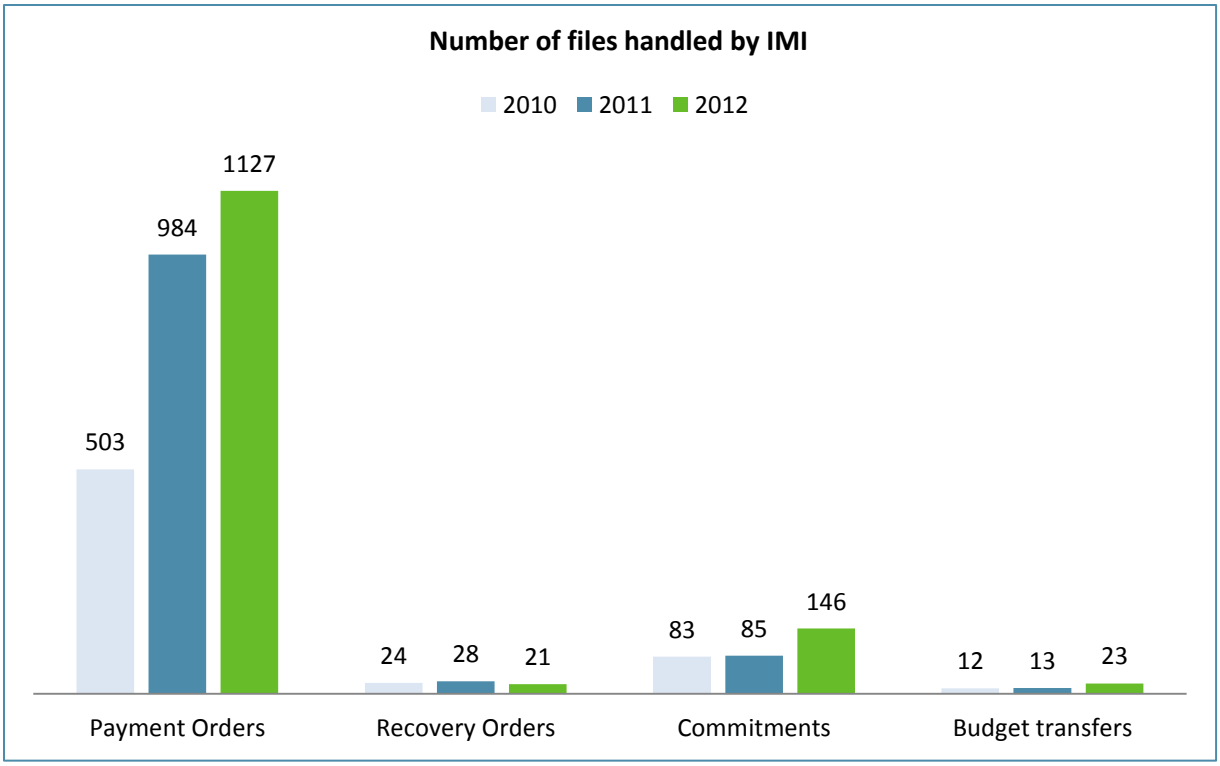
In 2012, the budget execution improved significantly compared to 2011, with 95.76% execution in commitment appropriations and 96.70% in payment appropriations. The graphs below set out achievements both for operational activities (Call-related) and for the running costs of the Executive Office (staff and infrastructures).





Financial operations

IMI handled a total of 1,317 financial files (payments, commitments, recovery orders and budget transfers) in 2012.



- The time to process financial files decreased in 2012 resulting into lower number of late payments compared to previous year. During the year, IMI updated the manual of procedures for financial operations and held several internal training sessions with staff in order to further reduce the number of late payments in the future.

- The table below shows the number of administrative payments processed on time and the number of late payments.

The difference between the total number of payments in this table and the total number of payment processed in 2012 represents the number of payments for which the deadline is not set in the system (e.g. reconciliation payments, salaries).

The time to pay for operational payments is set out in KPI, section 2.3.

Number of payments in 2012

	30 days	45 days (Title II)	60 days	45 days (Title III)	105 days	Total
on time	221	682	32	11	25	971
late	38	75	6	0	1	120
Total	259	757	38	11	26	1091

The payment appropriation of 2012 was mostly executed through pre-financing and intermediate payments to beneficiaries of IMI projects, as shown in the following table.

		2010	2011	2012
Call 1	pre-financing	34,704,183.27		248,003.00
	interim payments	534,382.03	15,213,165.83	24,751,103.64
	late Interests	3,472.49		
	Total	**35,242,037.79**	**15,213,165.83**	**24,999,106.64**
Call 2	pre-financing		28,529,305.01	
	interim payments			8,469,655.17
	late Interests			728.32
	Total		**28,529,305.01**	**8,470,383.49**
Call 3	pre-financing		25,237,455.00	10,543,702.00
	interim payments			
	late Interests			
	Total		**25,237,455.00**	**10,543,702.00**
Call 4	pre-financing			34,076,849.00
	interim payments			
	late Interests			
	Total			**34,076,849.00**
Call 5	pre-financing			20,604,175.87
	interim payments			
	late Interests			
	Total			**20,604,175.87**
Call 6	pre-financing			5,114,946.00
	interim payments			
	late Interests			
	Total			**5,114,946.00**
	Total Calls 1-6	**35,242,037.79**	**68,979,925.84**	**103,809,163.00**

In order to increase the quality of and reduce errors in periodic reports provided to IMI by the consortia, IMI organised jointly with EFPIA two financial management workshops, one for coordinators of IMI projects and one open to all beneficiaries of IMI projects. This initiative will continue in 2013.

State of play of founding members contribution

The following table provides details about the status of commitment of founding members per Call (source: SOFIA). From 2012, non-EU in kind contributions may be included in the total EFPIA contribution under conditions set out by the Governing Board.

Tracking	IMI JU			EFPIA		
	Committed	Reported	% Reported	Committed	Reported	% Reported
Call 1	110,368,443	40,738,117	36.91%	138,842,276	45,582,495	32.83%
Call 2	80,740,072	8,469,655	10.49%	68,060,321	6,423,159	9.43%
Call 3	111,816,124			69,560,138		
Call 4	97,943,541			106,891,787		
Call 5	79,999,157			91,337,070		
Call 6	99,017,213			112,534,022		
Call 7	13,000,000			13,964,319		
Call 8	143,300,000			99,400,000		
ENSO Call	5,378,249			5,378,249		
TOTAL	741,562,799			705,968,182		

6.2 Human Resources

- Recruitments were conducted in 2012 in line with the Multi-Annual Staff Policy Plan approved by the Governing Board. The authorised maximum ceiling of 36 staff members was reached on 1 July 2012. The post incumbency rate was very good.

- 6 new staff members in 2012 joined IMI as follows:

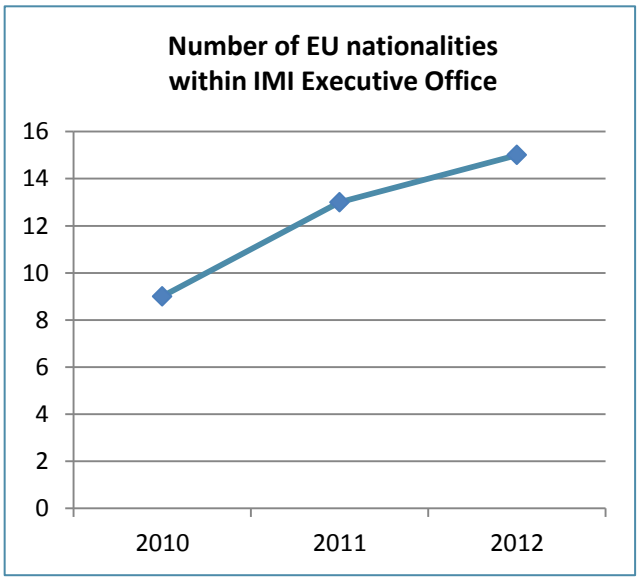
  – The Science pillar increased by 3 additional Scientific Project Officers and 1 Administrative Assistant. Another Administrative Assistant replaced a staff member who resigned at the end of 2011.

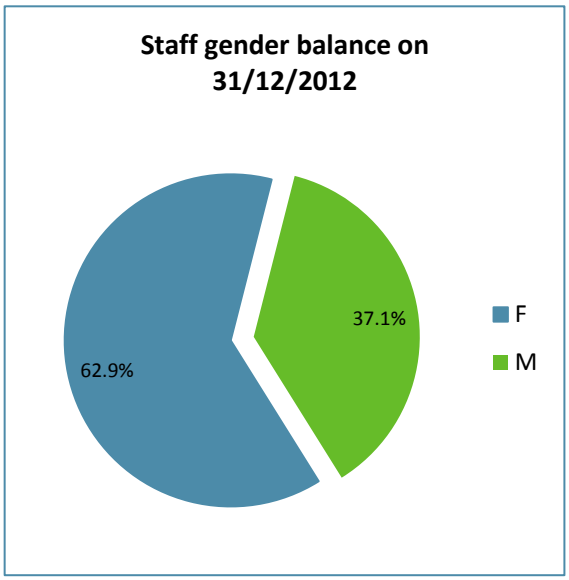
  – In Administration and Finance, a new Administrative Assistant joined following a resignation.

These new recruits enabled IMI to improve its geographical balance (two new EU nationalities represented in IMI in 2012) while the gender balance remains more or less the same as last year, as shown in the graphs below.

- The following selection processes launched in 2012 will be completed in 2013:
  – Ex-Post Audit and Finance Officer (AD5)
  – Communication and Events Officer (AD7)

- Rules on the set up of Staff Committee and implementation of staff appraisals were adopted.





6.3 Information and Communication Technology

IMI ICT strategic objective is to deliver value to the business and to be a key enabler of new business initiatives with the goal of supporting and shaping the present and future of IMI. IMI ICT applications and infrastructure support the implementation of the business objectives. 2012 marked the parallel implementation and delivery of integrated solutions across business processes as illustrated in the table below.

IMI core business	
SOFIA (Submission OF Information Application)	▪ Migration to new provider, server and technology achieving an application in line with the image of IMI ▪ Development of: Submission of Form C, Contract Negotiation, Grant Agreement, Project Phase, Export to CORDA
Business support tools	
Support to Governance Bodies (GB, SC, SRG)	▪ Improvement and migration to achieve integrated solution
Partner Search Tool	▪ Improvement and migration to achieve integrated solution ▪ Delivered content administration module
ICT internal support	
DORA (Document Repository Application)	▪ Implementation of a new tool for full electronic processing, storage and retrieval of documents
Events Registration Tool	▪ New modular tool to manage organised events
ISA (Information System for Absences)	▪ Implementation of a new tool to manage the several types of absences
Vacancies	▪ Implementation of a new tool to manage the applications to job vacancies
IMI Intranet	▪ Implementation of an intranet to centralise information and access to tools and applications

Support to IMI Core Business

▪ 2012 marked the migration and further development of IMI core business application: SOFIA (Submission OF Information Application).

▪ The migration aimed at improving the performance of the application with a view to enhance user satisfaction, notably through an effective helpdesk function. This was achieved with external contractor's assistance, with developments delivered and implemented within scope, time and budget. The functionality migrated from the old application now supports the 2 stage evaluation process in the following sequence:

▪ Submission of Expression of Interest (EoI) by Applicant Consortia.

▪ EoI evaluation through 1st peer review:

- assessment done in SOFIA by Independent experts + EFPIA topic coordinators. Independent Observers also have access to SOFIA during this phase.
- ranking done by Independent experts: with access to SOFIA as rapporteurs;

- Submission of Full Project Proposal (FPP) by Applicant Consortia and EFPIA consortium.

- FPP evaluation through 2nd peer review:
- assessment done in SOFIA by Independent experts. Independent Observers also have access to SOFIA during this phase.
- approval (or not) done by Independent experts with access to SOFIA as rapporteurs.

- Following the migration, a series of new developments were delivered and are summarised in the diagrams below. Overall, these new developments represent significant improvements in data processing and reliability, thereby enhancing the project management's efficiency.

- The submission of Form C is now available in SOFIA for project participants and third parties to provide financial statements in the framework of annual reporting. Each participant submits electronically the costs incurred and claims the requested IMI contribution per reporting period. This module facilitates the submission and checking of Form C by the Project Coordinators and IMI. Later on, this module will be incorporated in the Project Phase and Contract Management.

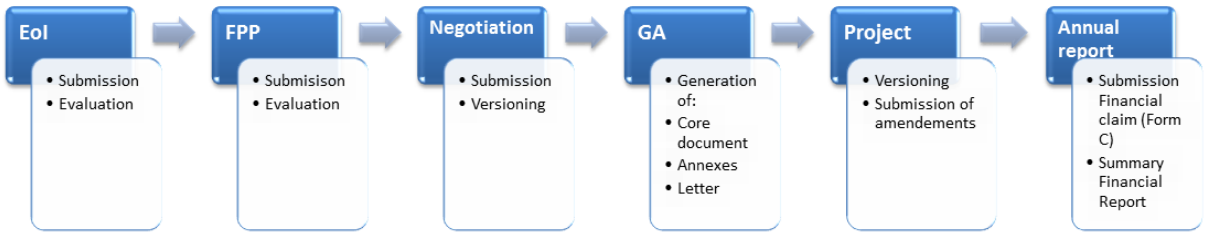
- In order to facilitate project monitoring and enhance coordination efficiency, a Reports' area was created to allow a read access for EFPIA ILG members to extract information of projects on-going or submitted proposals where their companies are involved either as coordinator or participant.

- The Contract Negotiation module was delivered and used for Call 5 project. It supports the submission of Negotiated Proposal with Description of Work (DoW) by Full Project Consortia (Applicant Consortia and EFPIA consortium) with the possibility to provide intermediate versions during Negotiation phase.

- SOFIA now supports the production of the Grant Agreement (GA). After closure of Negotiation, the IMI office is able to produce the GA, its annexes and the accompanying letter. After signature the GA shall be uploaded in SOFIA.

- All projects are now in Project phase in SOFIA and available in the corresponding amendment phase. History of the Call process and versioning is now kept in SOFIA.

- Below is a summary of the phases and items that are managed from SOFIA.



- Following the development of Contract Negotiation and Project phase the XML Export to CORDA has been enhanced to include data from these two phases. The development work has now been completed. SOFIA enables the full creation of XML files to be transferred to CORDA with the following data: Expressions of Interest (EoI), Full Project Proposal (FPP), Negotiation and Project data. Further steps will be conducted with DG RTD to confirm adequate reception, loading and availability of IMI data in CORDA.

Business Support Tools

- The collaborative platforms for supporting the Governance Bodies, the Governing Board, the Scientific Committee and the States Representatives Group were migrated to a new server and technology to provide an integrated solution, achieving one login to access all IMI tools.

- To support the collaborative work on projects between IMI, the EC and EFPIA a simplified platform prototype was developed.

- Also as part of this unification of IMI ICT architecture, the Partner Search Tool (PST) has been migrated and developed an administration module that facilitates the update and insertion of new keywords, thereby enabling IMI office to keep the PST up to date in view of the fast pace of launch of new Calls.

ICT Internal Support

DORA (DOcument Repository Application)

The IMI document management system was delivered and implemented. It enables full electronic processing, storage and retrieval of all official IMI documents.

Vacancies

An electronic tool for the submission of job applications was set up. It facilitates processing of applications by staff.

ISA (Information System for Absences)

A tool to manage the several types of absences was made available to staff. This represented a significant efficiency gain in processing requests.

IMI Intranet

IMI intranet was made available to staff in order to centralise information and the access to the several tools & applications needed by the IMI Office.

Web events tool

A tool in line with the core image of IMI has been delivered to manage the registration of attendees to IMI Events. The Events Registration Tool is modular and customizable depending on the needs for the event.

6.4 Procurement and Contracts

- The large majority of IMI's procurement in 2012 was done under existing multi-annual framework contracts. Of the framework contracts, the most significant in volume, namely in IT services, audits and interim staff provision, have been concluded jointly with other Joint Undertakings to avoid duplication and minimise administrative effort.

- The Joint Undertakings took the decision in 2012 to increase the contract volume ceiling of the framework contracts in IT infrastructure services, telecommunications services and software development (JTI/IT/2010/NP/01 - Lots 1-3) under a negotiated procedure under Art.126(1)(f) of the Implementing Rules of the Financial Regulation. The possibility was foreseen in the original tender specifications, because the Joint Undertakings had just been established, which made it difficult to estimate long-term needs.

- IMI also participates where possible in the European Commission's framework contracts. In 2012, the most significant of these in usage volume terms was in the field of support services for event organisation.

- There were only two new larger tender procedures carried out in 2012. The table below gives the details on these including the procedure used in each case, the publication date, the award date and the name of the contractor(s). Only tenders with a value exceeding EUR 60,000 are listed here.

Tender procedures in 2012

Reference and subject	Procedure	Publication date	Award date	Contractor(s)
IMI/2012/SC/85 Service contract to provide bibliometric data analysis of IMI's projects.	Negotiated procedure with min. 5 candidates – Service contract	31/05/2012	11/07/2012	Thomson Reuters Scientific Inc., United States
IMI/2012/SC/139 Framework contract for the provision of meeting premises and related services.	Open procedure – Framework contract with a cascade of max. 3 contractors	22/09/2012	21/12/2012	1. Le Nouveau Palace, Belgium 2. Renaissance Hotel, Belgium 3. The Hotel, Belgium

6.5 Data Protection and Access to Documents

6.5.1 Data Protection

In 2012 a more comprehensive and systematic approach to data protection issues was implemented at the IMI JU. Improved communication with IMI staff, with the network and the Joint Undertakings data protection officers, and with the European Data Protection Supervisor (EDPS) services enabled effective implementation. In particular, internal consultation of the data protection officer has increased in the areas of science, human resources, communication and IT.

Prior-checking activities

Staff recruitment

- In 2012 IMI continue to follow-up the IMI prior-check notification on the selection and recruitment of staff (case 2011-872).

- There was no particular specificity on the processing operations in the field that required further reporting.

- On December 2012, the EDPS acknowledge that IMI JU have taken into account the recommendations made by adopting specific measures and procedures. The EDPS has noted 2 additional issues:

  – Indicate in the specific privacy statement the time limits for storage of data adopted on 28 March 2012,

  – Limit the period for blocking data.

These issues are being implemented.

Consultations

Clinical trials

- Following a prior checking notification of the European Medicines Agency (Case 2012-704) related to personal information in clinical study of the IMI project PROTECT WP4, the EDPS has issued an opinion in which EMA is considered one of the controllers of the personal data received.

Reporting

DPO status

- On May 2012 IMI collaborated to the report by the EDPS on appointment and tasks of the data protection officer, as part of monitoring of compliance of European Institutions and bodies.

- As an outcome of the report issued in December 2012, IMI complies with the requirements established by the EDPS for this function.

EDPS Survey

- Within the review process, the Data Protection Officers (DPO) from agencies and bodies were consulted including IMI.

- The findings of the survey were assessed by a consultant. The most important issue identified was the need to address real risks for data subjects. The areas of improvement were related to ensuring clarity of messages and dialogue with institutions. Relevant actions are included in IMI's DPO Roadmap.

Inspections

Video Surveillance

- The purpose of the inspection was to control of the existence, location and content of selected on-the-spot notices on video-surveillance cameras, its content and the availability of the policy on-line (case 2012-446).

- The inspection was extended to other EU institutions and bodies located in Brussels and was concluded by an implementation report by the EDPS.

- The EDPS recognised that IMI and the other Joint Undertakings are not the controller of the personal data regarding video-surveillance, but the owner of the building where the Joint Undertakings are located. Nonetheless, recommendations were issued and forwarded to the owner.

Network activities

Data Protection Officers meetings

- In 2012, the IMI DPO participated to 2 meetings of the network hosted by the European Chemicals Agency and European Central Bank respectively).

- The network meetings are an important forum to exchange best practices among DPO and to get awareness of EDPS activities, such as developments related to the new data protection directive.

Data Protection day

- IMI participated in the activities related to the data protection day 2012.

- For the 6th celebration of the data protection day information and a video message from Peter HUNSTINX, European Data Protection Supervisor, and Giovanni BUTARELLI, Assistant Supervisor, was disseminated to all IMI staff members.

Complaints

- There were no complaints to the EDPS to report in 2012.

Trainings/Communication activities

- Information on developments of data protection activities was provided to the staff during internal meetings.

Thematic Guidelines

Follow up table

EDPS GUIDELINES	STATUS	COMMENTS
Tasks, duties and powers of the Data Protection Officer	*concluded*	
Recruitment	*under finalisation*	
Staff evaluation	*preparatory work*	
Leave & Flexitime	*preparatory work*	Issued by the EDPS in December 2012
Video-surveillance	*not applicable*	IMI is not the controller of the personal data
Anti-harassment procedures	*not applicable*	Not yet developed at IMI
Administrative inquiries and disciplinary proceedings	*not applicable*	Not yet developed at IMI
Health data at work	*not applicable*	IMI does not manage health related data

Other activities

- In 2012 the IMI data protection webpage was reviewed.
- In addition, with the collaboration of the IT manager, data protection issues and disclaimers were included in IMI tools such for the IMI event management tool.
- The Executive Director took measures to implement EDPS' recommendation on recruitment processing operations.

6.5.2 Access to documents

- On 2012 IMI continued to promote transparency and access to information and documents through the IMI info-desk managed by the Communications team. About 800 requests were received in 2012. The info-desk facilitated public interaction on key issues and improved awareness of IMI activities and processes. In 2012, IMI JU drew up guidance regarding access to data related to IMI projects.

6.6 Internal control strategy and 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.

- In 2012, the robustness of the internal controls continued to rely on an efficient and effective combination of ex-ante and ex-post controls, adequate segregation of duties, established and documented processes and procedures, the promotion of ethical behavior and sound management. These are embedded across the organisation's administrative, support and grant management system and workflows.

- Within IMI, internal control issues and actions are systematically discussed and reviewed on a regular basis through weekly management meetings. In parallel, the internal control coordinator monitored on a quarterly basis the progress made towards achieving compliance and effectiveness of the internal controls system, including the bi-annual review and updating of the ICS Action Plan. In addition, at the end of 2012, an assessment of the compliance and effectiveness of the ICS was performed in order to identify opportunities for action and improvement for the following year.

- Risks that pose a threat to the achievement of IMI JU`s mission and objectives were also systematically identified, assessed and managed through the annual risk assessment exercise (RAE). The 2012 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 or will be taken by the Executive Office to reduce the impact of risks to an acceptable level.

- Concrete actions were taken during the year to strengthen internal controls prioritised in the Annual Implementation Plan for 2012. These included the development of the Compendium of Standard Operating Procedures (ICS8), the adoption of the Business Continuity Plan, duly tested with the support of RTD (ICS10) and the IT Security Policy and Framework (ICS12), an updated validation of the accounting system, the first internal audit assurance engagement by the Internal Audit Service of the Commission, the successful set up of IMI's new Document Management System and prompt follow up of audit findings and recommendations.

- Ex-post control of operational expenditure also played an important role in the overall internal control framework, with over fifty audits concluded during the year. As a follow-up to these audits, adequate mitigating measures are being put in place to correct the identified errors. The Action Plan includes the extension of audits findings of a systematic nature to other claims, continued audit work and recovery actions, the strengthening of ex-ante procedures as well as ongoing training and guidance to participants.

- IMI's internal control system can be considered as having reached an adequate level of maturity and is working as intended, given also the limited lifespan and size of the organisation. Within this context, the internal control effectiveness will continue to be monitored closely and reinforced in 2013 through:

  - measures to enhance the quality of the accounting information (ICS 13);
  - the finalisation and implementation of a new policy on independence and Conflict of Interest (ICS 8);
  - the establishment of an internal scorecard to better monitor performance and report on achievements (ICS12/ICS 9); and
  - more emphasis on fraud prevention and detection (ICS2).

7. BUILDING BLOCKS LEADING TO THE DECLARATION OF ASSURANCE

7.1 Background

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

- Under these requirements, the Annual Activity Report must include an overall picture and structured assessment of the sound management and the effectiveness of internal controls of the JU based on pre-set building blocks together with a Declaration of Assurance by the Executive Director in his capacity as Authorising Officer. The Declaration is intended to provide reasonable assurance, and possible reservations, on the accuracy and completeness of the information included in the report, on the use of resources for their intended purpose, as well as on the legality and regularity of the underlying transactions.

- For this evaluation, the relevant management information and reports on the following were used:

  - The performance and results of the JU and the projects it supports.
  - Risk management, governance and internal control issues.
  - Findings and conclusions of audits and independent reviews on the JU's systems, individual processes and the underlying transactions.
  - Stakeholders' feedback.

7.2 Building block 1: Assessment by management

Implementation of operational and administrative budgets

The budgets for 2012 were adopted by the Governing Board together with the corresponding Annual Implementation Plan on 22 December 2011.

Operational budget

- At the end of 2012, 39 operational payments were made for a total of EUR 103,81 million. Budget execution was therefore 100% (compared to 87% in 2011).

- The short average time to pay for pre-financing payments achieved in 2011 was maintained in 2012 (5 days).

- The average time to pay for cost claims increased from 54 days in 2011 to 60 days in 2012. Each payment represents the end of a complex validation ex-ante procedure that comprises of an operational review of the periodic report and the validation of all financial claims and certificates of financial statements submitted by participants in the project (including any adjustments for previous reporting periods).

- As expected a larger number of payments were made in 2012 when compared to the previous year (from 16 in 2011 to 26 in 2012), with the receipt of the first claims from Call 2 projects. There was one payment during this year that exceeded the 105 days from the receipt of the project report and deliverables (excluding any suspended time for incomplete information or outstanding replies to requested clarifications).

Budget year	Number of payments	Average time of report submission after the end of the reporting period* (days)	Average suspension period** (days)	Average time to pay (days)	Average processing time (days)	Payment on time %	Late payment %
2010	1	84	87	66	237	100	0
2011	16	88	62	54	205	94	6
2012	26	76	65	60	201	96	4

*including 60 contractual days for submission

** Suspension time refers to those periods when one or more of the reports or appropriate deliverables have not been supplied, or are not complete or if some clarifications or additional information is needed or there are doubts concerning the eligibility of costs claimed in the financial statement and/or additional checks are being conducted. The suspension is lifted from the date when the last report, deliverable or the additional information requested is received by the IMI JU, or where the IMI JU decides to proceed with an interim payment in part in accordance with Article II.5.4 of the Grant Agreement.

- IMI is taking direct actions to further shorten processing times for the payment of cost claims by providing guidance and organising workshops for participants on the applicable financial rules and the correct completion of the financial statements. In addition, internal workflows and key documents have been streamlined and simplified and IMI's core business application - SOFIA (Submission OF Information Application) is being enhanced to automate and further support the project-related processes. These measures are particularly critical in view of the increasing workload related to the processing and payment of cost claims.

Administrative Budget

- Details on the budget execution and the time to pay for administrative payments are provided in Section 6.1 on page 56-57.

Control Systems

- IMI JU's ex-ante controls form an integral part of the respective procedures, workflows and financial circuits for both the administrative and operational budgets. These controls are documented and enforced through internal policies, management decisions, documented procedures and templates as well as by a series of established internal checks and balances aimed at primarily preventing errors from entering the process and to also detect and correct errors once they have. Such controls may also be complemented, if concrete risks arise, by an independent external investigation.

- 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. Six reports of the independent observers in 2012 which reviewed the publication of the Calls, the selection of independent experts and the evaluations for Call 4 (Stages 1 and 2) Call 5 (Stages 1 and 2), Call 6 (Stage 1) and Call 7 (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.

- In the case of payments to beneficiaries, 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 Reports, 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).

- IMI also actively monitors the progress of the funded projects through the systematic review of technical reports and through interim reviews of each project. 14 interim reviews were held in 2012 and these had positive conclusions on the early achievements of the 13 Call 1 projects and a Call 2 project (refer to section 3.1)

Ex-post controls: audit and recoveries

- 2012 was the first full year of implementation of IMI JU's ex-post audit strategy. The Joint Undertaking's strategy is harmonised with the EC's FP7 audit strategy and is, similarly, intended to ensure the legality and regularity of the operational expenditure on a multiannual basis by systematically detecting and correcting errors. 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 and corrected in the relevant claims.

- The main legality and regularity indicator is the representative error rate detected by ex-post audits as defined in the ex-post audit strategy. Audits of 60 unique beneficiaries covering 69 cost statements of Call 1 projects were carried out in 2012 using external audit firms. Fifty-five of these (covering 64 claims) have been closed and are now being reviewed by IMI staff for the implementation of the required corrective and recovery actions. The resulting error rate based on these first closed audits is 5.76% and the estimated residual error rate is 3.68%. This result is based on a relatively limited number of concluded audits, and concentrated on beneficiaries from the first IMI projects which where new or had not yet been audited. For these audits a higher rate of error can be expected.
- The next batch of audits from the representative sample will cover claims validated by October 2012 of 40 unique beneficiaries from Call 1 and Call 2 projects. In line with the ex-post audit strategy, this sample is comprised of a combination of the largest beneficiaries and randomly selected entities. The results of these audits will provide IMI with a more complete view of the underlying error rate from the submitted claims.
- In addition, the first ex-post review of in-kind methodology and the financial audit of cost claims of an EFPIA participant were launched in October 2012 and both are expect to be concluded by Q1 2013. In parallel, in December 2012, two other audits were launched and these are scheduled to be finalised by Q3 2013. As part of an overall risk-based strategy, additional audits will be launched in 2013 in order to cover all the largest in-kind contributors in IMI JU projects.

Validation of the Accounting System by the Accounting Officer

- During the year, IMI JU's Accounting Officer followed up on the validation of the accounting system carried out in 2011 and presented in September 2012 an updated report on the findings and conclusions. The Accounting Officer concluded that there were no major shortcomings. In addition, improvements in the underlying systems since the previous exercise were noted. Nonetheless, the Accounting Officer highlighted areas where there is scope for further improvement and strengthening of the processes. These related to the need to: (1) establish a final methodology for the calculation of accruals for operational expenditure, (2) improve treasury management, archiving practices as well as supporting documentation in payment files, (3) finalise the updating of the internal manual of financial procedures, and (4) consider procuring an IT tool to support the registration and management of contracts and agreements at IMI JU. Actions have been taken or are being taken by management to address each of these recommendations including the strengthening of archiving practices and ensuring better supporting documentation. A final methodology for the calculation of accruals was defined. The updated manual of financial procedures was finalised and implemented as from 1 November 2012.

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

Internal Audit

- During 2012, the Internal Audit Service of the European Commission carried out an internal audit assurance engagement of the negotiation, grant agreement preparations and pre-financing processes of IMI JU.

- The IAS concluded that it had reasonable assurance regarding the achievement of the business objectives set up for Grant Agreement (negotiation, preparation and pre-financing) except for the following issues:

  - Management of conflicts of interests. IAS noted that IMI JU is aware of the crucial importance of the matter and is using diverse means at different levels to address it (communication, awareness raising, training, Code of good administrative behaviour) but lacked a comprehensive policy to manage potential conflicts of interests covering all aspects of operations and procedures a declaration of interest of the staff involved in the negotiation process. Therefore, IMI JU faced a reputational risk in case of litigation on the grounds of conflicts of interests or of lack of independence and objectivity of its staff.

  - Documentation of the negotiation process and its controls. IAS observed that IMI JU, as a recent organisation autonomous from the European Commission since November 2009, with limited staff, has given priority to the day-to-day operations and not to the establishment and documentation of procedures (relying mostly on the guidelines developed by the EC). The IAS recommended the approval and implementation of a documented procedure and guidelines, specific to IMI covering all aspects of the negotiation process (technical, legal, and financial) in order to mitigate the risk of non-harmonised or inconsistent negotiation, jeopardized continuity of the process in case of the absence of key staff as well as a failure of the objective of the negotiation.

  - IT application (SOFIA) used during the negotiation process. IAS recommended further development of SOFIA to manage the technical negotiation as well as allow an accurate on-line information trail of the changes done to financial and legal data by the project participants.

- The audit also identified major strengths and no shortcomings in the other two audited processes related to the preparation of the

Grant Agreements and in the proper calculation and payment without delay of pre-financing.

- The audit resulted in 11 recommendations, none of which being flagged as 'critical'. Three of the recommendations were classified as 'very important' and the others as 'important'. All have been accepted by IMI and are in the process of being implemented.

- During 2012, the Internal Audit Manager of IMI JU who also acts as the Internal Audit Capability (IAC) of the organisation, was substantially involved in the setting up and implementation of IMI JU's ex-post audit strategy, a top priority for IMI JU's overall control and governance. The results of the first 55 closed audits are described in 7.2 above. In parallel, the Internal Audit Manager supported management through on-going consultancy activities and support related to governance, internal control and risk management issues.

External Audit

- In the report of the European Court of Auditors on the 2011 Accounts issued in November 2012, eight key recommendations were made.

- The most critical was the qualified opinion on the legality and the regularity of the transactions underlying the accounts. However, this qualification was linked only to the detected error rate for intermediate payments which accounted for 20% of total payments made by IMI JU in 2011. All other transactions (covering 80% of the payments in 2011) were considered by the Court to be, in all material respects, legal and regular.

- Moreover, the errors on which the Court based its qualified opinion were detected by IMI JU's own internal ex-post controls during the first full year of implementation and concrete remedial actions are being taken to correct these errors and reduce the error rate (refer to the analysis and action plan in 7.7 below).

- Considerable progress has been made on the other seven recommendations related to the implementation of the budget in terms of both commitment and payment appropriations as well as the clarity of the Governing Board decision on the approval of carry-overs (refer to the Financial Tables and graphs in 6.1), the timely launch of Calls for Proposals and the degree of utilisation of the total EC contribution for IMI (as outlined in chapter 4), the continued strengthening of internal controls and follow-up actions (presented in 6.6 and 7.2), the launch of internal audit assurance work (described above), the continued formalisation of IT policies and systems (reported in 6.3) and the introduction of a reservation in the Declaration of Assurance to reflect the limited results of ex-post controls (documented in 7.7 and 8).

7.4 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 2011.

Follow-up of the European Court of Auditors' recommendations

- Actions have already taken to promptly implement the recommendations of the Court in their report on the 2011 Accounts issued in November 2012 (reported in 7.3 above). In addition, other recommendations of the Court from previous years have been fully implemented. These include the clarification on the role of Internal Audit Function and the Commission's Internal Audit Service, the signature of the Host State Agreement, and

the approval of the methodology for the evaluation of in-kind contributions by EFPIA companies. Significant progress has also been made on the implementation of the budget in terms of both commitment and payment appropriations and the implementation of the internal control and financial reporting system.

Follow-up of the IAS and IAC risk assessment of 2011

- The joint IAS and IAC exercise led to the recommendation of six key areas of high risk, namely 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. All of these recommended measures and actions have been implemented.

7.5 Building block 4: Assurance received from other Authorising Officers

Not applicable.

7.6 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.

7.7 Reservations

- For claims submitted by beneficiaries, the representative error rate from the first 55 audits of 64 cost claims is 5.76%, but the precision of the result is limited as this sample was on the first claims from Call 1 projects and on mostly unaudited or new beneficiaries where a higher error rate can be expected. The final representative error rate for this first sample can increase to 8 – 9 % if the draft findings of the remaining audits in the sample are confirmed in the final audits reports.
- The residual error rate based on these first 55 audit results and their impact on the overall population of the audited period is 3.68%. This rate should develop as more audits are closed and more corrections and recoveries are undertaken. At this early stages of the ex-post audit process, the 'cleaning effect' of implementation and extension of audit results does not yet have a significant effect in lowering the error rate.
- Taking into account these first audit results as well as the similar experience of the European Commission in the management and control of research grants, it is not possible at this stage to state that by the end of the programming period the residual error rate will be below the materiality threshold as defined in Annex B 'Materiality Criteria'.
- In addition, as there are as yet insufficient results on the first ex-post review of in-kind methodologies and the risk-based financial audits of declared in-kind contributions, it is also not possible at this early stage of the process to reasonably determined whether the residual error rate for the declared in-kind contributions will also be below the 2% threshold at the end of the IMI programme.
- For these reasons, IMI JU introduces a reservation for its research programme.

Action Plan to address the reservation

The reduction of errors will be addressed through the following actions:

- The continued systematic launch of ex-post audits of beneficiaries and EFPIA participants together with the resulting corrective and recovery actions.

- The strengthening of ex-ante control procedures to allow higher detection and correction of errors before acceptance without increasing unduly the complexity and the processing time taken to pay beneficiaries and accept declarations of in-kind contributions from EFPIA companies. For this purpose, in 2012 IMI improved its checklists and internal procedures for the validation and acceptance of cost claims.

- Training actions through guidance and workshops for beneficiaries and EFPIA participants on IMI financial rules.

- Monitoring of the financial impact of identified errors, which might be lower, over the multi-annual period.

Title of the reservation, including the scope	Reservation concerning the rate of the residual errors with regard to the accuracy of cost claims submitted by IMI JU participants
Activity and amount	Payment appropriations related to intermediate payments to beneficiaries: EUR 33.2 million. Estimated in-kind contribution by EFPIA companies accrued under operational expenditure: 1. Cost claims € 59,688,744.38 2. In-kind contribution € 59,970,805 (Accrual 2012 only)
Reason for the reservation	At the end of 2012 it is not possible to state with certainty that the residual error rate of the level of financial impact of identified errors will fall below the materiality threshold at the end of the multi-annual period.
Materiality criterion/criteria	The materiality criterion is the residual error rate which is the level of errors that remain undetected and uncorrected by the end of the IMI JU programme. The control objective is to ensure that the residual error rate on the overall population is below 2% at the end of the IMI JU programme. As long as it cannot (as yet) be reasonably assured that the residual error rate is below 2% at the end of the reporting year a reservation would (still) be made.
Quantification of the impact	In the case of beneficiaries, the maximum impact is calculated by multiplying the estimate residual error rate in favour of IMI JU based on the first audit results of representative audits of beneficiaries as at the end of 2012 by the amount of intermediate payments made to them on the basis of submitted cost claims made in 2012. The estimated impact on cost claims submitted by beneficiaries is € 1,2 million. With regard to the declared in-kind contributions, it is still early in the ex-post audit process to quantify and determine the impact of the reservation as the first ex-post reviews of certified methodologies for the calculation of in-kind contributions and the audits of financial statements are on-going.

Title of the reservation, including the scope	Reservation concerning the rate of the residual errors with regard to the accuracy of cost claims submitted by IMI JU participants
Impact on the assurance	This reservation has an impact on the legality and regularity of the affected transactions, i.e. intermediate payments made by IMI JU against submitted cost claims from beneficiaries. It can also lead to adjustments in the total reported in-kind contributions.
Responsibility for the weakness and its correction	The principal underlying reason is the complexity of the eligibility rules as laid down in the basic acts decided by the Legislative Authorities. IMI JU is responsible for the management and control systems. Participants and certifying auditors are responsible for the declaration of costs and for audit certificates respectively. Within these parameters, IMI JU's remedial action is carried out through ex-ante controls, ex-post audits, the systematic correction of detected errors, as well as through on-going guidance, workshops and feedback to participants and certifying auditors.
Corrective action	The reduction of errors will be addressed through the following actions: The continued systematic launch of ex-post audits as well as corrective and recovery actions. The review and fine-tuning of ex-ante control procedures to allow higher detection and correction of errors before acceptance of cost claims whilst at the same time avoiding undue increase in the complexity and the processing time taken to pay beneficiaries and accept declarations of in-kind contributions from EFPIA companies. Initiatives to pre-empt and stem the occurrence of errors in cost claims and audit certificates submitted by participants through guidance and workshops for beneficiaries and EFPIA participants. Monitoring the actual financial impact of the identified errors, which can ultimately be lower, over the multi-annual period, than what is indicated by the current estimated error rates based on the audit results on the first cost claims received from beneficiaries.

7.8 Overall conclusions on the combined impact of the reservations on the Declaration as a whole

- No qualification is to be made on IMI JU's policy activities. There is also no reservation on the procedures relating to the selection of participants for IMI JU projects and the corresponding underlying financial operations (legal and financial commitments). This is also the case for IMI JU payments relating to administrative expenditure and procurement, as well as for pre-financing payments for grants.
- The accounts that may be affected by the errors are expenditure against cost claims of IMI JU participants.

8. STATEMENT OF REASONABLE ASSURANCE

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 results of the self-assessment, ex-post controls, the work of the internal audit capability, the observations of the Internal Audit Service and the lessons learnt from the reports of the European Court of Auditors for the years prior to the year of declaration;

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

However the following reservation should be noted:

The reservation concerning the rate of residual errors with regard to the accuracy of cost claims submitted by participants of IMI JU grants.

Signed in Brussels, 27 February 2013

Michel Goldman, MD, PhD
Executive Director

ANNEX A - FINAL ANNUAL ACCOUNTS FOR 2012

ASSETS

Heading	Account Description	G/L acct	Balance period 2012 EUR	Balance period 2011 EUR
I. NON-CURRENT ASSETS			**156,508,538.41**	**88,993,954.34**
Intangible fixed assets		21000000	**0.00**	**0.00**
Computer software			**177,506.24**	**256,674.08**
	Purchase price	21001001	350,752.37	342,232.11
	Depreciation	21008001	-173,246.13	-85,558.03
Tangible fixed assets				
Computer hardware			**50,717.41**	**85,838.60**
	Purchase price	24101001	126,647.91	123,702.17
	Depreciation	24108001	-75,930.50	-37,863.57
Office furniture			**175,546.52**	**180,498.38**
	Purchase price	24001001	227,964.36	205,274.10
	Depreciation	24008001	-52,417.84	-24,775.72
Long - term prefinancing		29911100	**156,104,768.24**	**88,470,943.28**
II. CURRENT ASSETS			**12,247,792.09**	**17,192,536.45**
Short - term receivables			**4,261,488.19**	**1,761,495.36**
	Receivable from EFPIA	40001000	1,410,000.00	1,660,162.00
	Receivable from other JU	40005300	2,783.51	2,906.72
	Pre-financing (Adminitrative Expenses)	40601100	16,270.66	0.00
	Pre-financing (Operational Expenses)	40601200	2,714,385.35	
	Bank interest to be received	49100000	101,700.29	94,579.09
	Advances on missions	45321000	0.00	3,133.70
	Advances on salaries	45311000	1,350.00	713.85
	Staff	40007000	0.00	0.00
	Cautions	42902000	296.78	0.00
	Deferred charges	49000000	14,701.60	0.00
Cash & Cash equivalents			**7,986,303.90**	**15,431,041.09**
Cash at banks			*7,986,303.90*	*15,431,041.09*
		55023000	7,986,303.90	15,431,041.09
Cash in transit		56023000	0.00	0.00
TOTAL ASSETS			**168,756,330.50**	**106,186,490.79**

LIABILITIES

Heading	Account Description	G/L acct	Balance period 2012 EUR	Balance period 2011 EUR
III. NET ASSETS			**-64,298,603.45**	**-22,986,571.92**
Members Contributions in Cash		14400000	**-230,731,219.90**	**-128,879,681.75**
European Commission			**-222,165,851.85**	**-124,381,891.85**
EFPIA			**-8,565,368.05**	**-4,497,789.90**
Members Contributions in Kind		14401000	**-52,005,654.00**	
Accumulated contributions used in previous years		14000000	**105,893,109.83**	**28,385,255.77**
result of the year: surplus(-) / deficit (+))			**112,545,160.62**	**77,507,854.06**
TOTAL NET ASSETS			**-64,298,603.45**	**-22,986,571.92**
IV. NON-CURRENT LIABILITIES			**0.00**	**0.00**
Long term provision		16320000	**0.00**	**0.00**
V. CURRENT LIABILITIES			**-104,457,727.05**	**-83,199,918.87**
Accounts Payables			**-126,899.05**	**-99,373.76**
	Accounts payables with consolidate entities	44005100		0.00
	Grant beneficiaries		*-4,314,668.72*	*0.00*
		44001000	0.00	0.00
		44004000	-4,314,668.72	0.00
	Suppliers		*4,187,769.67*	*-99,373.76*
		44001000	-4,008,438.42	-102,315.29
		44007000	-3,839.64	-638.59
	Eligibility to be confirmed	49030000	8,091,026.63	3,580.12
	Verification - invoices	49040000	109,021.10	0.00
Other accounts payables			**-104,330,828.00**	**-83,100,545.11**
	Taxes, salaries and social security		*-36.64*	*-15.70*
	Contribution for pension costs	45491000		0.00
	Contribution for sicknesscosts	45492000		0.00
	Contribution for taxes	45493000		0.00
	Contribution for accident costs	45622000		0.00
	Contribution for unemployment	45800000		0.00
	Contribution for nurserycosts	46207000	-36.64	-15.70
	Net salary to be paid	47530100		0.00
	Accrued charges:		*-104,330,791.36*	*-83,100,529.41*
	Estimated "in-kind" contribution of EFPIA members	44520000	-50,307,900.00	-52,755,564.11
	Cost claims received after the year end	49030000		0.00
	Accrued administrative charges	49055000	-517,419.40	-386,812.95
	Accrued operational cost claims	49055000	-53,505,471.96	-29,958,152.35
TOTAL LIABILITIES			**-104,457,727.05**	**-83,199,918.87**
TOTAL NET ASSETS & LIABILITIES			**-168,756,330.50**	**-106,186,490.79**

Economic Outturn Account

Heading	Account Description	G/L acct	Balance period 2012 EUR	Balance period 2011 EUR
I. OPERATING REVENUES			**26,658.59**	**289,966.27**
Miscellaneous income from other JU		74025000	**26,658.59**	**85,065.89**
Other Income	**(Fixes assets)**	74000700		**204,900.38**
II. OPERATING EXPENSES			**-113,096,889.18**	**-78,341,758.41**
Administrative Expenses			**-6,531,355.31**	**-5,201,608.12**
	Experts & Related Expenses	61085000	-619,070.59	-596,303.73
	Fixed Assets related expenses (Depreciation of Assets)	63020000	-153,779.67	-141,259.30
	Other administrative expenses		*-1,913,597.31*	*-1,402,533.72*
	Office supplies	61010000	-74,407.46	-64,124.75
	Communications& publications	61020000	-189,567.91	-159,000.99
	Publicity & Legal expenses	61030000	-8,625.00	0.00
	Miscelleneous insurances	61040000	-14.34	-20.00
	Transport expenses	61050000	-6,229.22	-4,478.45
	Recruitment costs	61060000	-456.47	-708.84
	Training costs	61070000	-62,827.84	-12,908.19
	Missions costs	61080000	-138,792.64	-114,443.85
	IT-development costs	61094020	-42,259.62	-104,627.71
	IT-operational costs	61094030	-421,201.22	-502,187.27
	Other external services non IT	61095000	-850,133.94	-339,976.13
	Other administrative expenses with Consolidated entities	61100000	-119,081.65	-100,057.54
	Rent expenses		*-360,735.77*	*-331,907.60*
	Rent of land & buildings	61001000	-355,918.35	-278,176.93
	Other rental expenses	61001500	-4,817.42	-53,730.67
	Staff expenses		*-3,484,171.97*	*-2,729,603.77*
	Staff costs	62000000	-2,755,870.81	-2,174,824.57
	Employer's contribution to unemployment costs	62020000	-30,921.60	-25,298.20
	Employer's contribution to Social Security	62030000	-89,520.09	-78,690.16
	Social activities	62040000	-52,534.24	-23,050.30
	Staff allowances	62050000	-555,325.23	-427,740.54
Operational Expenses			**-106,565,533.87**	**-73,140,150.29**
	Cost Claims paid to beneficiairies	60810000	-57,007,543.98	-34,545,033.18
	Contribution in-kind	60820000	-49,557,989.89	-38,595,117.11
DEFICIT FROM OPERATING ACTIVITIES			**-113,070,230.59**	**-78,051,792.14**
III. FINANCIAL REVENUE			**527,611.87**	**546,603.88**
Interest Revenue			**527,611.87**	**546,603.88**
	Prefinancing Interest	74005000	52,864.52	19,285.68
	Bank Interest	75016000	474,655.28	525,839.39
	Exchange Gain	74850000	92.07	1,478.81
IV. FINANCIAL EXPENSES			**-2,541.90**	**-2,665.80**
Financial Expenses and others			**-2,476.90**	**-2,650.80**
	Exchange Loss	64850000	-386.12	-1,979.17
	Interest on late payment	65010000	-1,708.27	-669.28
	Extraordinary losses	69000000	-382.51	-2.35
Bank fees		65025000	**-65.00**	**-15.00**
SURPLUS FROM NON-OPERATING ACTIVITIES			**525,069.97**	**543,938.08**
CONTRIBUTION FROM MEMBERS USED DURING THE YEAR			**-112,545,160.62**	**-77,507,854.06**

ANNEX B - MATERIALITY CRITERIA

- The control objective is to ensure that the residual error rate, i.e. the level of errors which remain undetected and uncorrected, does not exceed 2% by the end of IMI programme's lifecycle. The guidance of the European Court of Auditors as well as the applicable EC standards were taken in account for defining the 2% threshold. In addition, a qualitative and quantitative judgment was applied 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.

- 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 following considerations were taken into account:

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

- Moreover, basing materiality solely on operational expenditure for one year may not provide the most appropriate basis for judgements, as such expenditure often includes significant levels of pre-financing expenditure (e.g. in 2012, 68% of all operational expenditure was for pre-financing and only 32% was for intermediate payments). Pre-financing expenditure is very low risk, being paid automatically after the signing of the contract with the beneficiary.

- On the other hand, as the residual error rate for cost claims is not (yet) evidently below 2% at the end of a reporting year within the IMI programme's lifecycle, the likelihood of introducing a reservation for IMI grants is higher unless there is some other management information which indicates otherwise. The question of being on track towards this objective will nonetheless be (re)assessed annually, in view of the results of the implementation of the ex-post audit strategy and taking into account both the frequency and importance of the errors found as well as a cost-benefit analysis of the effort needed to detect and correct them.

ANNEX C - INTERNAL CONTROL FOR BUDGET IMPLEMENTATION

Management mode key figures

Details on budget execution and time to pay for administrative and operational expenditures are provided in section 2.3, 2.4 and section 6.1.

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 Executive Director acts as Authorising Officer with authority being delegated to the Head of Administration and Finance and, when necessary as back-up, to another member of staff. 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. The Executive Office also has an Internal Control Coordinator (ICC), an Internal Audit Capability (IAC) and the Internal Auditor (Internal Audit Service of the European Commission, IAS) to monitor and independently assess governance, management and control systems.

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.

- 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 meetings with stakeholders such as the SRG, ILG, and stakeholders, special information days linked to the different calls; 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 submit periodic reports which include financial statements and an explanation on the use of resources for all participants including EFPIA companies.
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 methodologies that are accepted by the EC and/or IMI.
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 participant 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 have also been systematically 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 main objective of the ex-post audit activity is to provide an adequate indication of the effectiveness of ex-ante controls as well as on the accuracy, 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 financial statements to be audited are based on a sampling strategy that

ensures comprehensive coverage of the audit population. This sampling includes primarily representative sampling to estimate error rates in the total population of beneficiaries, systematic coverage of the "largest beneficiaries" (with due consideration to any overlapping activity by the EC). It can also include risk-based sampling from the overall population of participants including EFPIA companies.

- The first ex-post audits were concluded in 2012 and new audits are continuously being launched to cover new cost claims. In parallel, follow-up corrective and preventive action is being taken and any amounts found to have been paid in excess will be recovered. Systematic errors detected on the audited contracts will also be corrected in the relevant non-audited claims. 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. Preventive measures, such as workshops and guidance to participants and auditors, further strengthening of ex-ante controls are also being implemented.

- Moreover, the first ex-post review of the certified in-kind methodology of an EFPIA company together with a sample of declared in-kind contribution was carried out in Q4 2012 and is at draft reporting stage. Similar exercises with two other EFPIA companies were launched in December 2012. This approach will be continued with other EFPIA companies particularly the largest contributors of in-kind.

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 planned or ad hoc checks carried out by the ICC and the IAC.

- An in-depth exercise is also carried out regularly (updated once per year) by the Accounting Officer to validate the underlying processes supporting the accounting system.

- Ex-post audits also provide an important source of information on the extent to which internal ex-ante control and verification systems are functioning as intended and effectively.

Monitoring of performance

- On a day-to-day basis, progress against objectives/deadlines and performance is discussed and monitored through regular team, management and cross-functional meetings. Information is presented in these meetings. Issues and risks (e.g. on call management status) are flagged, addressed and tracked.

- More specifically, systematic monitoring and tracking is undertaken by top and functional managers on specific processes and areas of activity, such as on the accounting system, on the evaluation stages (by independent observers), on internal controls and risk management, on finance issues and budget implementation, on the implementation of audit findings and actions arising from the annual risk assessment, on the impact of communication activities, IT, HR, etc.

- In addition, throughout the year, KPIs on the scientific achievements and results of IMI JU as well as on the operational efficiency of the organisation are systematically compiled and reported. The latter cover critical issues such as time-to-pay, time-to-grant, budget execution, etc.

- Monitoring is also done by the ICC and IAC on specific issues and the implementation of action plans. In addition, as from 2012, the IAS annually selects an audit topic on which it carries out primarily an audit assurance engagement with recommendation on improvements. In 2012, the IAS audit focused on the negotiations, grant agreement preparations and pre-financing processes. The report was forwarded to the Board and stakeholders, an action.

- In parallel, the European Court of Auditors carries out financial and compliance audits of the Joint Undertaking and provides draft and final audit reports on the reliability, legality and regularity issues. It also highlights any concerns and observations resulting from its audits. In 2012, the ECA also included IMI JU in a performance audit that was conducting on FP7 instruments. The results of this audit are expected to be published in 2013.

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 facilitates 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 GB 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.