Innovative Medicines Initiative

Annual Activity Report
2013

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FOREWORD

The year 2013 marked the end of the first phase of the Innovative Medicines Initiative (IMI) during which 11 Calls for proposals were launched. This will lead to the establishment of over 50 public-private consortia. IMI is now a mature organisation that is recognised worldwide as a model public-private partnership (PPP) in healthcare.

As this report demonstrates, 2013 was IMI's most fruitful year since its launch. The projects supported by IMI continue to address issues of great relevance to European citizens such as antimicrobial resistance, dementia and diabetes. More broadly, by creating new relationships between the multiple stakeholders in healthcare, IMI exerts a significant influence on pharmaceutical research and development for the common benefit of industry and society.

Importantly, the added value of IMI for the European Union (EU) has been documented by the second interim review conducted by independent experts on behalf of the European Commission (EC).

Furthermore, the entire budget has been executed, ensuring that the public and private resources are invested in the best interest of all parties.

On this solid basis, it is now time to prepare for IMI 2, the new PPP dedicated to research and innovation in healthcare under Horizon 2020. With its efficient and highly-motivated staff, the IMI Executive Office is fully committed to continuing its mission of facilitator to achieve the ambitious goals set for IMI 2, which should result in concrete improvements in the standard of care across the EU.

All this has been and will be possible owing to the efficient collaboration between the EC services and the European Federation of Pharmaceutical Industries and Associations (EFPIA), with the essential support of the IMI Scientific Committee and the IMI States Representatives Group (SRG). Furthermore, tribute should be paid to the over 6 000 scientists who every day contribute to IMI's reputation as a European flagship for pharmaceutical research.

14 February 2014
Michel Goldman, MD, PhD
IMI Executive Director

1. ACHIEVING IMI'S STRATEGIC OBJECTIVES

IMI, the largest PPP in the life sciences, was set up in 2008 with the important goal of significantly improving the efficiency and effectiveness of the drug development process and thereby helping to bring more effective and safer innovative medicines to patients.

At the end of its first phase, the programme has reached maturity and therefore its performance, impact on, and value to the stakeholders can be better assessed.

However, developing metrics to measure a PPP's performance is challenging. To quote from the recent 'Consortiopedia' report by FasterCures Milken Institute, there are currently 'no systematic methods that can be used to compare across consortia, with many organisations relying on those used by academic researchers to assess the impact of interdisciplinary collaborations such as number of patents, number of publications and the quality of journals, or number of citations'[1]. The report concludes: 'There is a need to move beyond these metrics and develop more quantitative measures of output that are meaningful to the audiences interested in the consortium.'

IMI's efforts to measure and analyse its output have evolved considerably since the initial key performance indicator (KPI) framework set out in 2011, and today IMI applies a mixture of metrics and qualitative assessments to measure the performance and impact of the programme, see the following table. These reflect the strategic objectives that were set out by the Council Regulation at the inception of IMI, notably to support coordinated 'non-competitive pharmaceutical research and development (R&D)' to overcome the research bottlenecks in the drug development process, by:

- increasing the research investment in the biopharmaceutical sector;
- pooling resources and fostering collaboration between the public and private sectors;
- promoting the involvement of small and medium-sized enterprises (SMEs) in its activities;
- implementing the research priorities as set out in the Strategic Research Agenda (SRA).

Nevertheless, IMI is convinced that its metrics can be developed and optimised further, and in collaboration with leaders in the field, is working on producing a reliable assessment framework that would be suitable to a new public-private and multi-sector collaboration model such as IMI.

Assessment of project achievements

An extensive analysis of IMI's ongoing projects has been performed by extracting project achievements from progress reports of the projects, interim reviews, and 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 the 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 patients to optimise data sharing and the analysis of 'big data' for the benefit of patients and industry.

[1] http://www.fastercures.org/reports/view/39

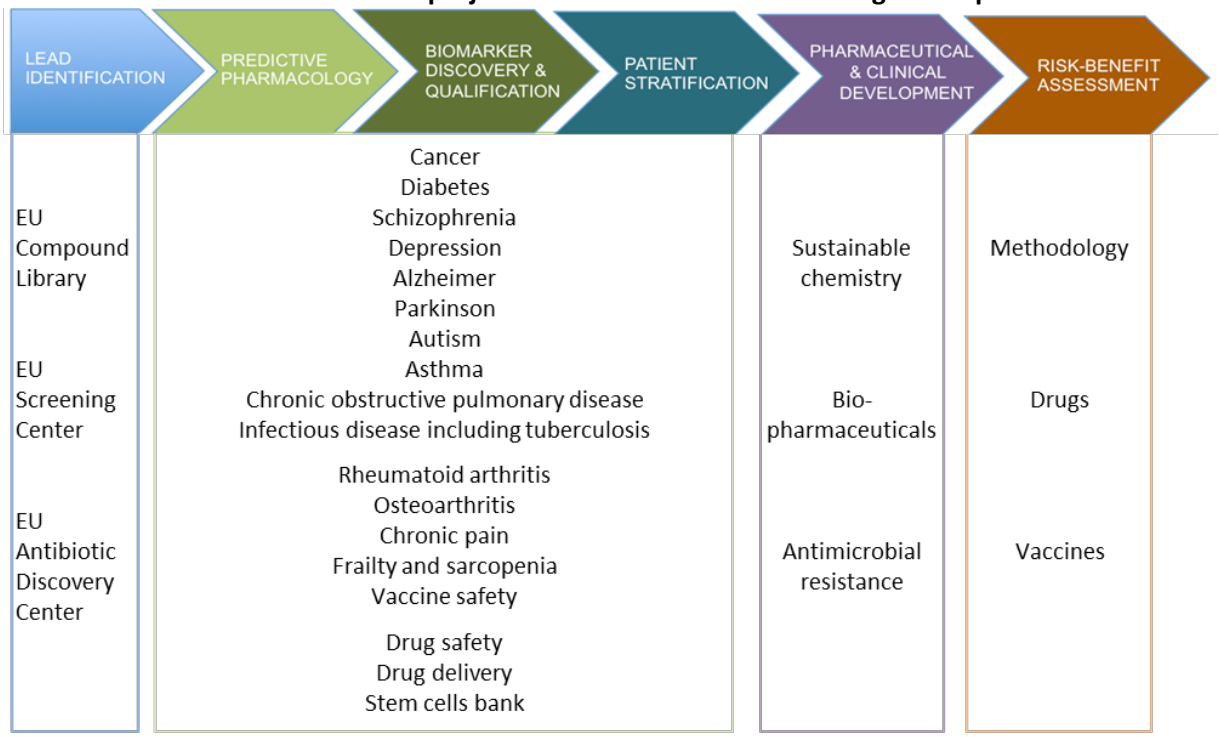
No.	KPI		
Reinforce pharmaceutical R&D in Europe by addressing bottlenecks and gaps in drug research		Target 2013	Results
1	The extent to which IMI projects cover the value chain of drug development	Qualitative assessment	Analysis was performed and results are reported in section 1.1
2	Percentage of projects achieving 75% of pre-set milestones within the first two years from the launch of the projects	▪ ≥90%	▪ 68% This shows the status at the end of the first two reporting periods of Calls 1 and 2 projects and at the end of the first reporting period for the more recently launched projects in Calls 3 and 4.
3	Measurable outputs in terms of: ▪ biomarkers, tools and models qualified for use in drug development; ▪ validated standards, measurements, methodologies, models, simulation technologies, tools and platforms successfully integrated in the R&D process; ▪ Students/scientists enrolled in education and training activities.	Quantitative and qualitative assessment	Analysis was performed and results are reported in section 1.2.2
4	Bibliometric indicator: Citation scores of project publications	Quantitative and qualitative assessment	Analysis was performed and results are reported in section 1.2.1
5	▪ Percentage of participants in signed Grant Agreements that are SMEs ▪ Percentage of overall budget for projects allocated to SMEs	▪ ≥13% ▪ ≥15%	▪ 15.2% ▪ 18.5%
6	Number of new ventures/collaborations, business activities, patents and licenses resulting from projects	Quantitative and qualitative assessment	Analysis was performed and results are reported in section 1.2.3 and 1.4
7	Impact on societal and healthcare challenges	Collect preliminary indications on the impact on society and healthcare from ongoing projects	Analysis was performed and results are reported in section 1.2.4
Maximise the Efficiency and Effectiveness of the Executive Office		**Target 2013**	**Results**
8	Average Time to Pay	▪ Pre-financing payments: ≤15 days ▪ Interim payments to beneficiaries: ≤45 days	▪ 18 days ▪ 66 days
9	Average Time to Grant	▪ ≤290 days	▪ 279 (from EOI submission to GA signature) ▪ 149 (from FPP submission to GA signature
10	Average monthly visitors to the IMI website	▪ ≥7 000 unique users	▪ 11 081
11	Percentage of filled positions	▪ 100%	▪ 100%
12	Annual budget execution	Running costs: ▪ 100% commitment and payment appropriations Operational costs: ▪ commitment appropriations as close as possible to 100% but ≥95% ▪ payment appropriations as close as possible to 100% but ≥90%	Running costs: ▪ Commitment 84.7% ▪ Payment 69.6% Operational costs: Commitment 100% Payment 99.4%

1.1 Implementation of the Strategic Research Agenda of IMI

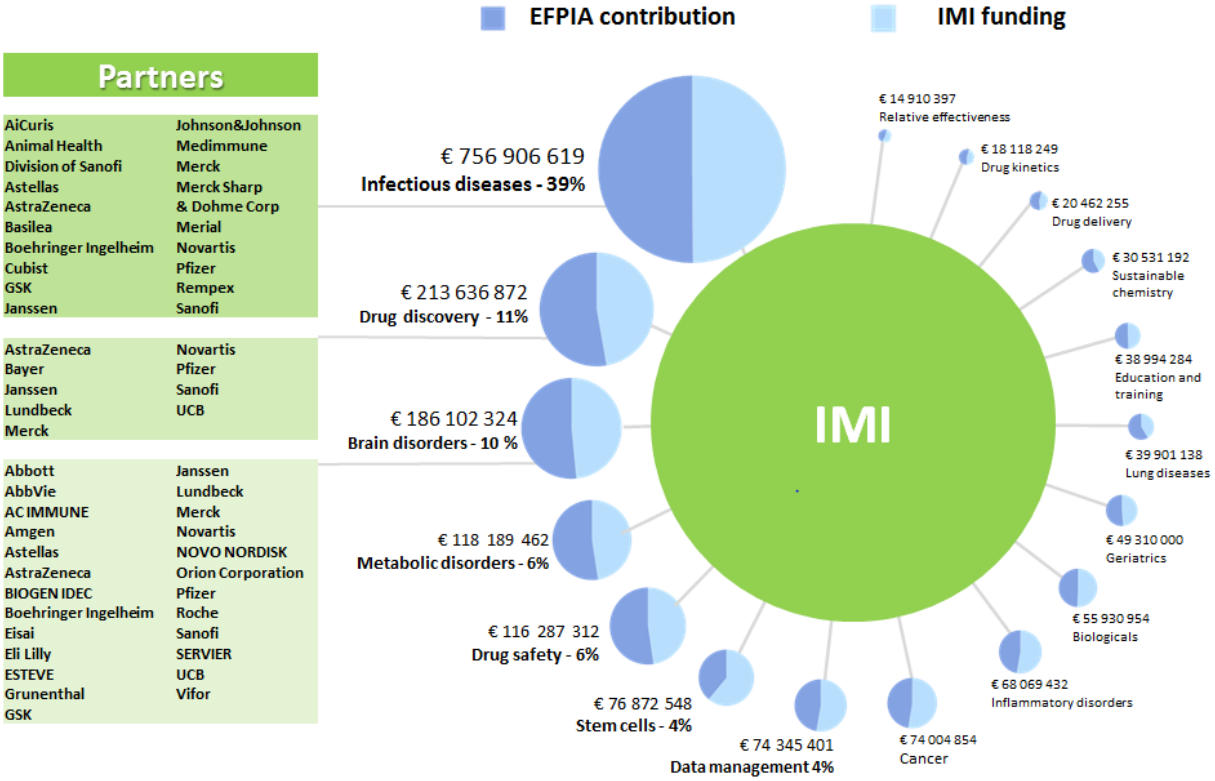
The first IMI Call for proposals was launched in April 2008. Since then IMI has launched 11 Calls for proposals and committed its entire budget envelope. Currently, there are 46 ongoing projects; once the last projects from the 11th Call are launched, IMI will have created a total of 59 projects. A key mission, and achievement, of the Executive Office team (36 people) has been to facilitate the mobilisation of the stakeholders and the creation of the networks behind these projects. It is estimated that these projects involve more than 6 000 scientists and 1 296 teams.

The content of IMI portfolio, as envisioned in the initial IMI Strategic Research Agenda (SRA) developed in 2007, includes projects focused on drug discovery and the early stages of the drug development process, as well as on education and training (E&T). However the trend towards later phases of the value chain such as clinical development and risk-benefit assessment, as well as an expansion into chemical development and pharmaceutical science, becomes more visible with Calls launched after the update of the SRA in 2011. From Call 5 onward there has been a shift towards 'think big' projects such as the European Lead Factory (ELF), and the antimicrobial resistance programme New Drugs for Bad Bugs (ND4BB). Moreover, efforts have been made towards creation of focused platforms where projects active in the same area work collaboratively in a legal framework that fosters synergies, complementarities and lessons learnt to optimise impact and resource exploitation. The figure below represents a mapping of current IMI activities according to the value chain of drug development and scientific or disease areas.

Extent to which IMI projects cover the value chain of drug development



The IMI portfolio is broad and comprehensively covers the full spectrum of the R&D value chain as well as many key disease and interest areas. The following figure[2] presents the breakdown of the IMI budget by the scientific areas supported and the ratio of IMI funding versus in kind contribution from EFPIA companies, as well as the list of industrial partners involved in the top three research areas.



1.2 IMI project output assessment

1.2.1 Bibliometric outputs

One of the traditional ways of measuring scientific output is via bibliometric analysis, which analyses how many scientific papers have been produced by a given group (in this case, IMI projects), what journals they were published in, and how often they have been cited by other researchers in subsequent publications. IMI conducts these analyses with the assistance of Thomson Reuters. The latest data has been is based on publications resulting from IMI project up to 31 December 2013.

657 PUBLICATIONS

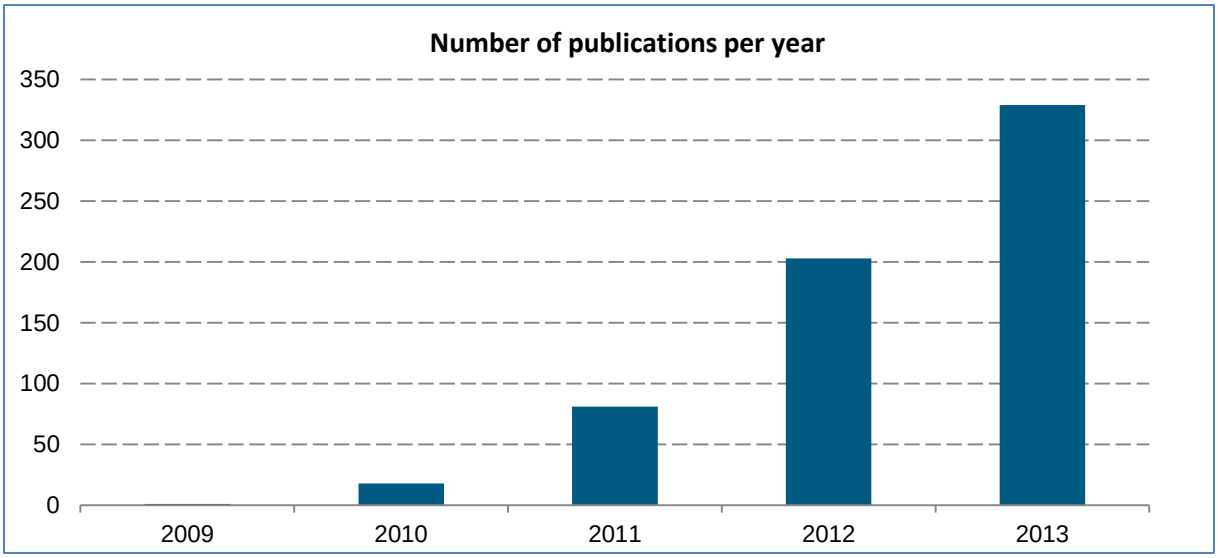
3709 CITATIONS

2.05 CITATION IMPACT vs. 1.15 EU average

24% HIGHLY CITED

The results show that the overall volume of IMI project research has increased rapidly since 2009 and the initiative continues to show rapid growth, as illustrated in the graph below. By 31 December 2013, IMI projects had produced 657 publications (629 of which are indexed in the Web of Science), half of which were published in 2013. It is expected that publication output will continue to raise as the number of projects increases and those projects yield results for publication.

[2] This diagram is adapted from *Nature Medicine* 20, 5 (2014) |News –'Infectious disease leads in first phase of Europe's IMI effort' published online on 07 January 2014 at http://www.nature.com/nm/journal/v20/n1/full/nm0114-5.html.



Source: Thomson Reuters analysis 2014

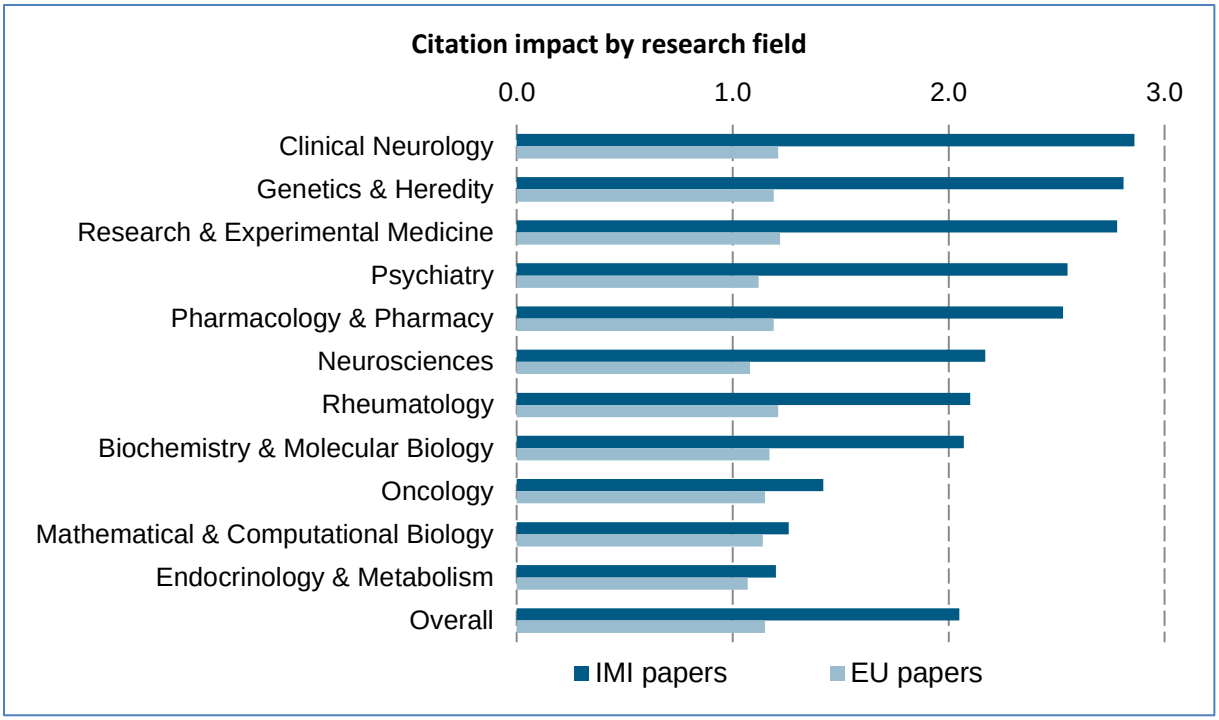
- IMI project publications have been published in a total of 301 journals, and 74.4% of papers were published in top quartile journals (determined by journal impact factor), including JAMA (the Journal of the American Medical Association), Science and Nature Publishing Group titles.

- The analysis also reveals that 24.4% of papers from IMI projects are 'highly cited', meaning they are in the top 10% of papers by journal category and year of publication.

- The average journal impact factor of all the journals in which IMI project publications have been published is 6.05.

- The citation impact of papers associated with IMI projects is internationally influential, with an average citation impact average of 2.05 for the four-year period 2010-2013 (compared to the world baseline of 1.0). This is a substantial increase since 2012 (when the average citation impact was 1.55) and indicates that the quality of IMI research has not only been maintained but has increased while output has grown. In comparison, the EU's average citation impact relative to world baseline for the same four-year period in similar research fields was 1.15.

- IMI project research published in, clinical neurology and genetics & heredity, research & experimental medicine as well as psychiatry 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. Hot papers are those which gather citations at a faster than average rate and may represent breakthroughs in the field(s) to which they relate.



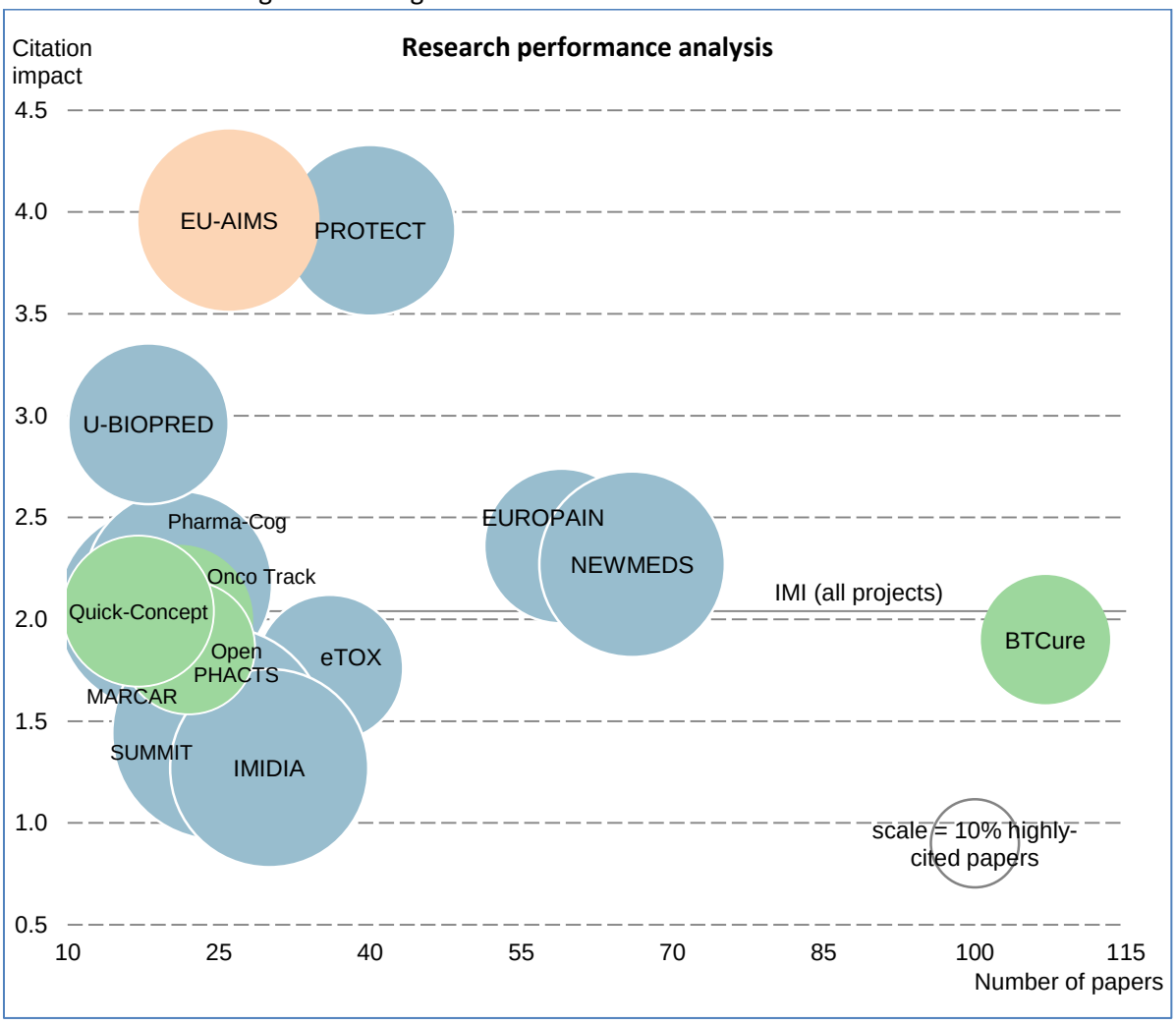
Source: Thomson Reuters analysis 2014

IMI project research also compares well to research supported by the Wellcome Trust, an established funding organisation. Research from both funders is internationally influential with a citation impact twice the world average and with just under one fifth of papers being highly cited, as shown in the table below.

	Number of papers 2010-2013	Citation impact (normalised)	Percentage of highly-cited papers
IMI project research	599	**2.05**	24.4%
Wellcome Trust research	21 421	**1.95**	23.4%

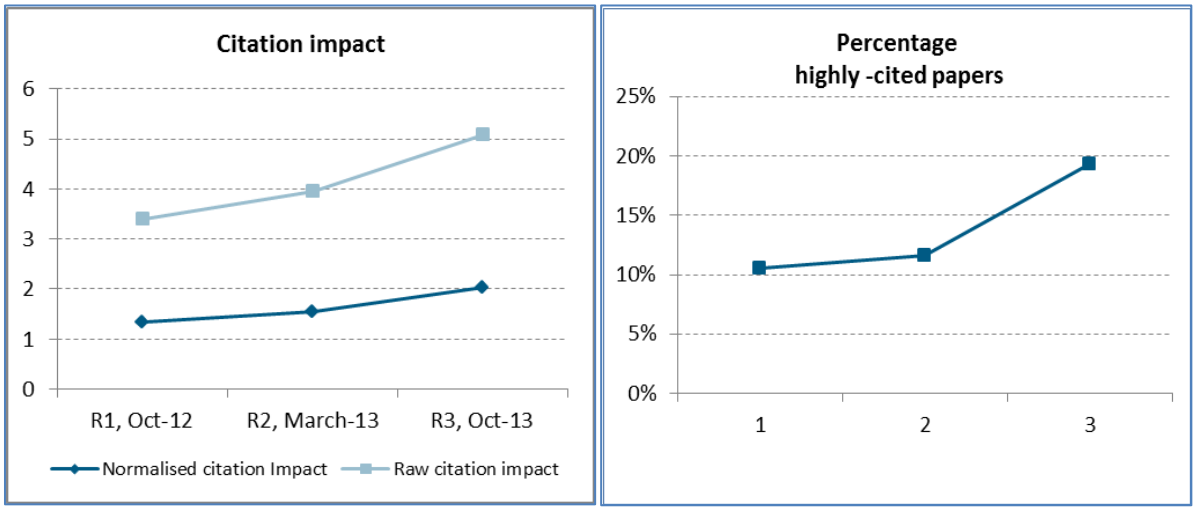
Source: Thomson Reuters analysis 2014

- In order to compare the research performance of individual projects, the number of papers, four-year average citation impact and share of highly-cited papers were calculated. Projects from Calls 1-3 with at least 10 publications during the time period 2010-2013 were included in the analysis.
- The average citation impact of all 14 projects is above world citation impact (1.0) Research associated with 9 of these 14 projects (Europain, MARCAR, NEWMEDS, Pharma-Cog, PROTECT, U-BIOPRED, QuIC-ConCePT, OncoTrack, and EU-AIMS) is very well cited, with a citation impact of at least twice the world average or even higher.
- Research associated with the PROTECT and EU-AIMS projects is exceptionally well cited (3.91 and 3.96 respectively). Both projects citation impact are nearly four times the world average and well above the average for all IMI projects.
- From Call 1 NEWMEDS is the most prolific project, followed by EUROPAIN, both cited more than twice world average.
- BTCure is the most prolific among Call 2 projects with 107 publications and its papers are cited nearly twice world average (1.90).



Source: Thomson Reuters analysis 2014

Trends in the normalised citation impact (i.e. the citation impact that has been adjusted to take account of differences between research fields) and raw citation impact (which does not take account of differences between research fields) have been analysed and visualised in the graph below. The graph demonstrates that the quality of IMI projects' published work, as indexed by citation impacts, as well as the percentage of highly-cited papers, has not only been maintained since the first report in October 2012 (R1), but has increased while output has grown (as measured in second and third reports, R2 and R3 respectively).



Source: 'Bibliometric analysis of ongoing projects', Thomson Reuters Third Report - October 2013

1.2.2 Research and development related outputs

The R&D-related outputs resulting from ongoing projects have been classified according to the following nine categories:

1. Identification and validation of new drug targets and novel hit and lead discovery
2. Establishment of robust, validated tools for preclinical drug development
3. Development of biomarkers and tools predictive of clinical outcomes (efficacy and safety)
4. Clinical trials - improved design and process
5. 'Big data' solutions to leverage knowledge
6. Implementation of data standards
7. Impact on regulatory framework
8. Implementation of project results inside industry
9. Education and training for a new generation of R&D scientists

The following table describes in detail many important results that are being delivered by IMI projects. These advances have a great potential to improve global healthcare and provide novel, more effective treatments to patients faster.

Significant progress has already been made to better understand the disease mechanisms and therefore enable development of better treatment in diabetes, lung disorders, autism, neuropsychiatric disorders, cancer and chronic pain.

IMI researchers are developing tools that will accelerate the medicines 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 as drug candidates; development of improved methods for monitoring adverse effects of medicines that is already available to patients in order to identify problems early and prevent serious complications.

Other benefits from IMI projects include tools that will result in the replacement, reduction or refinement (3Rs) of animal use in drug development, as recognised by the Fund for the Replacement of Animal Research in Medical Experiments[3].

Many of these achievements are completely novel, unprecedented, unique in scale, or moved earlier results to another stage.

Brief descriptions of the project outputs and objectives are set out as follows. The table below lists the new developments that have taken place in 2013. Earlier achievements are listed in the Annual Activity Report 2012.

Project	Area	Results
1. Identification and validation of new drug targets and novel hit and lead discovery Listed achievements contribute to better understanding of disease and therefore providing accelerated pathways towards new or improved treatments for various diseases in areas of unmet medical need. Furthermore the discovery programs assemble and screen large, unique compound collections therefore enabling identification of new potent molecules that might lead to novel medicines for rare or neglected diseases.		
Europain	**chronic pain**	Established the Pain Networks web database (www.painnetworks.org) that will allow the sharing of next-generation sequence data and the further integration of genetic data globally.
SUMMIT	**diabetes**	Determination that Nuclear Factor of Activated T-Cells (NFAT) signalling may be a novel and attractive approach for the treatment of diabetic macrovascular complications.
BTCure	**rheumatoid arthritis**	Identification of new targets for therapy, including 6 potential microRNA targets that are translatable between mice and RA patients.
ELF	**drug discovery in rare or neglected diseases**	326 486 unique and non-commercially available compounds received from the EFPIA partners and reformatted into screening plates and transferred to the relevant screening facilities at EFPIA partners and Pivot Park Screening Centre.
		Screening Selection Committee installed and 41 public target proposals received, of which 17 have been approved. 24 EFPIA targets nominated and approved.
		9 high throughput screening (HTS) campaigns on public targets completed and at least 10 HTS campaigns on EFPIA targets completed.
		Collected 170 proposals for new libraries from the chemistry public partners (academic and SMEs), of which 140 have been approved, 26 have been rejected, and 4 are under consideration. Of the approved proposals, 31 are in production (average expected size is 500 compounds/library, which would result in 15 000 compounds being generated for the public compound collection).

[3] Balls, M. (2012) 'FRAME and the Pharmaceutical Industry', ATLA 40, pp. 295-300.

Project	Area	Results
2. Establishment of robust, validated tools for preclinical drug discovery & development Listed achievements contribute to speeding up the development of new medicines by providing improved tools that more precisely predict whether given candidate molecule will be effective in patients before they are progressed into clinical development. The tools include unique in vitro or animal models that are more closely reproduce the patient reality, non-invasive imaging techniques, as well as computer models that allow efficacy prediction without the need to expose the patients or even animals test compounds.		
Europain	**chronic pain**	Development of three colonies of genetically modified-mice carrying clinically-relevant SCN9a mutations as novel surrogate models of spontaneous pain.
		Development of seven new rodent models of pain, including the Zucker diabetic fatty (ZDF) rat, the most viable and clinically-relevant animal model of painful diabetic neuropathy to have been described to date.
NEWMEDS	**schizophrenia, depression**	Publication of three Nature protocols describing assays developed within the NEWMEDS touchscreen platform to measure various aspects of executive and cognitive function in rodents.
		Demonstration of the test–retest reliability of the positron emission tomography (PET) tracer [11C]AZ10419369 binding to 5-HT1B receptors in the human brain.
		Development of a mouse model that recapitulates key features of the 15q13.3 microdeletion syndrome including schizophrenia- and epilepsy-related alterations.
		Establishment (by a novel application of multivariate analysis across the whole brain) of the modulation of the ketamine pharmacological magnetic resonance imaging (phMRI) response as a tool to investigate the mechanistic action of novel compounds relevant for psychiatric disorders such as schizophrenia and depression.
		Demonstration that cognitive and neural abnormalities observed in schizophrenia are also found in control carriers of CNVs (copy number variations) that confer a high risk of the disease. Findings published in Nature.
IMIDIA	**diabetes**	Validation of the efficiency and specificity of EnvKA-pseudotyped lentiviral vectors and definition of the best route to perform *in vivo* labelling of beta cells.
		Establishment of the largest collection of human islets from control individuals and type 2 diabetic patients, characterised by computational analysis of the genome, transcriptome, lipidome and morphological and physiological characteristics.
U-BIOPRED	**asthma**	Establishment of a new animal model of severe asthma by combining exposure to the house dust mite with exposure to a virus, which produces a model that is less responsive to standard therapy.
		Development of a human *in vivo* model of asthma exacerbations using a source rhinovirus inoculum produced according to good manufacturing practice (GMP).

EU-AIMS	**autism**	Generation of an inventory of applied rodent behavioural testing paradigms relevant to autism spectrum disorders (ASD).
		Demonstration of the high relevance of Nlgn4 null mutant mice as an ASD model with both construct and face validity and development of a gender-specific autism severity composite score.
PREDECT	**cancer**	Development of novel test models (*in vitro* models, genetically-engineered mouse models (GEMMs) and patient-derived xenograph (PDX) models) of prostate, breast and lung cancer.
		Characterisation of three-dimensional (3D) and slice platforms and development of guidelines on their use and limits for industry and academia - preventing the waste of resources on uncharacterised platforms.
MARCAR	**cancer**	Discovery of DNA modifications in liver cells representing fingerprints, termed an EPICODE, of exposure to non-genotoxic carcinogenic (NGC) compounds.
		Development of 'InCroMAP', a new tool for the automated mapping of relationships between biological processes at a molecular level. It allows the analysis and visualisation of high-level microarray data from individual or multiple platforms. The tool is open access at http://www.ra.cs.uni-tuebingen.de/software/InCroMAP/.
BTCure	**rheumatoid arthritis**	Development of standardised, multiplex assays for the analysis of auto-antibodies specific for rheumatoid arthritis (RA). The platform has been used to describe the emerging immune response that occurs before the development of arthritis and provides a basis for future clinical trials on pre-RA individuals.
		Enhanced tools and methods for the imaging of migrating lymphocytes in animal models of RA. This will form the basis for testing new drugs in animal models, when these drugs are directed towards molecules of importance for T- and B-cell migration.
		Standardisation of four mouse models for arthritis with an emphasis on the most clinically-relevant animal models described so far.
OncoTrack	**cancer**	Establishment of all the technologies and procedures required to generate and analyse the data for *in silico* modelling as well as for biomarker discovery using clinically-relevant samples.
		Established 70 novel xenograft models that can be used to explore response to treatment.
		Established 50 canceroid cell cultures established for investigation of tumour progenitor cell biology.
		Established drug sensitivity testing in high throughput screening (HTS) format established.

Project	Area	Results
3. Development of biomarkers and tools predictive of clinical outcomes (efficacy and safety) Listed achievements contribute to speeding up the development of new medicines by providing improved tools that will predict whether the studied medicine candidates will benefit the patents, whether they are safe and should be taken further into development process. The tools include markers that could be detected by a simple blood test, imaging technique or patient reported outcomes. Ultimately those reliable measures or tools will help eliminate ineffective or unsafe compounds early in the development process and therefore avoid unnecessarily exposing patients or investing in unnecessary development programmes.		
NEWMEDS	**schizophrenia, depression**	Demonstration by genome-wide association study (GWAS) in a cohort of 2 897 individuals of European ancestry that is not possible to associate a single common genetic variant with antidepressant response at a clinically-relevant level.
		Identification by whole-exome sequencing of a polymorphism in the BMP5 gene associated with response to selective serotonin reuptake inhibitor (SSRI) treatment for major depression.
		Establishment that DNA methylation in interleukin-11 predicts clinical response to antidepressants.
Pharma-Cog	**Alzheimer's disease**	Development of the analysis of electroencephalographic (EEG) rhythms in rodents as a translational biomarker of cognitive impairment.
		Demonstration that cortical resting state EEG in Alzheimer's disease (AD) patients is sensitive to pharmacological treatment with acetylcholine esterase inhibitors (AchEis) and memantine, and it is a marker of disease progression in mild cognitive impairment (MCI).
		Contribution of structural imaging data to the C-Path Coalition Against Major Diseases (CAMD) consortium for further validation by the United States (US) Food and Drug Administration (FDA) on the use of hippocampal volume as a marker of enrichment in clinical trials.
Europain	**chronic pain**	Demonstration by magnetic resonance imaging (MRI) that after repetitive pain exposure, healthy pain sensitizers exhibit grey matter changes similar to those seen in chronic pain patients.
		Demonstration that multi-arterial spin labelling functional magnetic resonance imaging (ASL-FMRI) has excellent reproducibility to investigate functional changes in brain activation both in surrogate pain models and chronic pain patients.
PROactive	**COPD**	Development of patient-reported outcome (PRO) tools to capture physical activity for patients with chronic obstructive pulmonary disease (COPD). Finalisation of the protocols of a set of collaborative studies to gather sufficient data on the robustness of the PROs with the view to the qualification of the tools.
SUMMIT	**diabetes**	Assembly of one of the largest, homogeneous population samples of European ancestry subjects with type 1 diabetes (more than 6 000 subjects), and identification by GWAS of novel susceptibility sites associated with diabetes neuropathy (DN).

IMIDIA	**diabetes**	Discovery of a lipid signature in the serum of mice fed with a high-fat diet that correlates with physiological readouts – a potential novel biomarker for diabetes.
EU-AIMS	**autism**	Demonstration that babies aged 4-6 months at risk of autism show a reduced response to social cues and different brain activity patterns compared to other babies.
EMIF-AD	**Alzheimer's disease**	Development of a comprehensive study protocol allowing the collection of the full range of AD biomarkers (including blood, cerebrospinal fluid (CSF), imaging, cognitive status, etc.) in 300 healthy elderly subjects.
		Development of a detailed questionnaire to characterise AD cohorts across Europe and collection of data from 23 cohorts out of 52. All information on the AD cohorts is made available in an EMIF browser to allow selection of relevant cohorts for further studies.
		Development of a flow diagram for MCI and AD to operationalise revised international and NIA-AA (National Institute on Aging–Alzheimer's Association) diagnostic criteria. This will allow the use of the criteria to tackle the investigation work of the project on the prevalence and risk factors for dementia in Europe.
		Setting up of a generic taxonomy for dementia cohorts. Data uploaded in tranSMART for the first AD cohorts. This is a key step towards the validation of the project's efforts on to define extreme phenotypes and discover new biomarkers.
EMIF-Metabolic	**metabolic syndromes**	Review and catalogue developed of all available industry data resources (electronic health records (EHRs) and clinical trials).
		Medium-size obese cohorts have been selected as well as internal EFPIA data resources (EHRs and clinical trials) so that questions on the predictors of the complications of obesity can start to be interrogated.
EMIF	**AD & metabolic syndromes**	Establishment of clinical protocol for a joint AD/metabolic study and start of patient recruitment.
SAFE-T	**safety**	Completed the evaluation of 153 potential biomarker candidates for drug-induced injury of the kidney, liver and vascular system. 79 have been selected for qualification studies.
		Assays for around 65 biomarkers developed; assay validation 95% complete.
e-TOX	**knowledge management, safety**	Released the first beta version of eTOXsys to the consortium. This application combines the outputs mentioned below to allow the querying of the eTOX database through standard chemical and text-based searches and gives a prediction of first-order toxicity for 65 endpoints.
		Has built a unique toxicology information database utilising legacy reports from industry partners and public data to develop better *in silico* tools for toxicology prediction of new compounds. This database contains 2 859 preclinical reports from the participating pharmaceutical companies available for predictive modelling with a further 3 030 reports being processed.

		Assembled a second database of publically-available data covering 169 000 compounds annotated to over 400 targets with more than 650 000 activities extracted from over 11 000 publications.
		Developed 89 *in silico* models and established a workflow for their formal documentation, verification and validation.
		Has built a series of ontologies to harmonise the verbatim terms compiled in the project database. More than 1.5 million terms have been curated.
MARCAR	**safety**	Gained novel insights into early mechanisms of non getotoxic carcinogens (NGCs) that might lead to novel target identification.
		Identification of novel genes that may be able to predict whether potential drugs have cancer-inducing properties.
PROTECT	**pharmacovigilance**	Establishment of the Drug Consumption Databases in Europe using data from European national sources and data from IMS Health for 17 countries– publically available.
		Establishment of the database of adverse drug reactions (ADRs) of centrally authorised medicinal products with 45 298 ADRs for 654 medicines – publically available.
		Developed a method to calculate the population exposed to drugs.
RAPP-ID	**infectious diseases**	Development of conceptual point of care test (POCT) platforms for community-acquired pneumonia, influenza, tuberculosis.
		Designed conceptual POCTs for the detection of antibiotic resistance for ventilator-associated pneumonia and tuberculosis.
BTCure	**rheumatoid arthritis**	Identification of biomarkers for response to therapy.
		Production of monoclonal human antibodies to autoantigenic targets in RA: these were generated in academia, produced by industry, and are now used by the entire consortium.
QuIC-ConCePT	**cancer**	Development and technical validation of 5 new cancer imaging biomarkers for tumour cell proliferation, cell death, apoptosis and invasion. Two of the biomarkers are moving into the biological validation studies with a goal to incorporate them into decision-making in Phase I trials of investigational cancer therapies by October 2016.
PREDECT	**cancer**	Set up of a central IHC (immunohistochemistry)/TMA (tissue microarray) platform as the common molecular pathology platform to assess the different models. TMA biobanking set up with over 1 071 samples.
OncoTrack	**cancer**	Design of a selector assay targeting 28 genes commonly mutated in solid tumours.
		Discovered over 170 potential biomarkers able to predict tumour sensitivity to certain drugs.
U-BIOPRED	**asthma**	'Omic' platforms completed and preliminary fingerprints and handprints generated through an interim analysis on limited subsets of various types of high-dimensional data aiming at better defining severe asthma.

Project	Area	Results
4. Clinical trials - improved design & process Listed achievements contribute to speeding up the development of new medicines by investigating novel clinical trial design that better reflect real life situations, relevant to the disease and its progression. Proposed new paradigms require less patients and time but at the same time generate more robust information/evidence. Various projects have made efforts to also improve patient recruitment, for example by utilizing of healthcare records or creating well characterised patient registries, to focus clinical trials on more precisely characterised patient population.		
NEWMEDS	**schizophrenia depression**	Demonstrated that it is possible to increase the power of a clinical study by combining into a single statistic the drug effect in those who complete a trial and the proportion of patients in each treatment group who complete a trial. This approach is more sensitive to the effects of an experimental treatment versus active controls (but not placebo) than the standard approach.
		Development of consensus criteria for the optimisation of clinical trials of pharmacological agents for treating negative symptoms in schizophrenia. Started informal consultation with regulatory authorities (FDA & European Medicines Agency (EMA)).
Pharma-Cog	**Alzheimer's disease**	Recruitment completed of 156 MCI patients for the clinical validation of the utility of the Pharma-Cog biomarker matrix to follow disease progression.
Europain	**chronic pain**	Improved description of pathogenic mechanisms and subgrouping of patients with persistent pain after previous hernia surgery, breast cancer surgery and pulmonary surgery.
EU-AIMS	**autism**	Development of a clinical network of over 40 partners across Europe.
		Development of an online survey tool to establish an inventory of ASD patient characteristics and clinical measures routinely used across Europe.
		Started recruitment of the to-date two largest European multi-site genetic/imaging/behavioural clinical studies on ASD: a high-risk infant sibling study, and an accelerated longitudinal clinical study.
		Discovered that autism affects different parts of the brain in males and females with high-functioning autism, suggesting that researchers should stratify their results by gender and avoid assuming that results found in males also apply to females.
U-BIOPRED	**asthma**	Completed recruitment of the cohorts of adult and paediatric patients with severe asthma, and appropriate controls (1 029 patients: 730 adults including severe smokers and 299 paediatric patients including pre-school children).
		Established a central registry of adults and children with severe asthma which can be used for future studies. Biobank of baseline samples established: Sample numbers over 100 000.
BTCure	**rheumatoid arthritis**	Identified and characterised cohorts and biobanks for different stages of RA (33 cohorts, more than 10 000 biosamples), to enable identification of factors for RA development in high-risk individuals.

EH4CR	**knowledge management**	Business modelling implementing exploitation of electronic health records for clinical research has been initiated.
		Released a reference implementation of the protocol feasibility service/demonstrator; currently nine hospitals in three countries are using actual anonymised EHR data.
		Ran pilots on identification and assessment of eligible patients through EHRs.
		Stakeholder environment scan published. Held a stakeholder awareness session for potential service providers with a demonstration of the tools.
		Assessment of the protocol feasibility services. Overall 373 free-text eligibility criteria were reviewed by clinical trial experts. 175 feasibility criteria were transformed into computable representation. Pilot sites mapped approximately 300 data fields from their local terminologies.
ND4BB - COMBACTE	**antibiotics**	Creation of a high quality, pan-European clinical trial network of hospitals prepared for and experienced in performing high-quality clinical studies with new antimicrobials against resistant bacterial pathogens (CLIN-Net), supported by a high-quality laboratory surveillance network (LAB-NET). 290 clinical sites in 33 countries are already candidates for joining CLIN-Net.
U-BIOPRED	**asthma**	Great involvement of patients in activities of the projects through the Ethics Board, Safety Monitoring Board and Patient Input Platform, allowing the inclusion of patients' perspective in project activities (clinical trial design, PRO development, informed consent form drafting, patient information forms), helping ensure project outcomes are more relevant for people with the disease.
PROactive	**COPD**	
GetReal	**relative effectiveness**	Created for the first time a public-private consortium bringing together all key stakeholders (namely industry, academia, regulatory agencies, reimbursement agencies, healthcare budget holders, and patient groups), who are not used to working together, to share their insights and know-how, with the view to developing new approaches for incorporating real-life data into drug development.

Project	Area	Results

5. 'Big data' solutions to leverage knowledge

Listed achievements contribute to speeding up the development of new medicines by providing solutions to best take advantage of existing or newly generated data. By pooling , linking and then analysing various vast collections of data one can make important discoveries that will further improve our understanding of disease, predict how test compounds will behave once administered to patients, or help best design clinical trials.

Open PHACTS	**knowledge management**	Integrated 13 pharmacological information sources into a modular platform to facilitate queries and analysis of data. The Open PHACTS infrastructure can support many different scientific domains and questions.

		12 applications for advanced analytics and prediction are using the Open PHACTS service.
		Setting up of a subscription-based, not-for-profit entity, the Open PHACTS Foundation, to ensure sustainability of the data integration services and data quality. The services will also be useful to current and future IMI projects.
EMIF	**knowledge management**	Completed curation of information from five AD cohorts, and uploaded three into EMIF-tranSMART; the other two are awaiting completion of contracts.
		Piloted the Private Remote Research Environment (a PRRE allows access to electronic health records in a secure manner for a given research question).
		Demographic and follow-up profiles have been summarised for all 13 EHR data sources covering 48 million patients in 7 European countries. A prototype fingerprint browser has been developed.
eTRIKS	**knowledge management**	Replaced a component of the open source tranSMART platform with an open source component, reducing the cost of software licenses for the user. Collaborating with the tranSMART Foundation to share platform development work.
		Supporting five collaborative projects with design and implementation of knowledge management solutions with four eTRIKS/tranSMART deployments. Preparing to support another four consortia.
		Established a public tranSMART version containing open access data from 22 subject-level translational studies and aggregated summary results from 1 400 Gene Expression Atlas studies.
DDMoRe	**knowledge management**	Clinical trial simulator (2nd release) and model-based adaptive optimal design tool (1st release) delivered.
		Initial version of modelling language standards (modelling description language (MDL) and pharmacometrics markup language (PharmML)) including an MDL editor released publicly on www.ddmore.eu. New standards will facilitate exchange/re-use of drug and disease modelling to guide quantitative decision-making.
		Piloted an interoperability framework that supports execution of 30 drug/disease models in diabetes, oncology, central nervous system (CNS), infectious diseases, and inflammatory diseases.
OrBiTo	**drug delivery**	Design and population of an OrBiTo database with historical *in vivo* pharmacokinetic data for novel compounds (so far over80 active pharmaceutical ingredients (APIs) and about 450 *in vivo* studies) from the EFPIA partners, which is a core resource for continued work in the project to improve and validate predictive methods.
K4DD	**drug discovery**	Defined selection criteria for target-related data harvesting from industry programmes.
		Completed a list of agreed targets to be shared among industry and public partners of the consortium including 14 fully-approved targets covering different classes of targets, as well as 31 partially-approved targets.

OncoTrack	**cancer**	The 'OncoTrack DB' (data-integration platform for systems biology collaborations) has been set up and expanded significantly. tranSMART (data warehouse and data mining infrastructure for hypothesis generation and testing) has been implemented.
U-BIOPRED	**asthma**	Severe asthma patient registry established from the baseline data collected. This relates to Adult Cohorts A (307 patients) and B (106 patients) and Paediatric Cohorts A (93) and C (81), after exclusion of screen failures, dropouts and violators.

Project	Area	Results
6. Implementation of data standards In an era of increased transparency and data sharing as well as large scale pooling and analyses of data from multiple origins, data standards are essential to ensure accuracy, reproducibility and scientific integrity. Quality of data is an essential pre-requisite for implementation of new research and regulatory paradigms		
eTRIKS	**knowledge management**	Developed and adopted translational information standards. Adopted the Clinical Data Interchange Standards Consortium (CDISC) data standards for clinical research data. Evaluation of standards for non-clinical data is ongoing.
BioVacSafe	**vaccines**	Implemented CDISC-CDASH (Clinical Data Acquisition Standards Harmonisation) for data collection in two large cohorts covering more than 4 600 disease episodes of the cohorts. The resulting data extracted is being transformed into CDISC-SDTM (Study Data Tabulation Model) format for the purpose of the data analysis. Full mapping and harmonisation with the BRIDG UML (Biomedical Research Integrated Domain Group unified modelling language). model will support the interoperability with EHRs and other data formats. Will be developing a vaccine-specific data standard in compliance with regulatory requirements and publicly reviewed as part of the CDISC/Critical Path Institute (C-Path) therapeutic area standards development effort for wide adoption.
SAFE-T	**drug safety**	Implemented the CDISC-SDTM to combine the clinical data and biomarker screening results as the common content standard for data management checks and statistical analysis.
EMIF	**Alzheimer's disease**	CDISC data standards were adopted and adapted to match additional AD neuropsychological tests available in the AD cohorts.
EU-AIMS	**autism**	Started evaluation of whether CDISC standards can be used/further developed by the project. Currently no data standards are available for autism.
PreDiCT-TB	**tuberculosis**	Contributed to the development of tuberculosis (TB) research data standard with CDISC and the C-Path CPTR (Critical Path to TB Drug Regimens) consortium.
EHR4CR	**knowledge management**	A first version of the EHR4CR information model (a platform-independent conceptual model) has been developed based on generic reference models for representing clinical data, such as standards developed by the International Organization for Standardization (ISO) Health Level Seven International (HL7), and CDISC.

Project	Area	Results

7. Impact on regulatory framework

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 medicines development efficiency as well as regulatory standards, guidance and practice for the benefit of public health. A number of projects have already taken steps to obtain advice from regulators on qualifying the tools, methodologies or standards resulting from their work. In addition, some projects have been instrumental in triggering the development of regulatory guidelines.

PROactive	**COPD**	Qualification advice completed at the EMA.
EU-AIMS	**autism**	Started EMA formal scientific advice procedure for qualification of 5 biomarkers in ASD.
eTOX	**drug safety**	Provided an update on the eTOX database and the prediction system to the EMA's Committee for Medicinal Products for Human Use (CHMP) Safety Working Party (SWP). The main focus was to develop a common understanding on the use of the system and expectation for validation of the systems. National representatives of the SWP expressed interest in accessing the database. In order to explore ways of cooperating between eTOX and regulatory authorities, a decision was taken to start a Scientific Advice Procedure.
MARCAR	**cancer**	Has developed new biomarkers, technologies, and alternative test systems that help explain or predict animal and/or human carcinogenic pathways and mechanisms for non-genotoxic carcinogenesis. This will provide enhanced scientific rationale for Carcinogenicity Assessment Document (CAD) submissions, with potential impact for revisions of the guideline on carcinogenicity testing of pharmaceuticals of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
SAFE-T	**drug safety**	Developed and progressed towards an aligned EMA/FDA qualification of a set of novel safety biomarkers for drug-induced kidney, liver, and vascular injury.
DDMoRe	**knowledge management**	In May 2012 an advisory meeting with EMA and FDA representatives was held. Through a Modelling Review Group, DDMoRe is in regular contact with both the EMA and FDA regarding the qualification of the content of the project's model library.

Project	Area	Results
8. Implementation of project results inside industry		
Listed achievements are examples of project results that have already been implemented in the internal processes and decision making of pharmaceutical companies, therefore speeding up the development of new medicines in a number of diseases.		
IMIDIA	**diabetes**	The human beta cell line EndoC BetaH1 has been further validated by Endocells and three pharmaceutical partners, confirming their initial insulin secretion capacity. These cells have been successfully transferred as a research tool for drug discovery to industrial partners.
DDMoRe	**knowledge management**	Several drug/disease models identified by DDMoRe have been adopted or are being further developed inside the industry.
eTRIKS	**knowledge management**	Adoption of the eTRIKS results (tranSMART deployments) in five pharmaceutical companies. Adoption of a company-developed curation tool in eTRIKS.
Europain	**chronic pain**	Developed, standardised and validated a preclinical model of spontaneous pain behaviour in rodents across several laboratories and pain models, in rats and mice. This model, which was previously lacking, is already being used for internal decision-making in the drug development process. The ultraviolet B (UVB) pain model has also started to be used for in-house R&D.

Project	Area	Results
9. Education and training for a new generation of R&D scientists		
IMI education and training programmes are meant to address the gaps in the required biomedical research and development expertise by training new generation of highly qualified individuals that will strengthen the position of the European scientific community in global drug research arena.		
EMTRAIN	**E&T, networking**	Catalogued over 5 000 masters, PhD, continuing professional development (CPD) courses, and short courses taught in 21 languages, from 39 countries, covering over 60 scientific, therapeutic and biomedical areas from about 1 000 universities.
SafeSciMET	**E&T in safety sciences**	Successfully completed its second cycle of courses in 2013, with participants giving very positive feedback. More than 320 students participated (55% from EFPIA companies).
		Provided 20 new courses in drug safety sciences.
Eu2P	**E&T in pharmaco-vigilance and pharmaco-epidemiology**	58 students are following the flexible and fully e-learning 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**	685 trainees have been following various courses (28% from EFPIA companies).
		Assembled a network of 24 universities and 16 affiliates.

		Performed a gap analysis on green chemistry in the industry. Reviewed 6 200 relevant chemical transformations from EFPIA members and nearly 400 significant publications.
CHEM21	**green chemistry**	Produced and disseminated 'green' metrics and a prototype of a reaction database and solvent guide to assess the sustainability of chemical processes used by industry in synthesis and manufacturing practices. These metrics are also part of the academic partners' training programmes in sustainable chemistry.

1.2.3 Business-related outputs

Based on the first analysis of IMI projects' outputs, EFPIA and the European Commission felt it necessary to identify where projects might have missed market opportunities and value creation for follow-up research geared towards product development and launch, patents, creation of joint ventures/spin-off companies, etc.

The Katholieke Universiteit Leuven (KU Leuven) was commissioned to perform a case study to:

- assess the effectiveness of PPPs;
- identify intellectual property (IP) and business opportunities;
- provide an evidence-based approach to evaluate these;
- identify successful components and characteristics to apply in future biomedical PPPs.

Due to the size of the projects, time constraints and the number of partners involved, the analysis was performed only on a selected sample of projects working in different areas: neuroscience (NEWMEDS), metabolic diseases (SUMMIT, IMIDIA), respiratory diseases (U-BIOPRED), knowledge management projects such as development of platforms for toxicity prediction (eTOX) and integrated pharmacologic data (Open PHACTS).

KU Leuven identified a range of valuable assets (innovative research tools, databases and knowledge), not all were being exploited or exploitable yet; these are listed in table below.

Scientific innovations	Management tools	Legal (IP) protection strategies
▪ Research tools such as animal models, biomarkers, monoclonal antibodies, validated cell lines, software tools, new imaging techniques, toxicity predictive models… ▪ Clinical trial design criteria, set-up of clinical trials, biosamples collected in biobanks ▪ Large unique datasets combined in massive database constructs	▪ Honest broker model ▪ Harmonisation and standardisation efforts	▪ Several patents in preparation ▪ Standard creation ▪ Wide public dissemination ▪ Database creation with promising potential

Conclusions of the study

IMI projects reflect successful partnerships towards innovative scientific research built upon trust.

- IMI portrays the important paradigm shift in business models at companies and in academia (e.g. IP strategy).
- Sharing resources and outcomes creates a multiplication effect in terms of scientific and business outcomes.
- The value of IMI projects for SMEs is high, however, the incentive for participation could be further enhanced.

Report recommendations

Report recommendations	IMI action(s)	Timeline
Creation of a forum to exchange best practices and dissemination of existing knowledge on the legal and regulatory landscape	Interactions between projects and sharing of lessons learnt best practices (including on sustainability plans) have been and will be promoted by organising joint and cross-projects meetings and/or using various other channels (e.g. the IMI Group on LinkedIn). In December 2013, IMI commissioned a consultancy service to set up a platform for stakeholder involvement to optimise the exploitation of IP and value generated in its projects (see below).	On-going and to be continued in 2014
Stimulation of positive peer pressure by public declaration and dissemination of expertise and commitment to the consortium	IMI, together with EFPIA, are promoting more strategic approaches to IMI portfolio management by setting advisory groups involving all healthcare-related stakeholders having then an overview on each scientific research area.	On-going and to be continued in 2014
Creation of sustainable legacy mechanisms	IMI will launch a tender procedure to make available the necessary legal and financial expertise and support to projects.	2014
Expansion of IMI's track record of success as Europe's largest PPP	IMI JU is exploring possible expansions (e.g. through a tender procedure) of the KUL case study notably by including a macroeconomic perspective.	2014
Organisation of dedicated workshops for SMEs	In order to promote the participation of SMEs in its activities, IMI is offering support to SMEs interested in applying for IMI projects. This has been primarily through an SME-dedicated contact person, via the SME webpage, and through interactions with Europe-wide umbrella organisations. Moreover, IMI is preparing dedicated workshops, notably with venture capitals in order to explore other funding opportunities across Europe.	On-going and to be continued in 2014

Report recommendations	IMI action(s)	Timeline
Stimulation of dialogue between researchers and patients	From June 2013, IMI has organised a pilot patient group meeting which will lead to two Patient Focus Meetings in 2014: one session on diabetes together with the Juvenile Diabetes Research Foundation (JDRF), and the second one around overall challenges facing patients regardless of the disease they are suffering from. Moreover, the IMI JU will invest in improving the patients and lay community understanding of what IMI delivers and how it might impact their lives by developing a patient-dedicated section on IMI's website, translating outputs from IMI projects into lay language, including patient sessions in IMI stakeholder forum and organising other dedicated patient meetings.	On-going and to be continued in 2014
Creation of incentives to attract young scientists	Besides the launch of competitive calls for proposals, IMI will explore any other necessary procedures to evaluate proposals and award funding to projects involving young scientists. IMI will further invest in the partnering and networking tool and/or events (in collaboration with the States Representatives Group).	2014

Follow-up to the KU Leuven pilot case study

These results provide a basis for designing means to optimise the exploitation of IP and value generated in a number of selected IMI projects. However, other areas of focus not necessarily directly linked to IP and commercial exploitation should be analysed to assure that the impact of IMI projects can be maximised and that the results are sustainable.

To help maximise the translation of project outputs into standard of care (new practices and processes leading to improved healthcare), all key stakeholders, including the clinical community (e.g. clinicians, physicians, nurses, pharmacists) and patients, should be brought together in a multi-stakeholder Exploitation of Results Forum.

The consultancy service to set up a platform for stakeholder involvement to optimise project outcomes was selected in December 2013 (see Section 5.4).

1.3 Stakeholder engagement[4]

IMI attracts participants from all key stakeholder groups, such as academia, research organisations, the pharmaceutical industry, SMEs, patient organisations, and regulatory bodies. This creates an integrated and collaborative approach leveraging the strengths and input of all stakeholders in the health system with the shared goal of delivering effective and sustainable healthcare solutions for society. The figure below shows the total number of participations by different stakeholders.

1.3.1 SME involvement

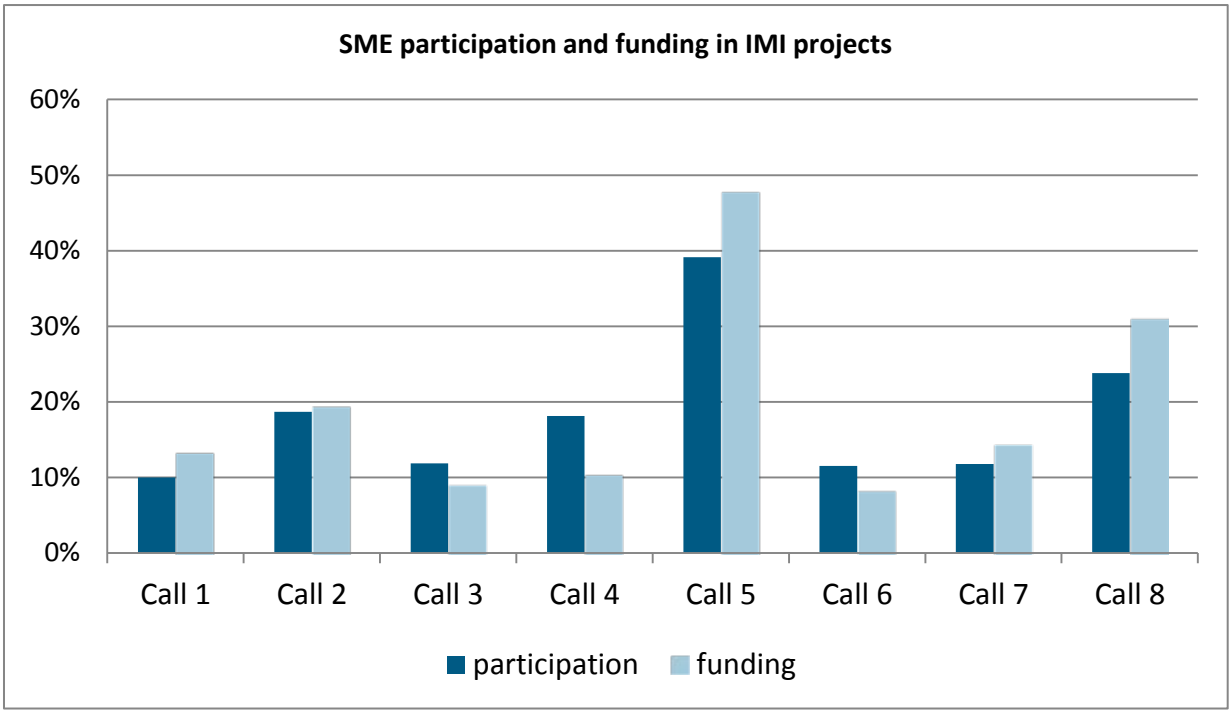
Throughout 2013, IMI continued to promote the participation of SMEs in IMI and offer support to SMEs interested in applying for IMI projects. This has been primarily through an SME-dedicated contact person, via the SME webpage, and through interactions with Europe-wide umbrella organisations.

Thanks to these efforts, SMEs now account for 15% of all beneficiaries (135 out of 886 in total) involved in projects up to and including Call 8. The SMEs involved in IMI projects also receive proportionally more funding compared to other IMI beneficiaries, although they only make up 15% of project partners, they receive 18.4% of the budget (€133 million out of a total committed by Call 8 of €723 million).

The IMI Executive Office has also been exploring other means to provide support to SMEs. This has most notably been in the form of providing more information on and access to additional sources of funding. This approach has focused on two main avenues. The first has been to explore other initiatives directed towards SMEs such as those within the European Cooperation in Science and Technology (COST) action, or how IMI's activities could be complemented with what is happening in other areas, e.g. vaccines. In addition, the availability of European Commission SME-specific financial instruments has been explored. While this is of great interest to SMEs due to the start date of Horizon 2020, it was not possible to align IMI approaches with the specific financial instruments currently available. However, this will be revisited in 2014 now that Horizon 2020 has been launched.

[4] For the purposes of the Annual Activity Report, figures on the total number of participations in IMI projects may count the same organisation multiple times, when involved in several projects.

The second approach has been to engage with venture capital (VC) funders and facilitate dialogue between VC funds and SMEs involved in IMI projects. VC funds are very interested and a series of meetings were held with representatives from organisations such as the International Venture Club (IVC), Vesalius Biocapital and FlandersBio to explore possible approaches. The output of these discussions is to be a SME-funding meeting to be held the first quarter of 2014, at which SMEs involved in IMI projects will be able to interact with VC funds, pharmaceutical company investors, and business development professionals with the aim of identifying other sources of financial support.



Overall, SME involvement in IMI (for Call 1 to 8) represents 15.2% of beneficiaries and 18.4% of IMI JU funding.

1.3.2 Patient involvement

At IMI patients are key stakeholders. IMI research is 'patient-centric' and IMI provides, and will continue to do so, a valuable opportunity for patient groups to participate in various activities to influence the development of new partnerships that aim to address current bottlenecks in pharmaceutical R&D. During the last year we have intensified our patient involvement efforts. The 1st Patient Focus Meeting was successfully held in June, 2013. Patients and patient organizations have expressed a lot of enthusiasm bout IMI and willingness to engage further as a result of our efforts.

The current status of patient involvement in IMI projects has been assessed. The Executive Office, with the support of the London School of Economics (LSE) conducted a short survey among ongoing projects. The survey was designed to determine which projects currently involve patients, how they are involved, and the related benefits and challenges.

- Responses were received from 39 out of 40 projects surveyed (Calls 1-6). Of these, 24 (61%) currently have some form of patient participation, mostly through clinical trials or research where patient samples are required.

- Less frequently, patient organisations are part of the project consortium or members of ethical boards. The most common reason given for not involving patients is that it was not envisaged in the project's scope, although a small number of respondents stated there is no clear benefit to involving patients, or that there are budgetary constraints.

- The benefits of involving patients generally revolve around the unique perspective patients can bring to a project, and patients' ability to improve dissemination, especially outside the scientific community. From the patients' perspective, participating in an IMI project helps them to build networks and better understand their conditions.

- The barriers to greater patient involved included the burden on the patient in terms of finance, time and energy; the logistical, ethical and legal requirements associated with involving patients, particularly across countries; language issues; and ensuring representativeness when involving a relatively small proportion of patients with a given condition.

In order to further improve the patient involvement at IMI the following primary objectives have been identified:

- Improving the patients and lay community understanding of what IMI delivers and how it will impact their lives - this will ensure the continued support to IMI/IMI2
- Improving on how IMI draws on the patient's expertise by enrolling patients into defining and executing projects
- Provide forum for discussion and interaction between the patients, the researchers and other interested stakeholders

Next important meeting, jointly organised between IMI and JDRF, will be held in May of 2014 and will focus on diabetes. The goal of the meeting is to focus on identifying research & development gaps in the diabetes area from the perspective of patient needs and challenges. Ultimately we envision that this input will guide decisions on future topics on diabetes in IMI2 and in JDRF's activities. Putting patients in the centre and leading the discussion with researchers and industry will give them the opportunity to become an influential force for priority setting in disease research.

1.3.3 Interactions and involvement with regulatory authorities

REGULATORS INVOLVED IN
12
PROJECTS

50% of projects have representatives of REGULATORY AUTHORITIES in their Scientific Advisory Boards

IMI has embarked on a number of initiatives to enhance interaction between regulators and its projects to ensure the translation of project outcomes into regulatory and clinical practice.

On 23 May 2013, IMI and EFPIA, together with the EMA and FDA, organised an information session for project coordinators on the processes for drug development tools advice and qualification[5].

On 30 October 2013, IMI hosted the third IMI regulatory summit meeting attended by representatives of EMA, FDA, Japan's Pharmaceuticals and Medical Devices Agency (PMDA), the EC, EFPIA, and relevant project coordinators. One of the outcomes of this meeting is continuous IMI support to the projects in engaging as early as possible with regulators for input on the strategy for the project work plan with a view to developing tools that would be accepted by regulators. The importance of involving regulators at the time of idea generation (topic development) was also highlighted. In this respect IMI has already taken steps to have representatives of the EMA attending workshops for the preparation of the topics for the 10th and 11th Calls for proposals.

In addition, IMI representatives attended several multi-stakeholder meetings, including regulators, aiming at exploring whether an IMI Call topic could be developed to move towards adaptive licensing, also referred to as 'medicines adaptive pathways to patients' (MAPP). There are already a number of outputs from IMI projects that could be help to support moving from a traditional, linear approach to drug development and registration to an approach that allows progressive patient access to new medicines based on a prospective plan agreed by all stakeholders. To this end, in December 2013 a consultancy service was contracted to set up a multi-stakeholder Exploitation of Results Forum to facilitate the relevant stakeholder involvement to optimise project outcomes (see Section 5.4).

In terms of involvement in IMI consortia, regulators participate in IMI projects either as participants or on advisory boards. For instance, the EMA is a partner in four IMI projects, including one, PROTECT, as coordinator. Other EU national authorities participate in eight projects. Representatives of regulatory agencies, including the FDA, are represented in the Scientific Advisory Boards of half of all IMI projects.
Moreover, the EMA's Work Programme 2013 includes specific objectives concerning IMI. These relate to facilitating biomarker development and strengthening research supporting safety monitoring as well as other novel approaches.

[5] www.imi.europa.eu/content/documents#regulators

1.4 Measures of collaboration – the added value of PPPs

1.4.1 Collaboration measured based on bibliometric outputs

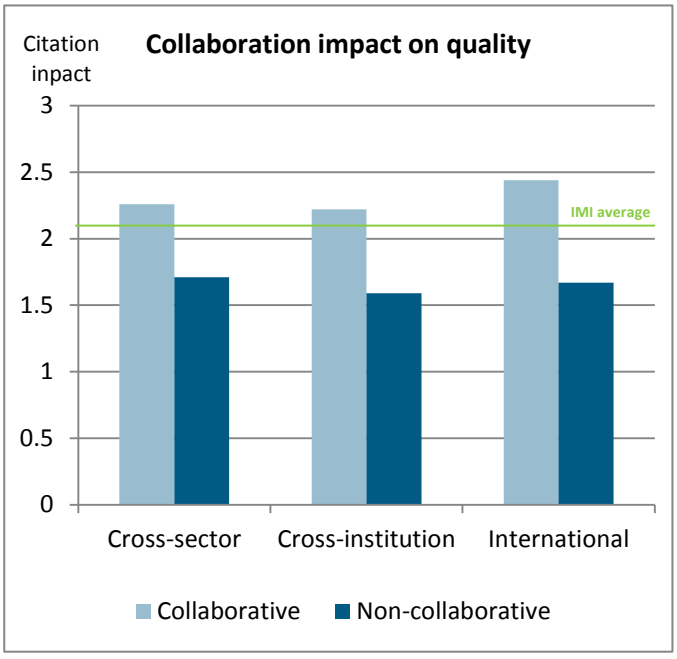
It has been recognised that "deciphering the complexity of human diseases and finding safe, cost-effective solutions that help people live healthier lives requires collaboration across scientific and medical communities throughout the health care ecosystem."[6]
As illustrated in the previous section, IMI is successfully bringing together the key stakeholders involved in IMI projects with a view to impact the productivity and success of the projects. Now we would like to know how well those stakeholders are working together.

How collaborative are IMI projects?

International research collaboration is a rapidly growing element of research activity.[7] In addition, international collaboration has been shown to be associated with an increase in the number of citations received by research papers, although this may vary across countries.[8] Co-authorship is likely to be a good indicator of collaboration, therefore co-authorship on IMI project publications has been analysed. The following table and graph compare the output and citation impact of IMI project papers that are co-authored between different sectors, institutions and countries.

- The data shows that IMI project research is collaborative at sector, institution and country level. Well over half (64%) of all IMI project papers have been published by researchers affiliated with different sectors (such as researchers with academia publishing together with researchers from industry or SMEs). Moreover within those cross-sector collaborative publications nearly one-third (32.6%) are between the public sector and industry. Three quarters (75%) of IMI project papers involve collaboration between institutions. Half (51%) of all IMI project papers have are internationally collaborative.

- The collaborative IMI publications are internationally influential, with a citation impact well over twice the world average (1.0). Within IMI project research, there is a clear difference in average citation impact between collaborative and non-collaborative publications. his supports the hypothesis that collaboration has a positive impact on the quality of research performed.



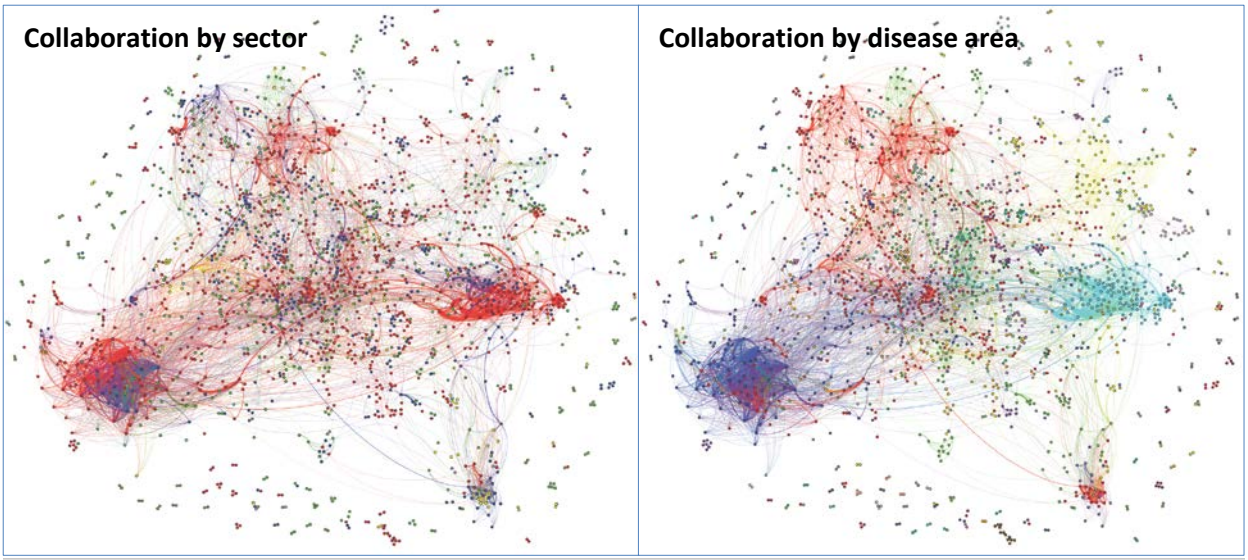
Source: Thomson Reuters analysis 2014

[6] Zerhouni, E. A. (2014) 'Turning the Titanic' *Science Translational Medicine*, vol. 6, pp 221ed2.
[7] Adams, J. (2013) 'Collaborations: the fourth age of research' *Nature*, Vol. 497, pp. 557-560.
[8] Adams, J., Gurney, K., & Marshall, S., *Patterns of international collaboration for the UK and leading partners*, Evidence Ltd, Leeds, 2007.

How collaborative are IMI researchers?

- An expanded collaboration analysis was carried out on the basis of co-authorship between IMI-supported researchers as well as between their co-authors. For this purpose, 4 861 individual researchers participating in 36 IMI projects from Calls 1-5 were identified. Of these, 2 659 researchers have published documents that were indexed in the Web of Science and over two thirds (76%) of these researchers collaborated (co-authored) with at least one other IMI researcher during the period January 2007 - December 2013.
- The patterns and frequency of 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 organisation (left pane) or according to the disease in which their project is active (right pane). Lines between researchers mark instances where 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 40% of all co-authorship activities during IMI's lifetime so far.

Source: Thomson Reuters analysis 2014



Sector	Proportion
Academia	45.07%
Corporate	25.00%
Research (other)	20.43%
Small or Medium Enterprise	4.72%
Not assigned	1.54%
Multiple	1.04%
Patient organisation	0.70%
Regulatory	0.60%

Disease area
Brain disorders
Drug safety
Metabolic disorders
Data management
Inflammatory disorders
Cancer
Lung diseases
Biologicals
Infectious diseases

Disease area
Multiple
Stem cells
Education and training
Vaccines
Drug delivery
Drug kinetics
Sustainable chemistry
Drug discovery

IMI facilitates widespread collaborations between researchers involved in IMI projects. This is illustrated by the 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 37 projects from Calls 1-5 and includes more than 29 064 publications published since 2007 by those researchers.

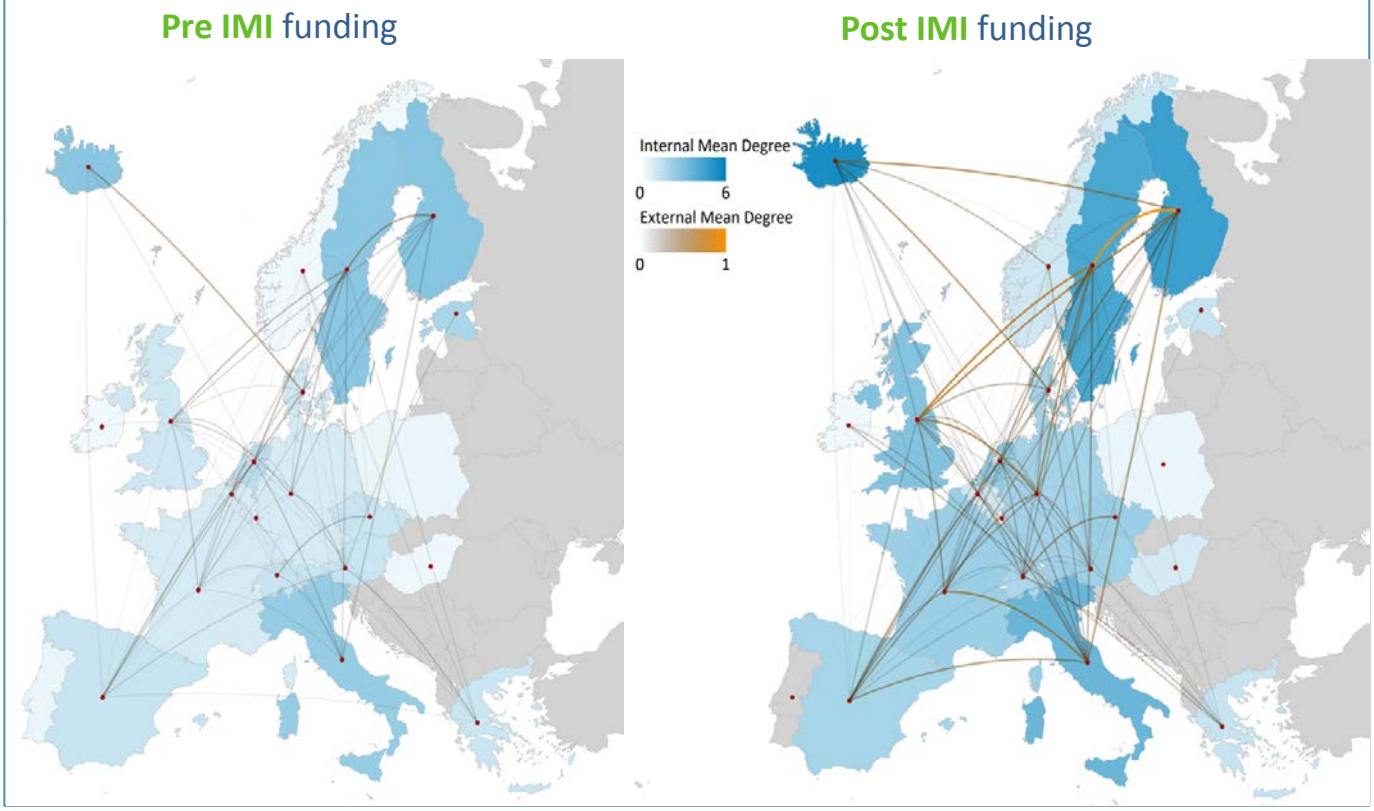
In order to determine whether participation in an IMI project has a positive effect on collaborative activities; co-authorship patterns were compared for the periods before and after the IMI grant award.

Geographical maps of collaboration among IMI researchers show that IMI research has led to an increase in the level of co-authorship between researchers both within individual countries and between countries.

The map visualises:

- The mean degree of collaboration – the average number of other researchers each researcher is co-authoring with – for researchers internally within each country (shaded from white to blue). Countries with no contributing output are shaded in grey.
- The mean degree of collaboration for researchers externally between pairs of countries (shaded from white to orange). For each pair of countries, the degree was calculated based only for researchers in one country who co-authored with researchers in the other country.
- The red dot indicates the approximate middle of each country.

Mapping Collaborative Research Links within and between countries prior to and after IMI funding award for IMI researchers in Calls 1-5

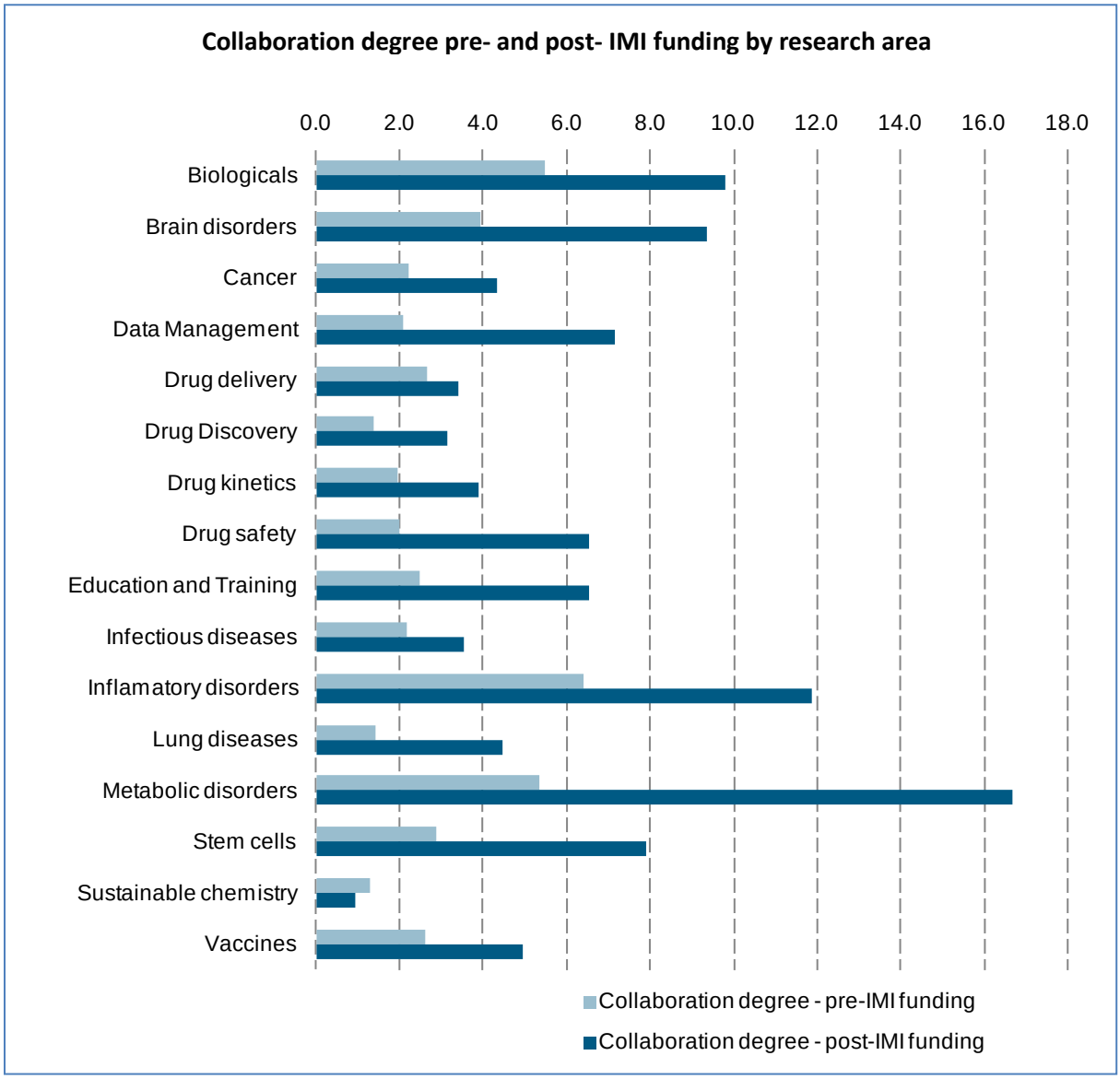


Source: Thomson Reuters analysis 2014

Collaboration by research area

Another way to assess the influence of IMI participation on collaboration between researchers is to look at the number of investigators and co-authorships by disease area, and also the average degree and average weighted degree of each author both pre and post the earliest IMI funding awarded. Below figure shows the average degree for the same two areas. The degree of an author is the number of distinct co-authors that author has; so a researcher who has written publications with, at most, three other researchers has a degree of three.

For most disease areas, the average number of co-authors for each researcher has increased since the researcher first received IMI funding; sustainable chemistry (the CHEM21 project) is the only exception. Four "disease" areas (data management, drug safety, lung diseases and metabolic disorders) have all experience a more than three-fold increase in mean degree since IMI funding began.



Source: Thomson Reuters analysis 2014

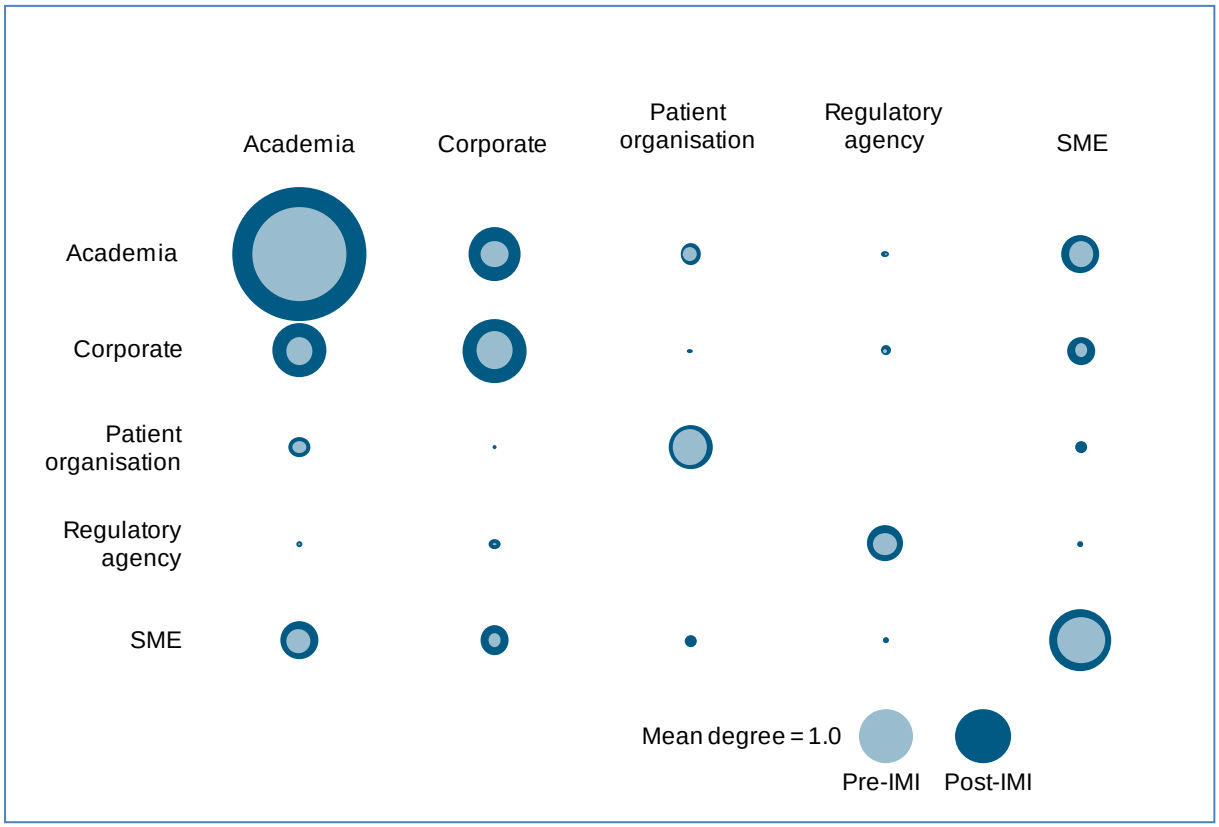
Collaboration between public and private sectors

Finally it is of high interest to assess collaboration between IMI researchers coming from different sectors, e.g. academia, pharmaceutical industry, SMEs, patient organisations, etc. For that purpose the number of collaboration pairs between the different sectors, both 'pre-IMI' and 'post-IMI' funding have been analysed.

The following figure illustrates a substantial increase in the number of co-authorships, both within sector and cross-sector as measeured by mean collaboration degree. The mean collaboration degree between researchers from the same sector is the average number of co-authors each author has who are from their sector; and "from different sectors" is the average number of those co-authors who are from the other specified sector.

The data suggest that IMI funding award has contributed to more than doubled academic-academic collaboration (2.91 to 6.12); corporate-corporate collaboration has nearly trebled (0.49 to 1.41); and academic-corporate collaboration has nearly quadrupled (0.25 to 0.96).

Cross – sector colaboration analysis, pre- versus post- IMI fundimg award



Source: Thomson Reuters analysis 2014

1.4.2 Collaboration among consortia and with external bodies within and beyond IMI

In order to ensure synergies between existing project from IMI and outside, inter-consortia collaboration is strongly encouraged. Many IMI projects have initiated collaboration with other consortia and a number of these resulted in signatures of formal memoranda of understanding (MoUs). Key collaborative activity areas have been: diabetes, CNS disorders, tuberculosis, patient reported outcomes, cancer, preclinical safety, and education and training.

IMI projects have signed

14

MEMORANDA of UNDERSTANDING

with other international consortia

Moreover IMI has signed horizontal agreements with C-Path, the Juvenile Diabetes Research Foundation (JDRF), and CDISC.

Collaboration with C-Path

The first-ever public conference co-sponsored by IMI and C-Path was held in March 2013 in Brussels. It featured cross-sector participants discussing challenges and opportunities in the rapidly-evolving PPP space, focusing on drug development in Alzheimer's disease and tuberculosis. IMI and C-Path 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 Pharma-Cog and EMIF-AD projects). Under the umbrella of the IMI-C-Path MoU, IMI has facilitated interactions between these initiatives.

Collaboration with the National Institutes of Health (NIH)

On 29 October 2013, IMI organised a meeting to review IMI's safety projects (see section on cross-project collaborations) and consider their impact on regulators. The meeting also represented an opportunity for IMI projects to establish links with US initiatives in the safety area, such as the NIH National Center for Advancing Translational Sciences (NCATS) and C-Path's Predictive Safety Testing Consortium (PSTC). The scope of IMI and US-based projects are broadly complementary, offering opportunities for collaboration. To coordinate efforts and avoid duplication, IMI and NCATS agreed to develop a white paper on innovative advances in the predictive safety area, identifying gaps for future research and setting out a framework for collaborative support.

CDISC

Collaboration with CDISC continued in 2013. Benefits of this collaboration for IMI project participants include access to CDISC's training activities. In addition, IMI was invited to join the Scientific Advisory Committee of the Coalition for Accelerating Standards and Therapies (CFAST), a joint initiative of C-Path and CDISC that aims to accelerate clinical research and medical product development by facilitating the establishment and maintenance of data standards, tools and methods for conducting research in therapeutic areas important to public health. As many therapeutic area standards under development relate to areas covered by IMI projects such as oncology, diabetes etc., being part of the CFAST Scientific Advisory Committee provides good opportunities for establishing synergies with IMI projects on the development of the standards.

2. MANAGEMENT OF ONGOING PROJECTS

2.1 Interim reviews for Call 2 projects

In 2013, IMI conducted six project interim reviews of Call 2 projects as shown in the table below.

IMI project acronym	Full project name	Interim review date
BTCure	Be the cure for rheumatoid arthritis	07/05/2013
DDMoRE	Drug disease model resources	31/05/2013
RAPP-ID	Development of rapid point-of-care test platforms for infectious diseases	04/06/2013
EHR4CR	Electronic health records systems for clinical research	07/06/2013
OncoTrack	Methods for systematic next generation oncology biomarker development	05/07/2013
PREDECT	New models for preclinical evaluation of drug efficacy in common solid tumours	02/10/2013

The expert reviewer panel consisted of at least three experts: one from the Scientific Committee, one from the original full project proposal evaluation panel, and one selected from suggestions provided by the consortium. These experts were appointed by the IMI Executive Office following screening of existing or potential conflict of interest.

Overall, the reviewers were satisfied with the progress made by the projects. The consortia have completed the majority of the milestones set and are now on track for the final, critical steps of the projects such as clinical and validation studies.
In most cases, the reviewers had some recommendations aimed at ensuring the delivery tangible achievements by the end of the funding period.

Recommendations were shared with the consortia, which are now in the process of responding to them by proposing appropriate actions and/or amending the work planned for the remainder of the project.

2.2 Cross-project meetings and collaborations

In 2013, IMI increased its focus on fostering cross-project interactions and collaborations, particularly with regards to promoting collaboration beyond IMI and Europe to achieve a global impact. Key IMI activity areas have been: diabetes, CNS disorders, tuberculosis, preclinical safety, education and training, knowledge management, and antimicrobial resistance.

Diabetes

The IMI portfolio includes three projects working on diabetes: The Call 1 projects SUMMIT and IMIDIA started in late 2009 and early 2010 respectively, while the Call 3 project DIRECT started at the beginning of 2012. The 3 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.

A MoU that covers the transfer of knowledge and materials and the handling of intellectual property was signed in 2012 between SUMMIT and IMIDIA. In September 2013 SUMMIT, IMIDIA & DIRECT announced the signature of a new MoU that provides the framework for taking collaborative activities between the three projects one step further – formally implementing the IMI Diabetes Platform and bundling of expertise, knowledge and findings across the projects.

- The 1st Symposium of the IMI Diabetes Platform was hold on the occasion of the 2013 annual meeting of the European Association for the Study of Diabetes (EASD) in Barcelona[9]. The three projects jointly presented their latest research on diabetic complications, the pancreatic beta cell, and personalised medicines to the public.

CNS disorders

- The IMI portfolio includes five projects focusing on CNS disorders. Europain, Pharma-Cog and NEWMEDS arose from IMI's 1st Call for proposals in 2009 and were launched in late 2009/early 2010. EU-AIMS, which started mid-2012, was generated from IMI's 3rd Call in 2010. Finally, EMIF-AD (which is part of the wider EMIF project), arose from IMI's 4th Call of 2011 and started working in January 2013. The total budget of the projects is over €160 million. The Europain project focuses on chronic pain; Pharma-Cog and EMIF-AD focus on Alzheimer's disease (AD); NEWMEDS focuses on schizophrenia and depression; and EU-AIMS focuses on Autism Spectrum Disorders (ASD).

- On 6 March 2013 the lead players of the Pharma-Cog and EMIF-AD projects met with the representatives of the C-Path CAMD initiative to identify areas of common interest and synergy. The output of the meeting was the creation of joint working groups in the areas of biomarkers, data modelling and simulation, data standardisation and remapping, cognition and integrative approaches to AD.

- On 13 May 2013 the IMI CNS coordinators met in Brussels to discuss project achievements, address major challenges, and explore synergies. The meeting was also attended by an EMA representative. Areas where the projects agreed it would be important to work together are:

1) Consolidation of project outputs with those of other initiatives active globally to avoid duplication of efforts and ensure synergy (e.g. standardisation of clinical end points at global level in ASD, disease modelling in AD)

2) Creation of an environment for ensuring harmonisation and acceptance of results not only by EMA, but also FDA.

3) Improve and enhance the involvement of SMEs as they can represent ideal exit solutions for output of the projects.

4) As there are clear commonalities in the issues and challenges faced by the different CNS disease areas, it is necessary to create synergies and learn from each other to further optimise use of resources and allow for cross-fertilisation.

5) Provide ways to better link the projects to the in-house strategies and portfolios of the industrial partners.

6) Focus more on training to create a workforce that is able to work cross-sector.

- The EU-AIMS project is also continuing its collaboration with the Neuroscience Steering Committee of the Foundation for the NIH Biomarker Consortium to maintain an open dialogue and alignment between initiatives in the area on the two sides of the Atlantic.

[9] http://2013.easd-industry.com/industry-programme/symposia-programme/symposium-details/imi-diabetes-platform.html

Tuberculosis

The IMI portfolio includes one project focusing on tuberculosis, PreDiCT-TB, which resulted from IMI's 3rd Call for proposals of 2010 and started in mid-2012. PreDiCT-TB is a multidisciplinary consortium bringing together experts in microbiology, pharmacology, engineering, mathematical modelling, and clinical trials to create a new integrated framework for TB drug development, making optimal use of preclinical information to design the most efficient clinical trials.

- On 8 March 2013 the lead scientists from PreDiCT-TB and the C-Path CPTR project held a very fruitful meeting in Brussels. Both consortia shared ideas and resources that could significantly strengthen the fight against TB. Initial priorities included building a comprehensive database of TB clinical trials, and developing more effective modelling approaches using preclinical and clinical data.

- The meeting paved the way for the signing on 14 March 2013 of a MoU between the two consortia, which will help them to tackle important obstacles to developing combinations of old and new anti-TB drugs that could shorten the length of TB treatment.

Safety

IMI has a rich portfolio of pre-clinical safety projects including the ABIRISK, BioVacSafe, eTOX, MARCAR**,** MIP-DILI**,** SafeSciMET**,** and SAFE-T. Furthermore, the project StemBANCC includes activities for the development of stem-cell-based assays of novel drugs and predictive toxicology.

- An IMI Safety Projects Review meeting was held on 29 October 2013 in Brussels. The meeting reviewed the progress to date of IMI's safety projects with particular reference to their expected regulatory impact and therefore their current interaction with regulators. In addition, this meeting aimed to explore the areas for and means of establishing effective collaborations between IMI and the NIH (and other major global initiatives), ensuring synergy and avoiding duplication of effort in the safety sciences area. The key output from this meeting, the current and expected regulatory impact, was presented the following day at IMI's Regulatory Summit.
The meeting was well attended by coordinators of IMI's safety projects, representatives from the regulatory agencies EMA, FDA, and PMDA, representatives from the European Commission, and senior managers in the safety area of EFPIA companies. In addition, the meeting also heard from both NCATS and PSTC with a view to exploring how to further develop interactions between IMI's safety projects and their US counterparts.

- SAFE-T established a formal collaboration with C-Path's PSTC on drug-induced liver and vascular injury (DILI and DIVI). In September 2013, SAFE-T and PSTC finalised their joint work plans for collaborative studies. The work plans define specific areas of collaboration that will help advance the objectives of both consortia and include deliverables. Specific areas of collaboration for DILI are: biomarker assay development, pre-clinical and clinical assay validation and performance, biomarker translation strategy, and regulatory strategy.

- SAFE-T also established a collaboration with the NIH Foundation Biomarkers Consortium entitled 'Clinical Evaluation and Qualification of Kidney Safety Biomarkers', for the study of drug-induced kidney injury (DIKI). In September 2013, the two projects signed a confidential disclosure agreement (CDA).

Education and training

IMI's five education & training (E&T) projects EMTRAIN, Eu2P, EUPATI, PharmaTrain, and SafeSciMET increased their collaboration during 2013.

- On 6 March 2013, the Drug Information Association (DIA) EuroMeeting featured an entire theme dedicated to IMI's five E&T projects. The sessions highlighted the latest news from the projects and demonstrated how they are collaborating and helping to advance education in the biomedical sector in Europe.

- As a result of the collaboration, the EMTRAIN, SafeSciMET, PharmaTrain[10], and Eu2P projects submitted a joint, cross-project Exploring New Scientific Opportunities (ENSO) application for the last ENSO Call of 2013.

Knowledge management

2013 was an active year for IMI's knowledge management projects as demonstrated by their achievements (see previous chapter) and cross-project and collaborative meetings.

- A two-day workshop entitled 'Translational Knowledge Management in Pharmaceutical R&D' was organised in Brussels on 11-12 July 2013 to review the state of play in the area. The workshop was organised in collaboration with the INBIOMEDvision project, which is funded under the EU's Seventh Framework Programme (FP7) under grant agreement no. 270107.

- Open PHACTS, DDMoRe and eTOX project members held a workshop on tissue knowledge management on 30-31 October 2013 to discuss resources (data, information and knowledge) and standards to support physiology based modelling and simulation.

- On 21 November 2013, six IMI projects attended the meeting 'Global approach to accelerating medical research', during which the CDISC standards were presented. The training was appreciated by the participants and deemed very useful.

- The eTRIKS project supports collaborative projects with the design and implementation of knowledge management solutions. eTRIKS is currently actively supporting four IMI projects (ABIRISK, OncoTrack, PreDiCT-TB, U-BIOPRED) and the Medical Research Council (MRC) project (RA-MAP). This support includes assistance with four local eTRIKS/tranSMART deployments and one centrally-hosted deployment. All five projects received tranSMART training. eTRIKS provides curation support for three projects, enhancements to the tranSMART platform in terms of data types covered and cross-study querying/analysis. eTRIKS is preparing to support a further four consortia.

- eTRIKS is also collaborating with the tranSMART Foundation and the Translational Research Information Technology (TraIT) project[11] to share user experience of the current tranSMART deployments and the development the next generation of tranSMART. TraIT is another informatics and analytics knowledge management project supporting collaborative projects funded by the Center for Translational Molecular Medicine (CTMM[12]). The result will be one global informatics-based analysis and pre-

[10] The PharmaTrain project ends in April 2014. Sustainability is a key deliverable of PharmaTrain., and the PharmaTrain Federation has been established to this end as the successor organisation. The PharmaTrain Federation will become a new partner in the EMTRAIN consortium and therefore is part of the ENSO application. With the E&T cross-project activities platform, the four IMI E&T projects have developed a unique collaborative and synergistic effort which is reflected in the cross-project ENSO application.

[11] http://www.ctmm.nl/en/projecten/translational-research-it-trait/translationele-research-it-trait?set_language=en

[12] http://www.ctmm.nl/en/over-ctmm

competitive data-sharing platform for clinical and translational research.

- Several IMI projects eTRIKS, EHR4CR, PREDICT-TB worked on a draft 'Code to re-use health data in collaborative scientific research projects'. The draft guidance is of general interest to multiple IMI projects as well as other collaborative projects in FP7.

- eTRIKS in collaboration with OncoTrack developed a key data loading module for variant call format (VCF) data. VCF-formatted data is a standard technical format (.doc; .xls; .pdf; .xml are technical formats) for storing the differences between for example the genome of a cancer cell as compared to the genome of a normal cell of a patient (of note, there can be up to 30 000 variants in a cancer genome and thus a special storage format exists). The data load module will be made available to all tranSMART installations and users as part of version 1.2 which is scheduled for public release in the 1st quarter of 2014.

Antimicrobial resistance

2013 represented the first year of activities for the antimicrobial resistance platform, New Drugs for Bad Bugs (ND4BB).

- TRANSLOCATION and COMBACTE, the first two antimicrobial resistance projects of the ND4BB programme signed a MoU in November 2013 to facilitate their collaboration. The MoU covers issues such as data sharing (and confidentiality), communication and coordination, and the creation of a shared Ethics Committee.

Other areas

- In the area of respiratory diseases, the project PROactive signed in July 2013 a MoU on the use of PROactive's daily patient reported outcomes (PROs) with COPDMAP. COPDMAP is supported by the Inflammation and Immunology Initiative of the MRC and the Association of the British Pharmaceutical Industry (ABPI).

- In addition, PROactive signed a MoU with the Urban Training study Catalonia for the use of the PROactive clinical visit PRO.

- The European Lead Factory project is preparing a MoU to allow collaboration with the European initiative EU-OPENSCREEN.

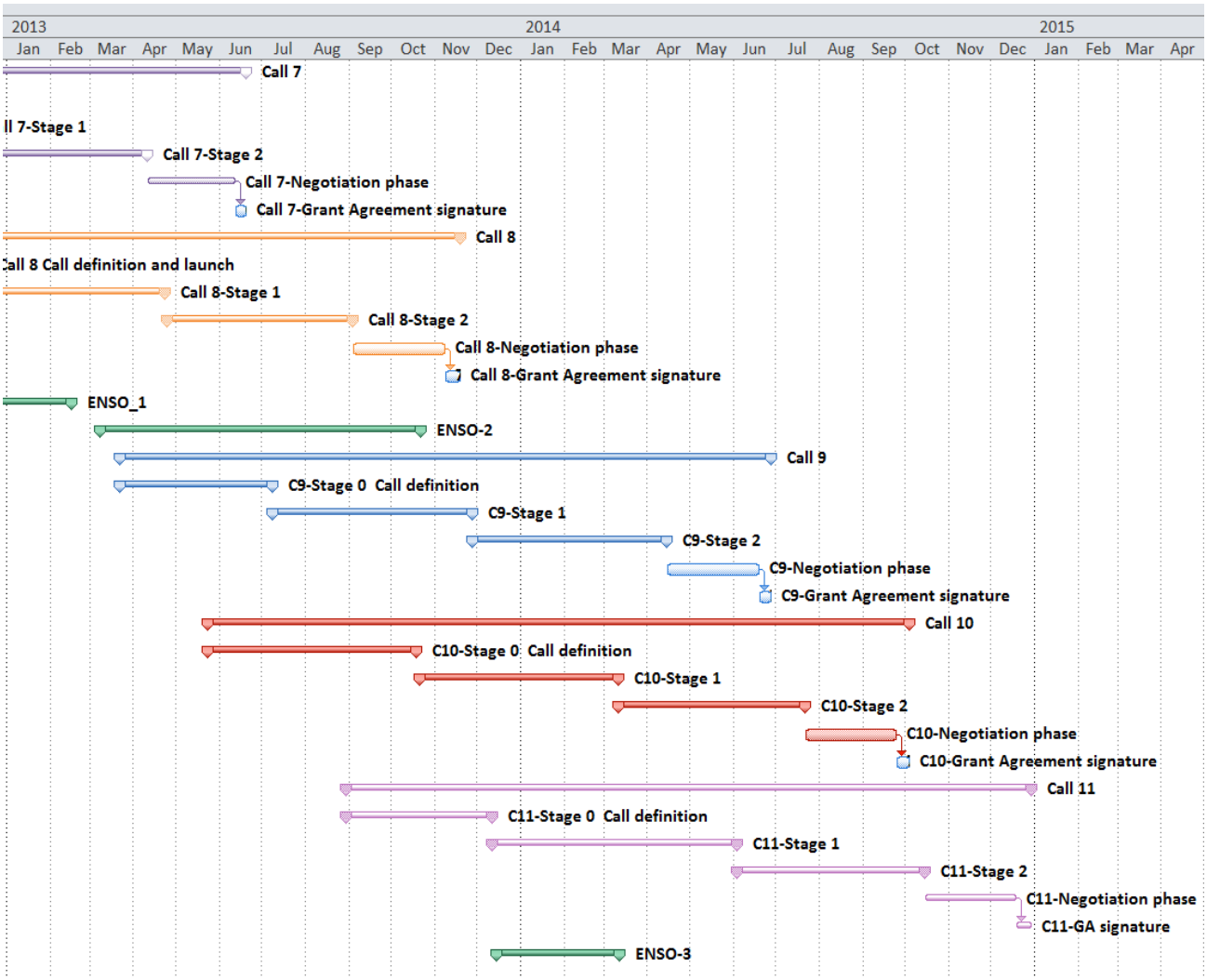
- The European Lead Factory has also initiated collaboration with the IMI project Open PHACTS.

3. IMPLEMENTATION OF THE 7th TO 11th CALLS FOR PROPOSALS

- In 2013 the new process of continuous Call launches was maintained.

- In addition to the implementation of the final stages of Calls 7 and 8, three new Calls were launched (Calls 9 to 11) and two ENSO deadlines reached (ENSO-2 and ENSO-3) in 2013.

- An overview of these activities is displayed in the chart below (2012 – 2014).



Most of the experts (57 of 76) involved in the review of proposals submitted in response to Calls 7, 8 and 9 and the ENSO-1 and ENSO-2 Calls came from EU and FP7 associated countries.

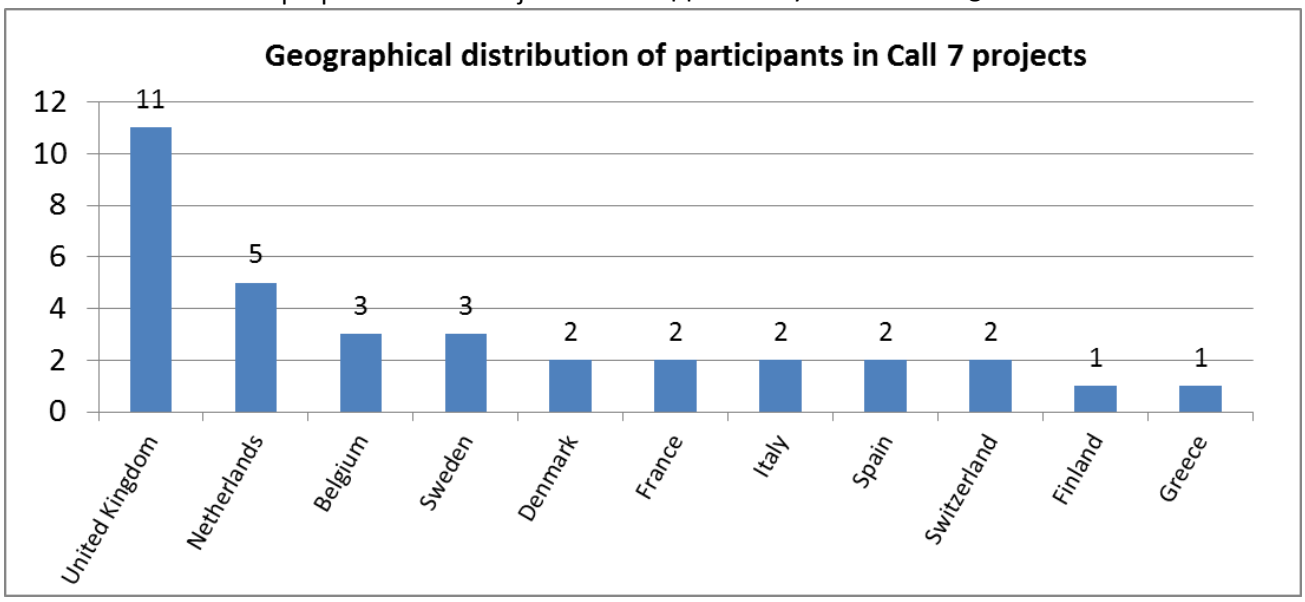
3.1 Implementation of the 7th Call for proposals

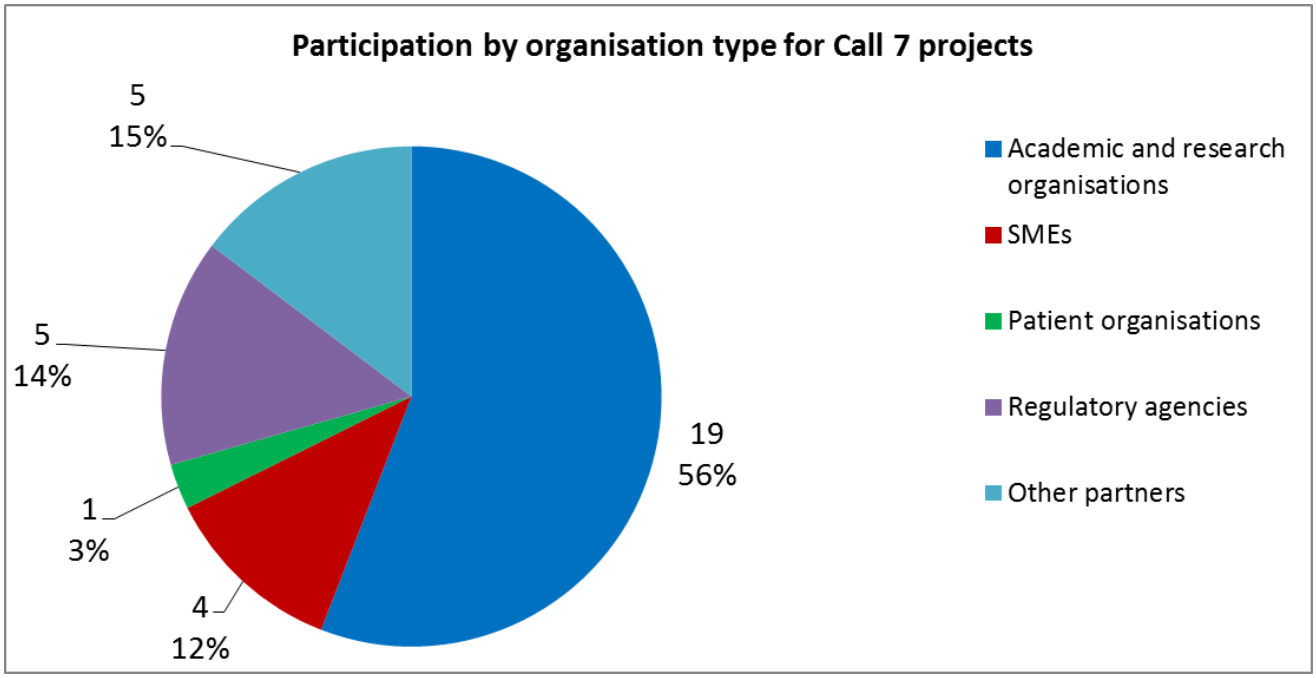
The 7th Call for proposals included two topics:
1. Developing a framework for rapid assessment of vaccination benefit/risk in Europe
2. Incorporating real-life clinical data into drug development

- Following the approval of the recommendations of the Expression of Interest (EoI) evaluation panels by the Governing Board in 2012, 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 was 7 March 2013.

- The evaluation of the resulting two FPPs was conducted by the external experts working initially remotely and then at a consensus panel meeting.

- Both FPPs, ADVANCE and GetReal were recommended for funding by IMI and approved by the Governing Board.





The Grant Agreements for both ADVANCE and GetReal were signed in 2013 and both projects also received pre-financing.

The two 7th Call projects pre-financed in 2013 (in EUR)

IMI Project	EFPIA + IMI Funding	EFPIA Funding	IMI Funding	SME	Academic	Research	Patient Org.	Other
GetReal	14 910 397	6 910 397	8 000 000	860 242	4 262 571	1 110 546	125 128	1 641 513
ADVANCE	10 017 164	5 017 353	4 999 811	1 032 626	2 102 804	673 706	0	1 190 675
TOTAL	24 927 561	11 927 750	12 999 811	1 892 868	6 365 375	1 784 252	125 128	2 832 188

3.2 Implementation of the 8th Call projects

The 8th Call for proposals included the following five 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 was planned to run under the same Grant Agreement as the COMBACTE project of Call 6 as mentioned in the 8th Call for Proposals 2012[13].

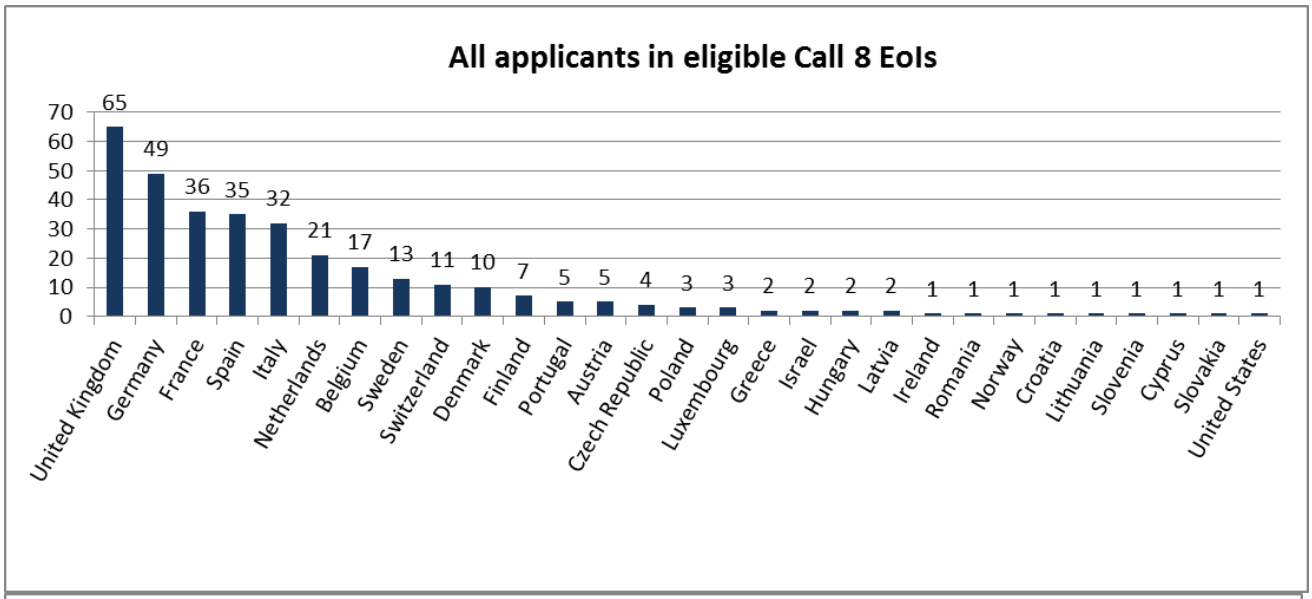
- The 8th Call for proposals was launched by the IMI on 17 December 2012 with a deadline for submission of EoIs of 19 March 2013.

- The Call launch was widely promoted in December 2012 and January 2013 via the IMI Newsletter, the IMI website, a press release, webinars, targeted and general emails, network organisations and IMI ambassadors at various events.

- 26 EoIs were received by the submission deadline, all of which were eligible for evaluation.

- Analysis of the applicants revealed that 333 legal entities took part; of which 242 (73%) were academic and non-profit organisations and 81 (24%) were SMEs. On average, there were 12.8 entities per EoI. Key figures regarding the EoIs are presented below.

[13] http://www.imi.europa.eu/sites/default/files/uploads/documents/8th_Call/IMI_8thCallText_FINAL.pdf (p.14-15)


All applicants in eligible Call 8 EoIs
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Austria
Czech Republic
Poland
Luxembourg
Greece
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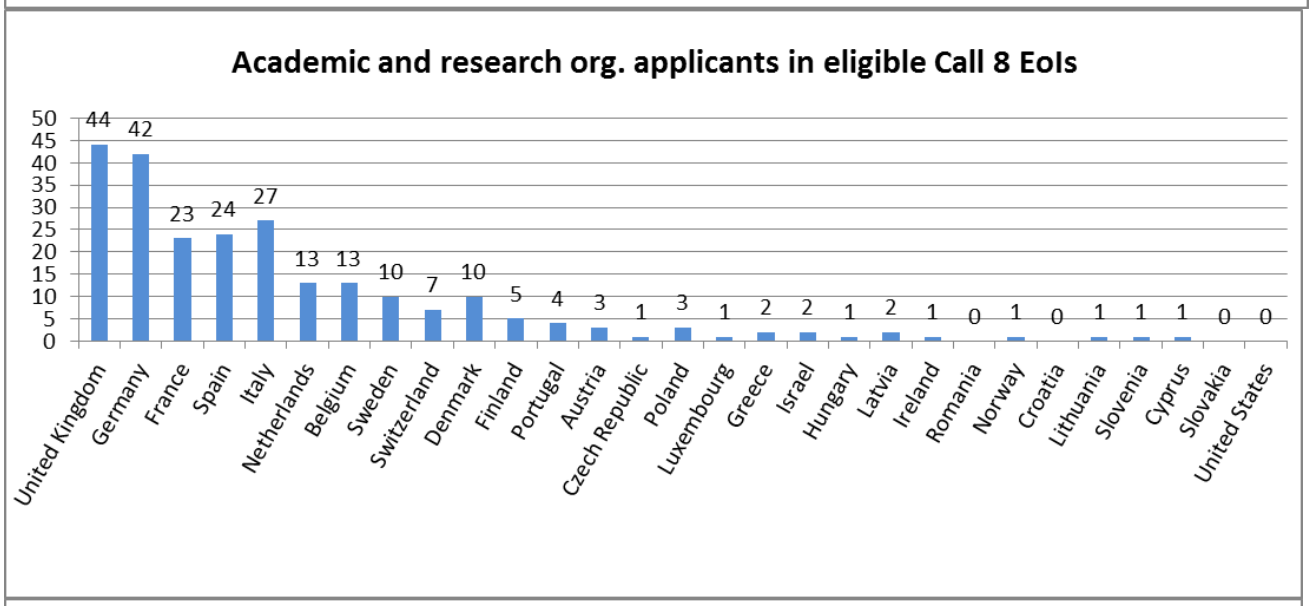
Hungary
Latvia
Ireland
Romania
Norway
Croatia
Lithuania
Slovenia
Cyprus
Slovakia
United States


Academic and research org. applicants in eligible Call 8 EoIs
50
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Czech Republic
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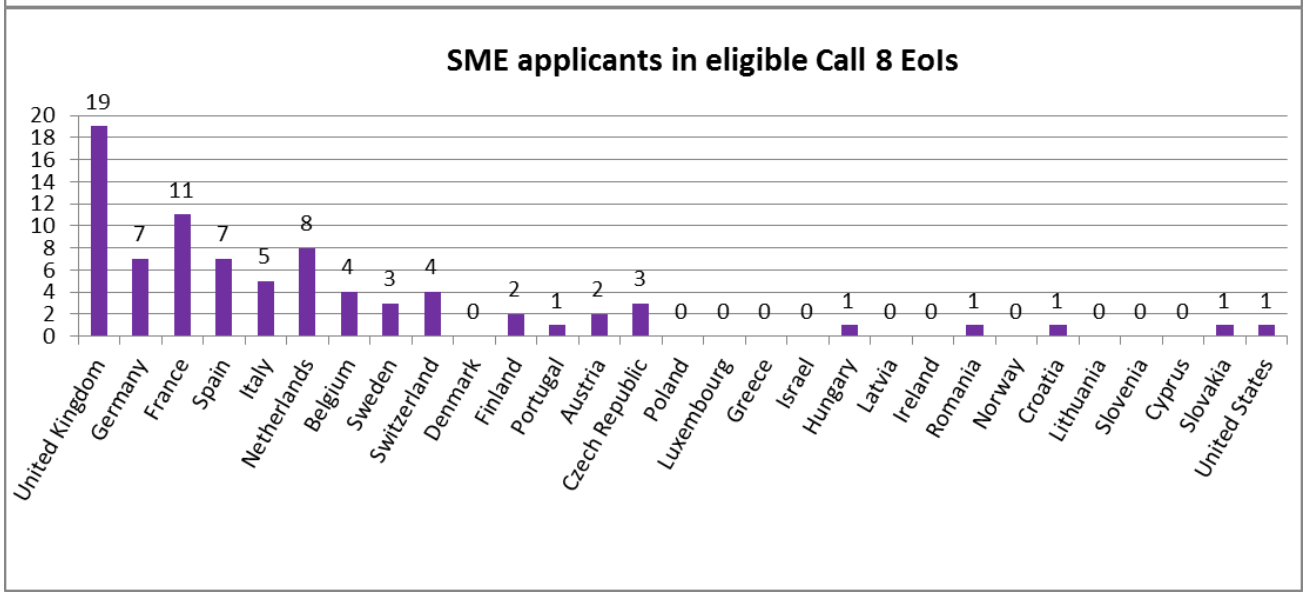
SME applicants in eligible Call 8 EoIs
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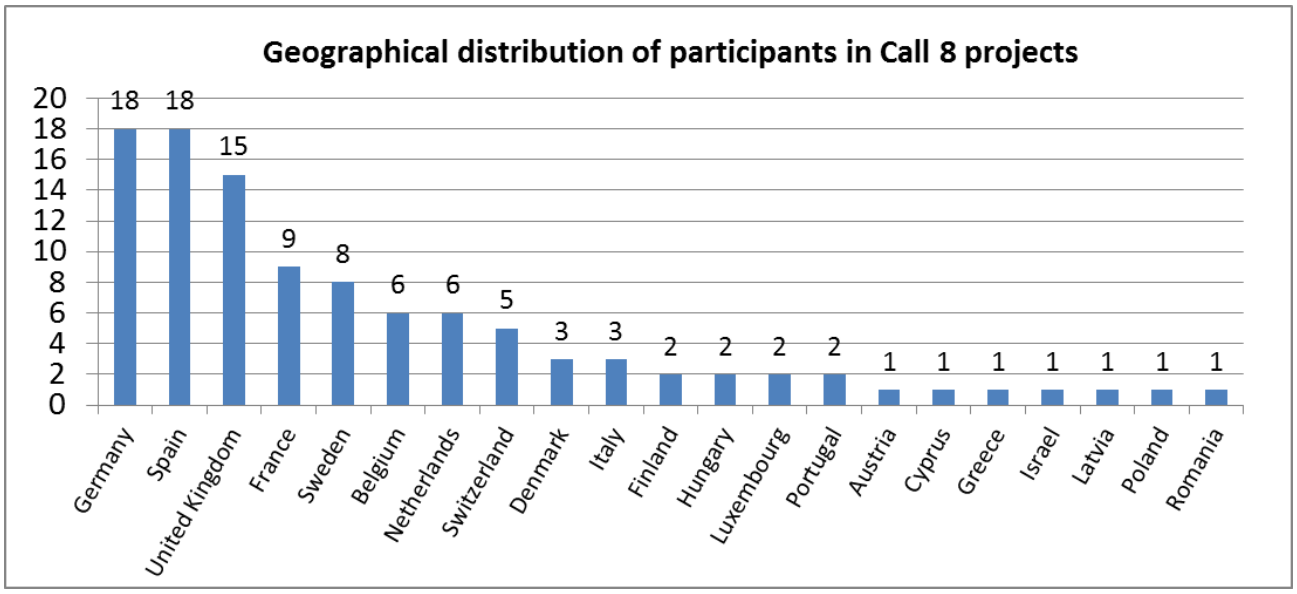
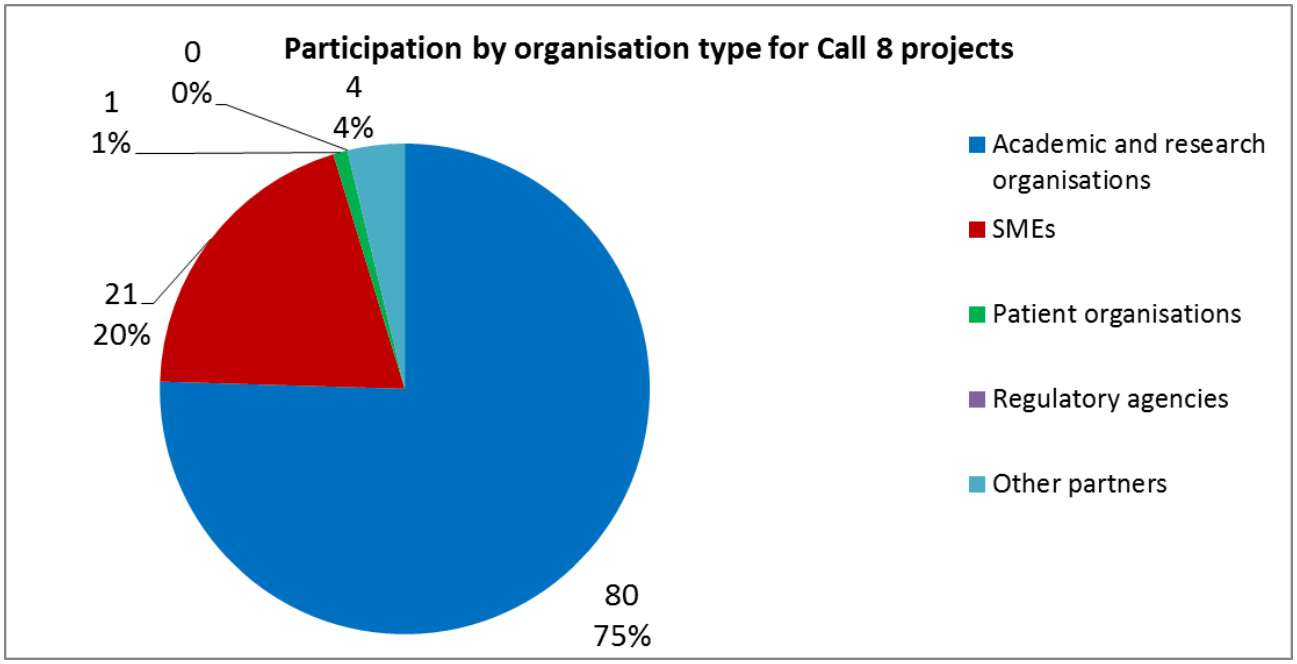
Switzerland
Denmark
Finland
Portugal
Austria
Czech Republic
Poland
Luxembourg
Greece
Israel
Hungary
Latvia
Ireland
Romania
Norway
Croatia
Lithuania
Slovenia
Cyprus
Slovakia
United States

- The in-house evaluation of the EoIs was conducted by separate panels of independent experts mainly from Europe. The first ranked EoI consortia were merged with the EFPIA consortia and invited to submit their FPPs by 26 July 2013.
- The FPP evaluations were successfully completed during August 2013 with the Expert Panel recommending to the IMI Governing Board that the all five consortia progress to the negotiation stage.
- The negotiations for the Call 8 projects were concluded in December 2013. The Grant Agreement[14] signatures took place and pre-financing was released in December 2013. The projects are scheduled to begin in the first quarter of 2014.
- The key figures of the participants in the Call 8 projects are presented below.





[14] For Topic 1, the applicant consortium merged with the Call 6 project, COMBACTE, via an amendment to the Grant Agreement.

The four 8th Call projects pre-financed in 2013 (in EUR)

IMI Project	EFPIA + IMI Funding	EFPIA Funding	IMI Funding	SME	Academic	Research	Patient Org.	Other
ENABLE	81 852 360	22 952 360	58 900 000	20 130 258	23 864 443	12 592 854	0	2 312 445
PRECISESADS	19 890 188	9 890 865	9 999 323	1 136 987	3 629 210	4 561 186	0	671 940
AETIONOMY	16 024 944	8 031 710	7 993 234	672 605	3 559 154	3 662 475	99 000	0
EBiSC	30 129 098	8 288 718	21 840 380	8 772 455	7 085 539	5 982 386	0	0
TOTAL	147 896 590	49 163 653	98 732 937	30 712 305	38 138 346	26 798 901	99 000	2 984 385

3.3 Launch of the 9th Call for proposals

The 9th Call for proposals included the following topics:

1. WEBAE – Leveraging emerging technologies for pharmacovigilance
2. Developing innovative therapeutic interventions against physical frailty and sarcopenia (ITI-PF&S) as a prototype geriatric indication
3. ND4BB Topic 4: Driving re-investment in R&D and responsible use of antibiotics
4. ND4BB Topic 5: Clinical development of antibacterial agents for Gram-negative antibiotic resistant pathogens

- Workshops were held by the IMI Executive Office in May 2013 in Brussels to discuss the proposed topics. The topics discussed were:
  - Developing innovative therapeutic interventions Against physical frailty/sarcopenia
  - Driving re-investment in R&D and responsible use of antibiotics
  - Correlates of protection for influenza vaccines

- As with previous workshops, members of the Scientific Committee chaired the sessions, and for each topic the EFPIA coordinator made a presentation, after which there was a discussion with a panel of invited experts. These 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 to the start of the final consultation of the SRG and Scientific Committee.

- Topic 1, WEBAE had been the subject of previous workshop in 2012. The IMI antimicrobial resistance programme (ND4BB Topic 5) had also been the subject of a workshop dedicated to this programme in 2011. Therefore these two topics were not on the agenda of the May workshop.

- As a result of the workshop and further discussions amongst the EFPIA companies, it became apparent that an extended period of time was required to ensure the topic 'Correlates of protection for influenza vaccines' would meet its full potential. It was, therefore, decided to delay this topic to a future Call.

- The final text of the Call 9 topics was sent for consultation on 28 May 2013, and following Governing Board approval, the 9th Call for proposals was launched on 9 July 2013. The deadline for submission of EoIs was 9 October 2013.

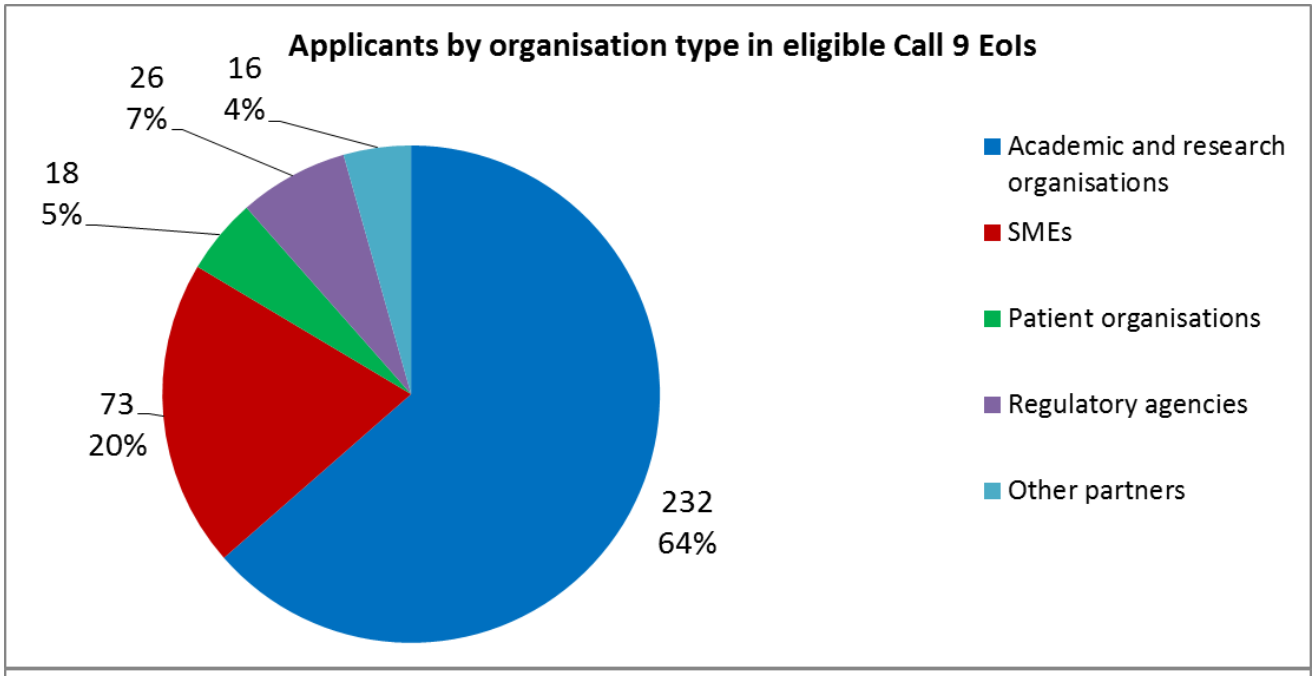
- The launch of the 9th Call was announced to the media with a press release entitled 'IMI 9th Call For proposals: Focus On frailty, use of social media to monitor drug safety, and antibiotic development'.

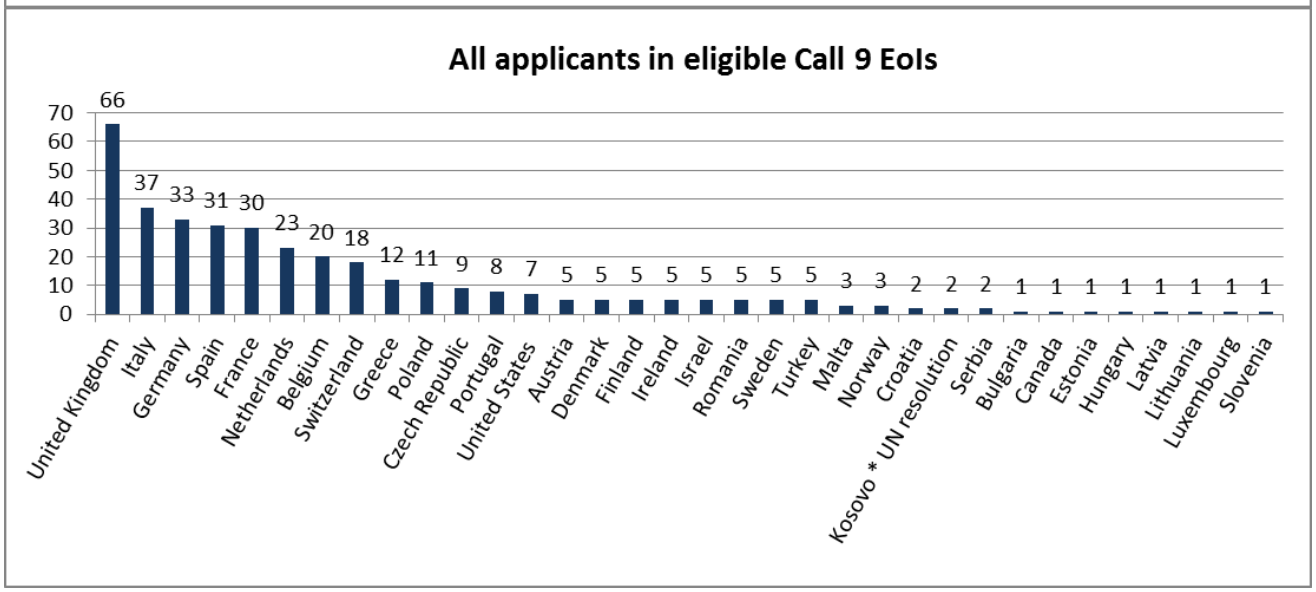
- Webinars were held in early July 2013 to present the topics to potential applicants. The EFPIA in kind contribution committed to the 9th Call projects was €72.25 million and the IMI JU contribution was €63.12 million.

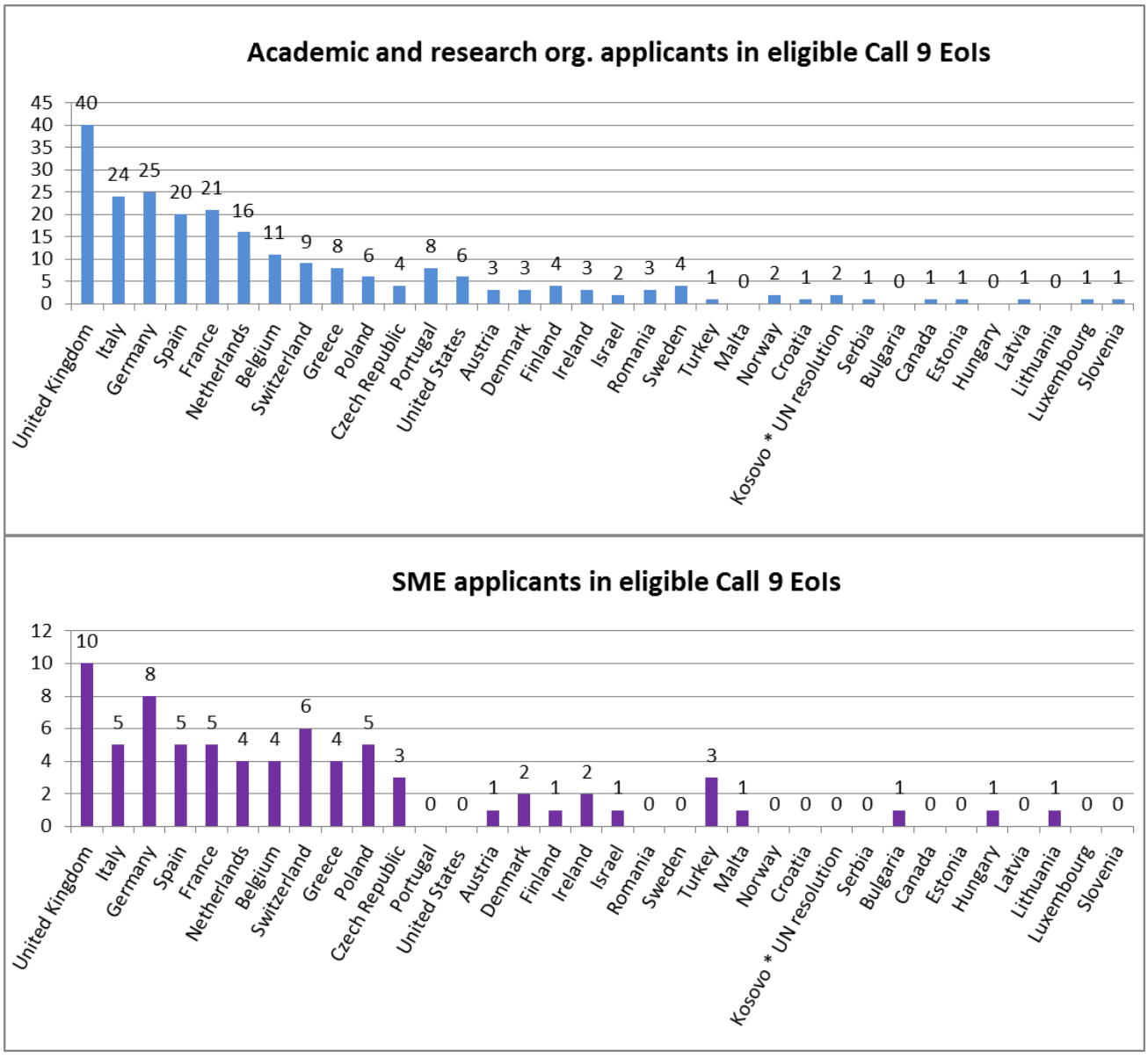
- 37 EoIs were received by the submission deadline, 33 of which were eligible for evaluation.

- Analysis of the eligible EoI applicants revealed that 365 legal entities took part; 232 (64%) were academic and non-profit organisations and 73 (20%) were SMEs. On average, there were 11.1 entities per EoI.

Key figures regarding submitted EoIs are presented below.



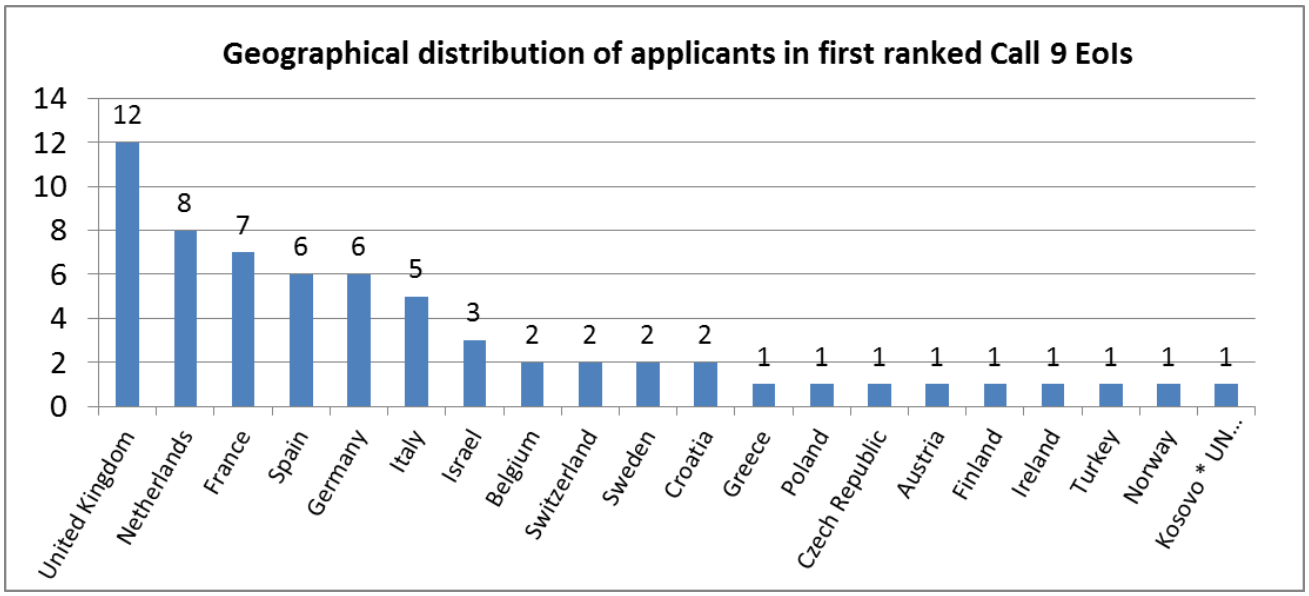




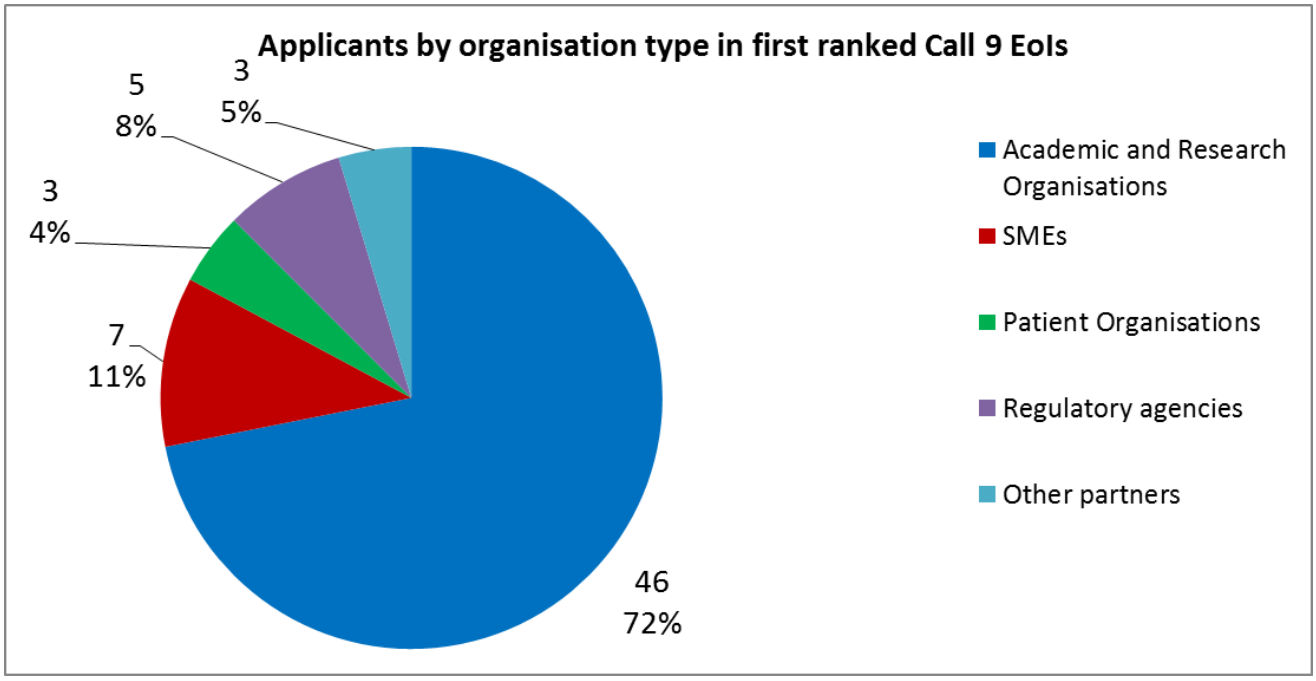
- The evaluation of the EoIs was conducted by panels of independent experts from Europe and the US working initially remotely and then at a consensus meeting. 26 external experts worked in 4 panels (1 panel per topic) moderated by IMI's Scientific Officers.

- Following the approval of the recommendations of the evaluation panels by the Governing Board, the four first-ranked EoIs were invited to prepare FPPs together with the pre-established EFPIA consortia.
The deadline for submission of the FPPs is 4 March 2014. The evaluation of the resulting FPPs will be conducted in 2014.

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



*UN resolution



3.4 Launch of the 10th Call for proposals

The 10th Call for proposals included the topic on Immunological assay standardisation and development for use in assessments of correlates of protection for influenza vaccines.

- The consultative workshop had previously been held in the IMI Executive Office alongside the Call 9 topics in May 2013.
- The final text of the Call 10 Topic was sent for consultation on 12 September 2013, and following Governing Board approval, the 10th Call for Proposals was launched on 29 October 2013. The deadline for submission of EoIs was 28 January 2014.
- The launch of the 10th Call was announced to the media with a press release entitled 'IMI launches Call for proposals with focus on flu vaccines'
- A webinar was held on 24 October 2013 to present the topic to potential applicants.
- The EFPIA in kind contribution committed to the 10th Call projects is €6.1 million and the IMI JU contribution is also €6.1 million.

3.5 Launch of the 11th Call for proposals

The 11th Call for proposals included following topics:

1. Applied public-private research enabling osteoarthritis clinical headway (APPROACH)

2. European platform to facilitate proof of concept for prevention in Alzheimer's disease (EPOC-AD)

3. Blood-based biomarker assays for personalised tumour therapy: value of latest circulating biomarkers

4. Zoonoses anticipation and preparedness initiative (ZAPI)

5. Generation of research tools to enable the translation of genomic discoveries into drug discovery projects

6A. ND4BB Subtopic 6A: Epidemiology research and clinical development of a novel bispecific IgG antibody, BiS4αPa, for the prevention of serious *Pseudomonas aeruginosa* disease

6B. ND4BB Subtopic 6B: Clinical development of a novel resistance-breaking beta-lactam antibiotic, AIC499, in combination with a beta-lactamase inhibitor (BLI) against severe bacterial infections due to Gram-negative pathogens.

7. ND4BB Topic 7: Development of novel inhaled antibiotic regimens in patients with cystic fibrosis (CF) and patients with non-CF Bronchiectasis (BE)
8. Ecorisk prediction (ERP)

- Consultative workshops for all topics were held during October 2013. A workshop was also held for an additional topic, 'Remote assessment of disease and relapse', however, following discussions among the EFPIA companies, it became apparent that extra time would be needed to further develop the topic. It was, therefore, decided to delay this topic to a future Call.

- In order to facilitate the Call launch in December 2013, the consultation workshops were held via web conference and were chaired by the IMI Scientific Officer. The EFPIA coordinators presented the topics, and this was followed by a discussion with a panel of invited experts. These 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 the final consultation of the SRG and Scientific Committee.

- The final text of the Call 11 topics was sent for consultation on 7 November 2013, and following Governing Board approval, the 11th Call for proposals was launched on 11 December 2013. The deadline for submission EoIs is 8 April 2014.

- The launch of the 11th Call was timed to coincide with the G8 health ministers meeting in London, and was announced to the media with a press release entitled 'IMI launches €371 million Call with focus on Alzheimer's, arthritis, cancer, and more'.

- Webinars to present the topics to potential applicants will be held in January 2014.

- The EFPIA in kind contribution committed to the 11th Call projects is €201.1 million and the IMI JU contribution is €171.4 million.

3.6 Implementation of ENSO Calls for proposals

- The rolling Call for proposals inviting ongoing projects to submit applications to Explore New Scientific Opportunities (ENSO) was launched in August 2012.
- The deadlines were 15 December 2012, 31 May 2013, and 15 December 2013.
- To promote the ENSO Call among IMI project participants and clarify the key points a question and answer (Q&A) document on the ENSO Call was published and updated on the ENSO web page[15]. Presentations were given to the projects via webinar on 24 April 2013 and 7 November 2013.

ENSO-1: 15 December 2012 deadline

In total, five applications were submitted by the following projects for the 15 December 2012 deadline: eTOX, IMIDIA, PREDECT, BTCure, EHR4CR. The evaluations were held in January and February 2013.

- The evaluation of the five applications was conducted by a single panel of five independent experts working initially independently and then at a consensus telephone conference.
- Following the approval of the recommendations of the evaluation panels by the Governing Board, all five applicant proposals were invited to negotiate an amendment to the Grant Agreement to incorporate the new ENSO activities. All amendments were signed, and the projects pre-financed in 2013.

ENSO-2: 31 May 2013 deadline

- One application was received from the U-BIOPRED project by the 31 May 2013 deadline. The evaluation was held in June 2013
- The evaluation of the application was conducted by a single panel of three independent experts working initially independently and then at a consensus telephone conference.
- Following the approval of the recommendation of the evaluation panels by the Governing Board, the successful proposal was invited to negotiate an amendment to the Grant Agreement to incorporate the new ENSO activities. The amendment was signed, and the project pre-financed in 2013.
- The remaining unspent budget earmarked for this cut-off date became part of the total available IMI budget of €7.5 million for the following cut-off date of 15 December 2013.

ENSO-3: 15 December 2013 deadline

- 8 applications were submitted by the 15 December 2013 deadline. The evaluations are scheduled for January and February 2014.

[15] http://www.imi.europa.eu/content/new-opportunities

4. COMMUNICATION AND NETWORKING

4.1 Strategy and key messages

In 2013, IMI's communication strategy focused on promoting IMI's successes and attracting applicants for Calls for proposals. Hiring a public relations (PR) agency helped IMI to formalise its Communication Strategy and refine its key messages for different target audiences.

As the highlights below reveal, IMI achieved considerable visibility in both specialist and general media.

Furthermore, the fact that a number of opinion leaders spontaneously cited IMI in various outlets demonstrates a high level of awareness of IMI among key stakeholders.

IMI also continued to work on outreach to researchers in the newer EU Member States, and with the help of the PR agency Media Consulta, achieved considerable media coverage there. It should be noted that IMI's communication successes in 2013 were boosted by the efforts of the European Commission and EFPIA, as well as the SRG, Scientific Committee, and the projects themselves.

4.2 Improving IMI outreach

Events

In line with the Communication Strategy, IMI's events in 2013 were designed to:

- promote IMI's successes and its Calls for proposals;
- provide stakeholders with an opportunity to give feedback on IMI's work;
- facilitate networking between IMI stakeholders.

Event	Date & location	Outcome
Collaborating for cures - leveraging global public-private partnerships (PPPs) to accelerate biopharmaceuticals development ▪ Joint event with C-Path on the benefits of and challenges faced by PPPs in health research	7 March 2013 Brussels, Belgium & online	▪ Over 100 attendees, including policy makers, regulators, researchers, IP experts ▪ Event broadcast over internet ▪ High-level speakers from both sides of Atlantic ▪ Lively debate on challenges faced by PPPs ▪ Press coverage
IMI and personalised medicine ▪ Event organised in framework of conference 'Innovation and patient access to personalised medicine' organised by the European Alliance for Personalised Medicine (EAPM) under the auspices of the Irish Presidency of the EU Council.	20 March 2013 Dublin, Ireland	▪ Over 70 attendees, including researchers, patient groups, policy makers ▪ IMI projects on personalised medicine presented to broad audience ▪ Chapter on IMI in report on main event.

Event	Date & location	Outcome
IMI Stakeholder Forum 2013 ▪ Morning dedicated to brain research (in line with broader EU Month of the Brain initiative) ▪ Afternoon focused on IMI in the European Research Area ▪ High-level speakers included immunologist and Nobel laureate Rolf Zinkernagel, Richard Frackowiak of the Human Brain Project, and Françoise Grossetête MEP (Member of the European Parliament)	13 May 2013 Brussels, Belgium & online	▪ Over 250 attendees, including policy makers, patient groups, researchers, regulators ▪ Event broadcast over internet ▪ IMI projects given high visibility ▪ Press coverage ▪ Networking opportunities
Info Session: funding opportunities with the Innovative Medicines Initiative ▪ Event held in framework of Health Management & Clinical Innovation Forum (MIHealth) ▪ Focus on 9th Call for proposals and other future topics ▪ Combined with SRG meeting	28 June 2013 Barcelona, Spain	▪ Over 100 attendees, including academics and SMEs ▪ Spotlight on, and tips from, local project participants ▪ Networking opportunities ▪ Local press coverage
IMI 9th Call webinars ▪ Webinars held on all Call topics plus IMI's rules and procedures	1-15 July 2013 Online	▪ Opportunity for potential applicants to discuss topics with coordinators
IMI 2 proposal launch ▪ Event organised by European Commission ▪ IMI support re success stories, speakers	10 July 2013 Brussels, Belgium	▪ Press coverage
Moving translational immunology forward through public-private partnership ▪ IMI symposium at the 15th International Congress of Immunology (ICI2013)	26 August 2013 Milan, Italy	▪ Over 200 attendees ▪ Focus on contribution of PPPs to immunology research ▪ Promotion of forthcoming IMI calls for proposals
Innovation through collaboration - The role of public-private partnerships in translational medicine ▪ IMI symposium at the 11th Congress of the European Association for Clinical Pharmacology and Therapeutics (EACPT 2013)	29 August 2013 Geneva, Switzerland	▪ Over 100 attendees ▪ Focus on IMI projects on autism, diabetes, and antimicrobial resistance
The Innovative Medicines Initiative (IMI): Putting Europe at the forefront of innovation in drug development ▪ Dinner debate at the European Parliament	10 September 2013 Strasbourg, France	▪ Attendees included 8 MEPs ▪ Speakers included academic and patient representatives from IMI projects / committees

Event	Date & location	Outcome
Joint Technology Initiatives [JTIs] - Innovation in Action ▪ Joint event with the other JTIs at the European Parliament ▪ Week-long series of events included exhibition, press conference, debate	30 September – 4 October 2013 Brussels, Belgium	▪ Interactions with several MEPs and other key stakeholders ▪ Press coverage
IMI 10th Call webinars ▪ Webinars held on all Call topics plus IMI's rules and procedures	24 October 2013 Online	▪ Opportunity for potential applicants to discuss topics with coordinators
Open Info Day - Horizon 2020 'Health, demographic change and wellbeing' ▪ Event organised by European Commission ▪ IMI stand at exhibition	22 November 2013 Brussels, Belgium	▪ Promotion of IMI's 10th and 11th Calls for proposals
G8 Dementia Summit ▪ Event organised by UK presidency of G8 ▪ Regular contact between organisers and IMI in run up to event ▪ IMI contributed to speaking notes of relevant speakers IMI mentioned in event press materials	11 December 2013 London, UK	▪ Event attended by G8 health ministers, researchers, patient and carer representatives ▪ High visibility of 11th Call Alzheimer's disease topic thanks to announcements by Commissioner Tonio Borg, Paul Stoffels (J&J) and Michel Goldman ▪ IMI mentioned in official summit communique ▪ Press coverage

Promoting IMI's Calls for proposals

IMI launched its 9th, 10th and 11th Calls for proposals in 2013. Calls were promoted via the following channels:

- IMI website
- Press release
- Webinars (NB the 11th Call webinars are planned for January 2014)
- IMI Newsletter
- Social media (Twitter, LinkedIn)
- Flyers
- Events organised by others (e.g. SRG members) – for this, IMI often provided speakers and materials.
- Direct e-mails to stakeholder organisations (e.g. academic societies, patient groups) and relevant individuals
- IMI events
- Presentations by IMI staff at external events

IMI also held two webinars on the ENSO Call for proposals, one in April, the other in November.

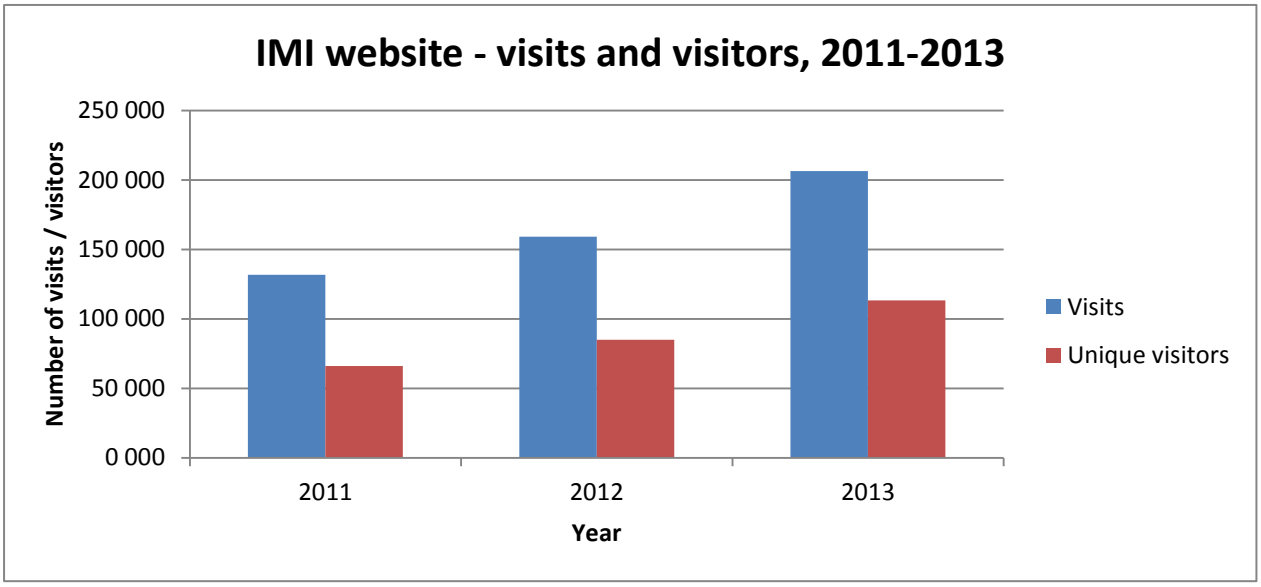
Promoting IMI's project successes

The Communications Team promotes the successes of IMI projects through a variety of channels:

- IMI newsletter
- IMI website
- Social media (Twitter, LinkedIn)
- IMI press releases
- Other organisations' press materials (e.g. European Commission)
- Press and scientific articles by the IMI office
- Examples given to journalists writing about IMI
- IMI events
- Presentations by IMI staff and ambassadors at external events

IMI website

The IMI website continues to attract growing numbers of visits and visitors.



Data source: Google Analytics, data downloaded on 6 January 2014.

Infodesk

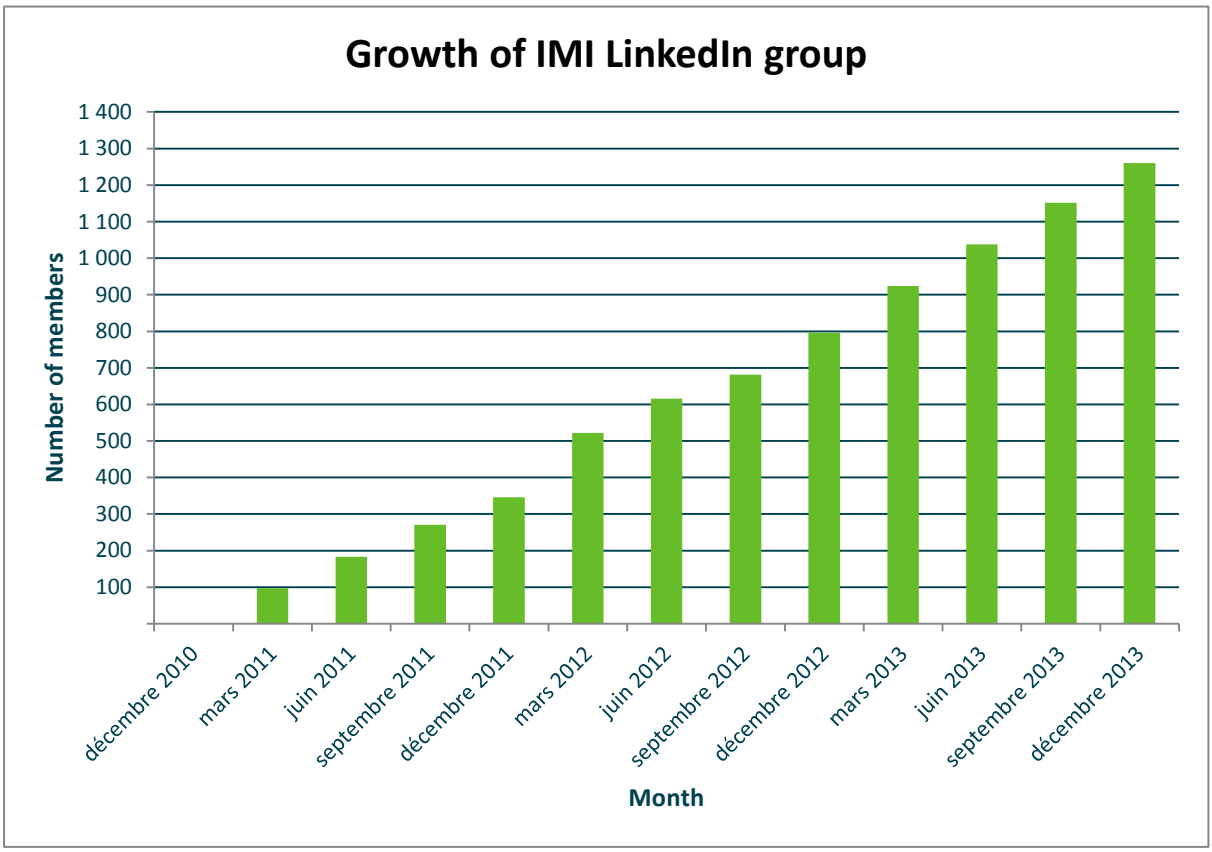
In 2013, the IMI infodesk e-mail address, managed by the Communications team, received more than 1 000 requests. The infodesk facilitated public interaction on key issues and improved awareness of IMI activities and processes.

IMI Newsletter

IMI sent out 10 newsletters in 2013, covering Call launches, new projects, IMI event announcements, news on IMI reports and publications, and news from the projects. At the end of 2013, there were over 3 000 newsletter subscribers.

Social Media

At the end of 2013, IMI's LinkedIn group had 1 260 members, up from 784 at the end of 2012.



Data source: LinkedIn group statistics, accessed on 22 January 2014

IMI continued to increase its Twitter activity throughout 2013, with regular tweets on project successes and press articles mentioning IMI. IMI also tweeted live from a number of events. By the end of the year, the @IMI_JU account had over 1 300 followers (data source: Twitter).

4.3 Key publications

Media highlights

In collaboration with the PR agency, IMI expanded its press list in 2013 to take in more journalists from across Europe. In addition to sending out 15 press releases (on Calls for proposals, the launch of new projects, project results, and certain events), IMI invited journalists to some of its most important events. Media monitoring by Media Consulta revealed that IMI has achieved coverage in almost all EU Member States, and featured in some of Europe's most influential news outlets. An analysis of the coverage by Media Consulta reveals that the tone of most articles is neutral or positive, with very little negative coverage.

The following list sets out the top 10 media highlights from 2013. A more exhaustive list can be found in Annex D and on the Media Coverage page of the IMI website.

- Wall Street Journal, 30 December 2013
  Researchers Aim to Speed Cures to Patients
- Financial Times (UK), 6 December 2013
  Science: High-tech drug research gives us a fuller picture

- Financial Times (UK), 17 October 2013
  Doctor prescribes boost for biomedicine in EU
- Science (US), 12 July 2013
  E.U. Commission Beefs up Research Partnerships with Industry
- Euronews (European), 25 June 2013
  Developing a treatment for autism
- Scrip (international), 21 April 2013
  INTERVIEW: Goldman's dreams of competitive collaboration as IMI 2 considered
- Deutsche Welle – Spectrum (Germany), 4 March 2013
  Make drugs not war
- Nature (UK), 7 February 2013
  Europe bets on drug discovery
- Reuters (international), 7 February 2013
  Drugmakers, academics pool R&D in $265 mln EU project
- BioCentury (US), 24 January 2013
  IMI's collaborative chemistry

Spontaneous citations – a sign of growing awareness of IMI

While the majority of press articles and scientific publications mentioning IMI came about as a result of efforts on the part of the IMI office, 2013 saw a number of cases where journalists and opinion leaders spontaneously mentioned IMI.

Some of the most prominent examples of this are listed below:

1. Nature Medicine, 5 December 2013
   Timeline of events: A brief history of what made news this year (highlights the launch of the European Lead Factory as a highlight in 2013)
2. Science Translational Medicine, 28 August 2013
   Curing Consortium Fatigue (article discusses how to improve the way multi-stakeholder collaborations work)
3. World Health Organization, 9 July 2013
   Priority Medicines for Europe and the World Update Report, 2013 (emphasises effectiveness of IMI and other PPPs in precompetitive research)
4. Europe's World, 1 June 2013
   Everything that's wrong with the EU budget … and how to fix it (MEP and former Belgian Prime Minister Guy Verhofstadt cites IMI in section on importance of investing in research and innovation)
5. Science, 12 April 2013
   Opening Industry-Academic Partnerships (section on IMI in article on academia-industry collaboration)
6. Nature Careers, 17 April 2013
   Regulatory science: Researchers in the pipeline (mentions IMI's PharmaTrain and Eu2P projects)
7. Chief Medical Officer for England, Dame Sally Davies, March 2013
   Annual Report of the Chief Medical Officer - Infections and the rise of antimicrobial resistance (report cited IMI as an example of what is needed to tackle antimicrobial resistance, generating a lot of media coverage for IMI)

8. The Guardian, 27 January 2013
   Science funding and the EU: you've got to be in it to win it (Nobel laureate and President of the UK's Royal Society Sir Paul Nurse cited IMI in an article on the benefits to the UK research community of EU membership)
9. Nature Reviews Drug Discovery, January 2013
   News and Analysis - 2012 in reflection (highlights the launch of the Calls for proposals on antimicrobial resistance and the European Lead Factory)

IMI in scientific journals & reports

- Science Translational Medicine, Vol. 5 (216) pp. 216ed22
  Goldman, M. (2013) New Frontiers for Collaborative Research
- Computational and Structural Biotechnology Journal, Vol. 6 (7), e201303017
  Vaudano, E. (2013) The Innovative Medicines Initiative: a public private partnership model to foster drug discovery
- Alternatives to Laboratory Animals (ATLA), Vol. 40 (6), pp. 307-312
  Gunn, M. et al. (2013) The rational use of animals in drug development: contribution of the innovative medicines initiative
- European Journal of Immunology, Vol. 43 (2), pp. 298-302
  Goldman, M. et al. (2013) The Innovative Medicines Initiative moves translational immunology forward
- Clinical and Translational Medicine, Vol. 2 (2), published online 15 January 2013
  Goldman, M. et al. (2013) Public-private partnerships as driving forces in the quest for innovative medicines

4.4 Support to Governance and Consultative bodies

IMI provided continuous support to its governance and consultative bodies. Efforts were made to improve communication and feedback on IMI's 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. In April 2013, Dr Rudolf Strohmeier (EC) became Chairman and Mr Roch Doliveux (EFPIA) became Vice-Chairman for a one-year mandate. The Governing Board met three times (in March, July, and October), adopting various decisions and reports that include the Annual Activity Report 2012, the Annual Implementation Plan for 2014, Call texts and budgets, and the outcome of evaluations. 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 2013 (in March, June, and November). They were chaired by Professor Christian Noë until the end of his term in June 2013.

The composition of the Scientific Committed was partially renewed in September with the appointment of eight new members to replace those whose mandate ended in June.

By the end of the year, the Scientific Committee appointed its new Chair, Mrs Béatriz Da Silva Lima.

Key activities included an update on IMI project achievements, notably on the occasion of the interim reviews of the Call 2 projects, and consultations on future and new Call topics.

Furthermore, the Scientific Committee was periodically informed by the IMI founding members about the preparation of the IMI -2 proposal within the new Framework Programme Horizon 2020.

States Representatives Group SRG

The SRG held four meetings (in February, June, October, and December) chaired by Dr Gunnar Sandberg. Detailed updates on IMI activities in terms of ongoing projects' achievements were provided and consultations on future Calls were organised. Open discussions with the founding members provided the opportunity for SRG members to discuss the IMI 2 proposal and related ongoing debates.

Stakeholder Forum

Through its annual Stakeholder Forum, IMI engages key stakeholders in discussions about its activities. IMI held its 2013 Stakeholder Forum in Brussels on 13 May. As May was the European Month of the Brain, the morning session was dedicated to presentations by and discussions on IMI's brain projects.

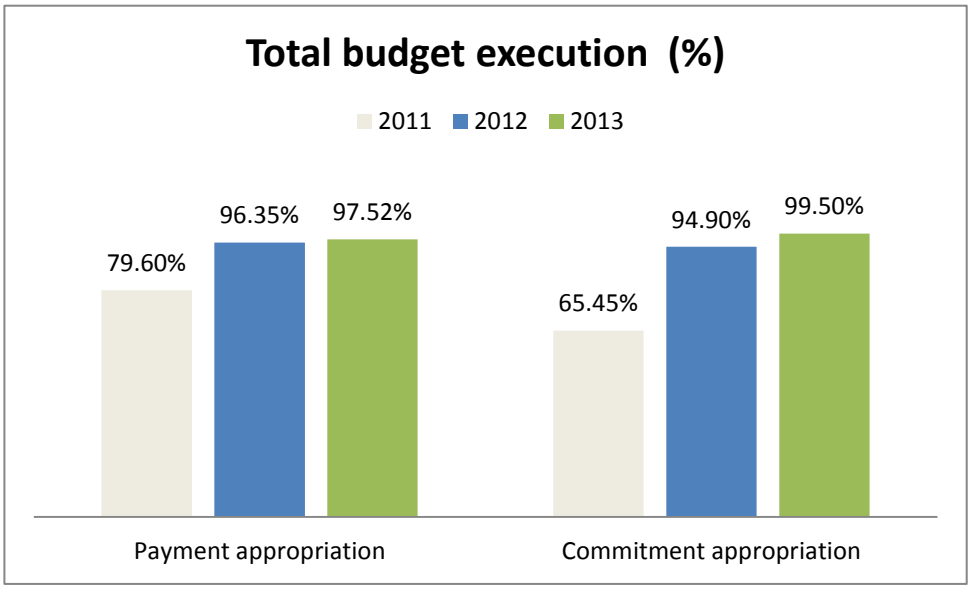
The afternoon was devoted to a debate on IMI's role in the European Research Area (ERA). High-level speakers included immunologist and Nobel laureate Rolf Zinkernagel, Richard Frackowiak of the Human Brain Project, and Françoise Grossetête MEP. The event attracted over 250 participants and was also broadcast over the internet.

5. EXECUTIVE OFFICE MANAGEMENT

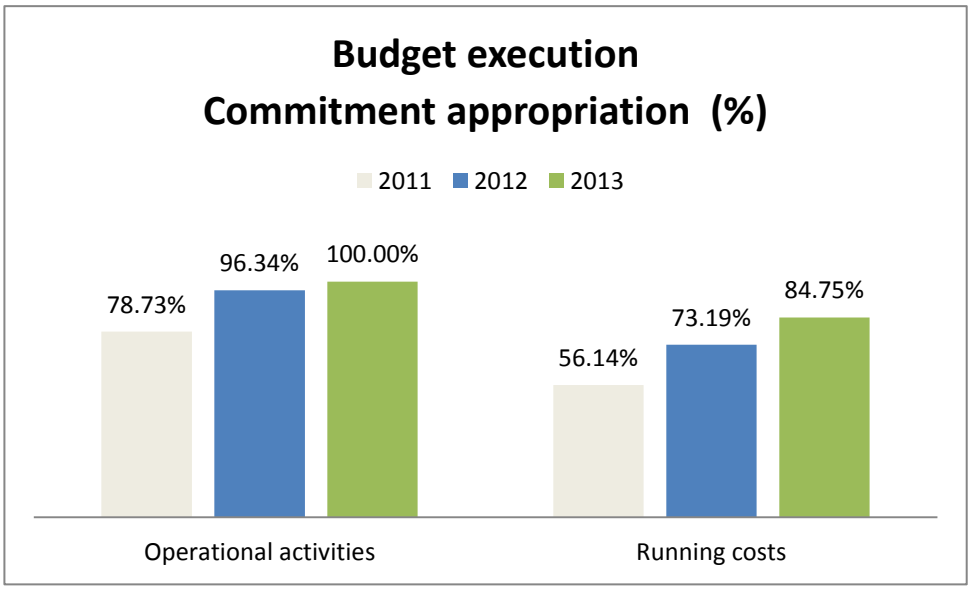
5.1 Budget and finance

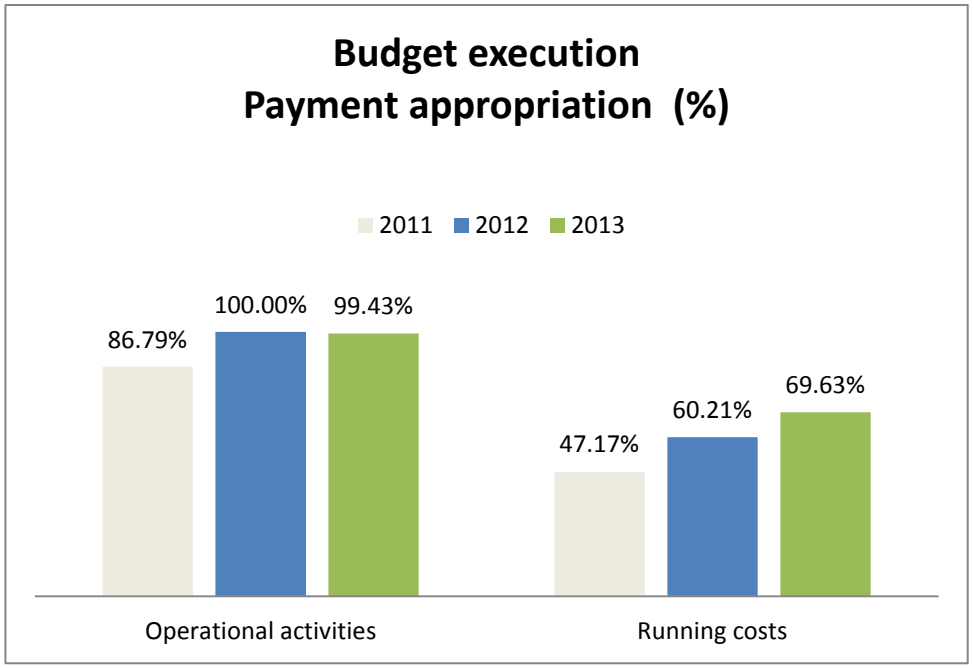
Budget execution

In 2013, the budget execution further improved, compared to 2011 and 2012, reaching 99.50% in commitment appropriations and 97.52% in payment appropriations.



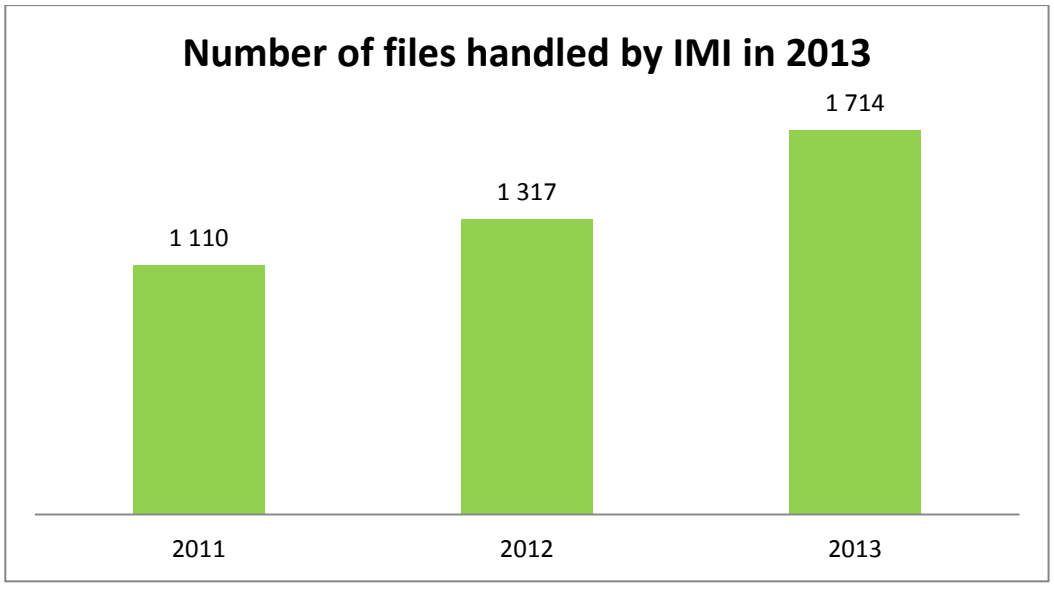
The graphs below show the difference in budget execution between operational activities (project-related) and the running costs of the Executive Office (staff and infrastructures).





Financial operations

IMI handled a total of 1 714 financial files (payments, commitments, forecasts of revenue, recovery orders and budget transfers) in 2013.



More detailed information is presented on the Annex A.

Since January 2013, IMI has had to comply with the payment time limits set out in the new Financial Regulation. The table below shows the average time to pay, which is in all cases below the targets set. Average time to pay regarding operational payments in 2011 and 2012 is not mentioned as the payment limits were different than in 2013 and are therefore not comparable.

Maximum payment time limit	Average time to pay (days)		
Year	**2011**	**2012**	**2013**
Administrative payments			
30 days	39	17	15
45 days*	44	23	19
60 days	47	25	14
Operational payments			
30 days			18
90 days			66

*In 2013 the maximum payment time limit is 30 days

Though the majority of processed files relate to payments for running costs, the payment appropriation is mainly executed through operational payments (IMI contribution to projects). In order to raise the quality of, and reduce errors in, periodic reports provided to IMI by the consortia, IMI organised four financial management workshops in 2013. In total, 124 representatives of IMI beneficiaries participated in three financial workshops for beneficiaries and 31 representatives of EFPIA companies attended the workshop for EFPIA companies. This initiative started in 2012 and will continue in 2014.

State of play of founding members' contribution

The following table provides an overview of reported contributions for EFPIA companies and beneficiaries as at 28 January 2014. It shows that the balance between public funding and industry contribution has been maintained to date.

Reported contributions include submitted claims reported but not yet accepted for Call 1 - period 4.

	Nbr of projects	EU (EUR)			EFPIA (EUR)		
		Committed	Reported		Committed	Reported	
Call 1	15	113 603 647	71 252 168	62.7%	148 604 419	88 229 618	59.4%
Call 2	8	82 796 204	27 594 996	33.3%	71 165 346	18 312 697	25.7%
Call 3	7	111 816 124	10 144 282	9.1%	70 953 085	5 422 543	7.6%
Call 4	7	97 943 541	6 367 511	6.5%	111 046 803	7 390 422	6.7%
Call 5	1	79 999 157			91 337 070		
Call 6	2	125 417 213			142 058 215		
Call 7	2	12 999 811			11 927 750		
Call 8	4	98 732 937			49 163 653		
Call 9	4	63 120 000			72 250 000		
Call 10	1	6 100 000			6 100 000		
Call 11	8	171 424 773			201 045 105		
ENSO-3		6 471 146			6 497 305		
	59	**970 424 553**	**115 358 957**	**11.9%**	**982 148 751**	**119 355 280**	**12.2%**

Notes:

- Call 8 resulted in five successful projects, of which one (APC) became an amendment to the existing Call 6 project COMBACTE. Accordingly, the commitment of that project has been included in Call 6 (which increased compared to last year's commitment).
- Call ENSO-3 amounts are based on the submitted proposals on 15 December 2013.

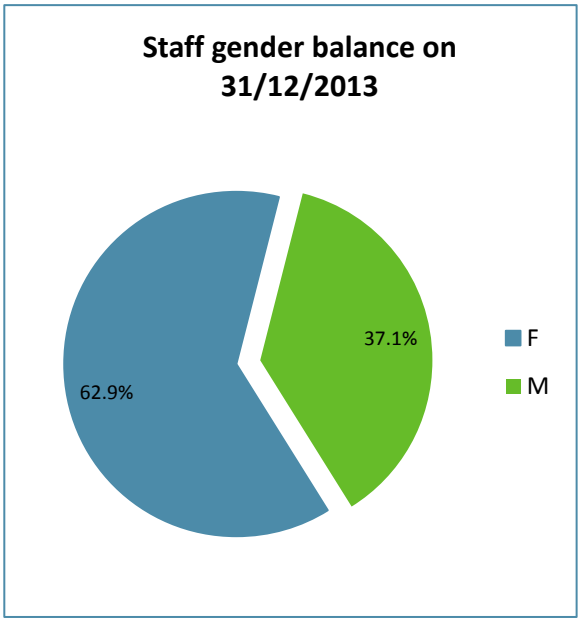
5.2 Human resources

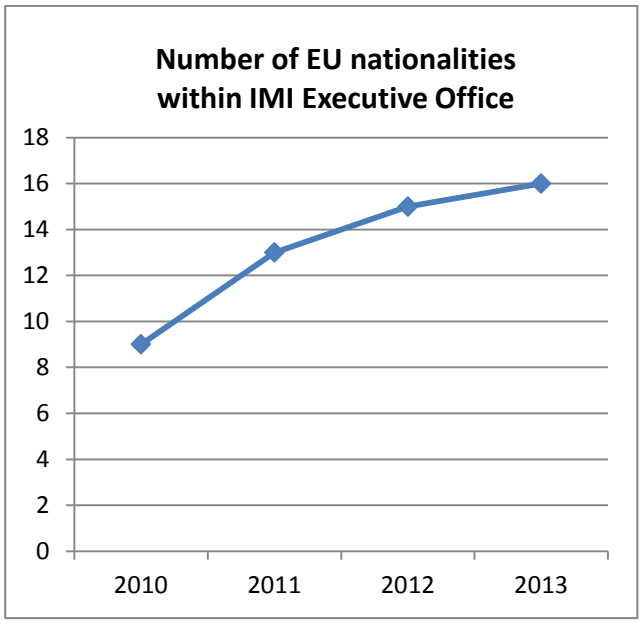
- The authorised maximum ceiling of 36 staff members was reached on 1 July 2012.

- Recruitment in 2013 was conducted in line with the Multi-Annual Staff Policy Plan approved by the Governing Board. Four new staff members joined IMI during the year following the departure of staff members.
  - Two administrative assistants joined the scientific team.
  - One Communication and Events Officer joined the communication team.
  - One Ex post Audit and Finance Officer (new position) joined the finance team.

These new recruits enabled IMI to keep improving its geographical balance while the gender balance stayed the same as last year, as shown in the graphs below.

- For the first year, IMI implemented its learning and development policy. The main areas covered were:
  - IT skills (on Microsoft office tools as well as IMI's own IT tools);
  - Communication (public speaking and languages);
  - Ethics and integrity (follow up actions);
  - How to better work together? (Team-building seminar organised in May 2013 with a follow-up action plan implemented in the second half of the year).





5.3 Information and communication technology

IMI's strategic ICT objective is to deliver value to IMI 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's ICT applications and infrastructure support the implementation of IMI's strategy and business objectives with the aim of making all IMI processes simpler and more efficient.
With a view to contributing to the effective operation of the IMI IT project environment, the IMI IT Manager achieved PM² (Project Management Methodology) certification in 2013. PM² certification provides knowledge and tools customised for the EC.
The year 2013 marked the technical consolidation and delivery of enhancements for integrated solutions across business processes as summarised in the table below.

IMI Core Business	
SOFIA (Submission of Information Application)	• Automatic export to CORDA (Common Research Data Warehouse) and eCORDA (External Common Research Data Warehouse) • Reporting application - QlikView - for IMI, EC, EFPIA, SRG • Industry Liaison Group (ILG) overview • Enhanced Annual Periodic Reporting • ENSO Calls • Ethics Review • 3rd login for Project Managers • Training and support to project participants
Other IMI Business Applications	
Events Registration Application	• Extended to manage events organised jointly by the five JUs (Joint Undertakings)
IMI website and newsletter	• Migration to new server and provider
ICT Internal Support	
DORA (Document Repository Application)	• Enhanced and extended to include annexes • Implemented integration with scanner
ISA (Information System for Absences)	• Enhanced and extended to manage additional types of absences: teleworking and part-time
eCDR (electronic Career Development Report)	• New web application for managing staff appraisals
BIT (Booking of IT material)	• New web application for managing the booking of IT materials
ICT Internal Support to other Jus	
Vacancies and ISA	• Two IMI web applications have been configured and made available to two other JUs

Support to IMI core business

SOFIA is a fully-integrated web application to support the management of the Call process and project life cycle. It is an important element of the simplification of IMI processes. In 2013 SOFIA was subject to significant development improvements described in the sections below.

Back office

Automatic export to CORDA and eCORDA

Since the third quarter of 2013, IMI has been exporting its Call and project data from SOFIA to the EC's Common Research Data warehouse (**CORDA).** The exports are done automatically and on a daily basis. The **external CORDA** data warehouse (eCORDA), for external stakeholder users, has also been updated with IMI data.

This is a major achievement on the integration of **SOFIA with the EC IT architecture for reporting** of Call and project data which is now available in CORDA along with data from the other EC Framework Programmes for Research.

Upload of past data

Call 1 was managed before the set-up of the IMI online submission tool; therefore, non-successful Call 1 EoIs and consensus reports were manually encoded in SOFIA.

Generation and upload of negotiation letter

SOFIA has been enhanced with functionality to generate the negotiation letter at the end of the negotiation process. After signature, the negotiation letter is uploaded in SOFIA.

Front office

Reporting application - QlikView - for IMI, EC and EFPIA

During 2013, a **statistics and KPI monitoring module**, with a variety of tailor-made dashboards, was implemented using QlikView. It is integrated with SOFIA and enables the analysis of IMI scientific and financial Call and project data. In third quarter of 2013 it was made available to the IMI founding members and SRG for their real-time analysis of IMI data.

ILG overview

Following a request from EFPIA/ ILG members, SOFIA was enhanced with a report on project reporting deadlines. In addition the EFPIA/ILG members' access to SOFIA was enhanced, allowing ILG members to update their own company's administrative data for a specific project or across several projects and to view the budget of a project, including details of EU and non-EU in kind contributions.

3rd login for project managers

A 3rd login access per project for the project manager was made available in SOFIA, in addition to the login access of the Coordinator and of the Managing Entity.

Enhanced annual Periodic Reporting

In SOFIA, the annual reporting functionality has been enhanced to include the uploading of the signed Form C (Financial Statement and Adjustments to previous periods), CFS (Certificate of Financial Statement) and Periodic Report files, in PDF format. The upload functionality is available to project participants during submission of their annual Periodic Report.

Training and support to project participants

On the occasion of IMI financial workshops for project beneficiaries and EFPIA participants, IT trainings was provided on the use of SOFIA for reporting, namely for amendments and annual financial reporting.

Back and front office

ENSO Calls

As of the beginning of 2013, project consortia could submit, via web form, applications for the ENSO Calls. In addition to this, the ENSO evaluation web form, to be used by the experts, was launched.

Ethics Review

The Ethics Review was integrated in SOFIA with the existing online Stage 2 evaluations by means of implementing a web form for submission by the experts of the remote review. The web form for generating the consolidated review by the rapporteur was also created.
On a daily basis, any SOFIA user can receive online technical support via the *helpdesk* (sofia@imi.europa.eu), which is monitored by the IMI IT Manager.

ICT internal support

DORA (Document Repository Application)

Training has been given to staff on the use of DORA. Several additional functionalities were implemented throughout the year (e.g. annexes area with versioning for existing documents; integration with IMI multifunctional printer and scanner). New functionalities were presented to staff in morning sessions which included staff feedback on current usage and useful future developments.

ISA (Information System for Absences)

ISA was extended to manage additional types of absences: teleworking and part-time. Also the status of leave requests is now clearly displayed in the application using a traffic light approach.

BIT (Booking of IT material)

A new web application was implemented to manage the booking of IT material that is taken by IMI staff when going on business trips or for meetings. This represented an efficiency gain for the Executive Office: an overview of available material is available in real-time, helping the staff with the planning of future needs for IT material.

eCDR (electronic Career Development Report)

A new web application was implemented to manage IMI staff appraisals. Both staff and line managers are guided through the different steps of the appraisal workflow. After completion, the appraisal is available for viewing online, and can also be saved in PDF format.

ICT internal support to other JUs

The year 2013 ended with close collaboration with other JUs. Two **IMI web applications** – ISA and Vacancies - of the IMI administrative platform for ICT internal support have been configured and **made available to two other JUs** – Fuel Cells and Hydrogen (FCH) and Clean Sky – which share the premises with IMI.

The web applications in question are now common to the three Jus, with the advantage that there is a unique source code, while the front end is re-branded for each JU and data segregation is guaranteed. Best practices are shared and it is the most efficient, economic and effective solution to put in place for the other JUs for their absences management and electronic recruitment.

In addition, the IMI Events Registration application has been extended and customised to allow shared events of the JUs. It helped greatly the management of registrations for an event at the European Parliament which was jointly organised by the JUs.

5.4 Procurement and contracts

The large majority of IMI's procurement in 2013 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, were concluded jointly with other JUs to avoid duplication and minimise administrative effort.

Where possible, IMI has made use of the European Commission's framework contracts to which it is party. In 2013, the most significant of these in usage volume terms were in software licenses and in communications consultancy services.

One open procedure was carried out in 2013, for a service contract under the operational budget, for consultancy services to set up a platform for stakeholder involvement to optimise project outcomes.

On the administrative side, an open procedure was launched for a framework contract for the organisation and management of events. However, during the course of the procedure, the European Commission's Directorate-General (DG) for Research and Innovation invited IMI to join a procedure it was to launch for a similar contract. IMI therefore decided to abandon its own procedure, judging it more efficient and economical to join the Commission's procedure.

The table below gives the details of these activities, 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 €60 000 are listed here.

s

Tender procedures in 2013				
Reference and subject	Procedure	Publication date	Award date	Contractor
IMI/2013/FWC/029: Service contract for the organisation and management of events	Open procedure – framework contract	16/04/2013	Not awarded; procedure abandoned on 04/09/2013	N/A
IMI/2013/SC/154: Consultancy services to set up a platform for stakeholder involvement to optimise project outcomes	Open procedure – service contract	17/08/2013	05/12/2013	University of Oxford, United Kingdom

5.5 Data protection and access to documents

Data protection

In 2013, IMI achieved maturity in the implementation of data protection principles within its activities involving the processing of personal data. The General Report of the European Data Protection Supervisor (EDPS) on 'Measuring compliance with Regulation (EC) 45/2001 in European Union institutions' of 24 January 2014 presents the results of a survey carried out in 2013 in all institutions. In terms of compliance with the notifications required by Articles 25 and 27 of the Regulation, **IMI is one of the 5 best EU institutions, with a 100% compliance rate.** All notifications on the existing processing operations of IMI were submitted to the EDPS. Internal administrative notifications were also prepared for all the existing processing operations. Regular communication with IMI staff, with the network and the JUs' data protection officers, and with the EDPS services, enabled the effective implementation of data protection principles. In particular, there were regular internal consultations with the data protection officer (DPO) in the areas of science, human resources, communication and IT.

Prior checking activities

- In July 2013 IMI concluded the notifications to the EDPS related to all existing processing operations.
- Only notifications related to new processing operations are being developed from that date, in line with the recommendation of the EDPS to all EU agencies and bodies.
- There is no specificity on the IMI processing of personal data to report.
- Recommendations from the EDPS as an outcome of IMI notifications were all implemented.

Notifications to the DPO

- By December 2013, the DPO had received 17 notifications from staff members responsible for the processing of personal data within IMI. This covers all IMI activities including communication with IMI bodies, organisation of meetings, remuneration schemes, audits, grants and procurement schemes, business trips, conflicts of interest & confidentiality, HR matters, and invitations of experts.

Consultations

- There were no formal consultations of the EDPS in 2013.

Inspections

- There were no site visits by the EDPS in 2013.

Complaints

- There were no complaints to the EDPS in relation to IMI processing of personal data to report in 2013.

Network activities

- In 2013, the IMI DPO participated in two meetings of the network hosted by the EU's Judicial Cooperation Unit EUROJUST and the EDPS.
- The network meetings are an important forum to exchange best practices among DPOs and to learn more about EDPS activities, such as developments related to the new data protection directive.
- IT and DPO participated in two workshops on e-communication (June) and EU websites and mobile devices (September).

Trainings/Communication activities

- The DPO participated in a course organised by the EDPS on the tasks of DPOs & reporting to the EDPS.
- Information on developments in data protection activities was provided to the staff during internal meetings.

Other

Inventory & register

- IMI has updated its inventory of processing operations and the register established under article 26 of Regulation 45/2001.

DPO mandate

- The mandate of the DPO was renewed until 2016.

EDPS Surveys

- IMI participated in the following surveys:
  -general monitoring exercise;
  -cloud computing;
  -guidelines on EU websites and mobile devices;
  -transfer of data from permanent representations.

- The findings of the surveys were used as a basis to prepare the EDPS guidance in those areas. Guidelines on EU websites and mobile devices are expected soon.

Data Protection Day

- IMI participated in the activities related to Data Protection Day 2013 and information was provided to all IMI staff members.

Thematic guidelines

Follow-up table

EDPS GUIDELINES	NOTIFICATION TO EDPS	STATUS OF PROCEDURE	COMMENTS
Tasks, duties and powers of the DPO	*YES*	*concluded*	
Recruitment	*YES*	*concluded*	
Health data at work	*YES*	*Final stage*	
Staff evaluation	*YES*	*Final stage*	
Leave & flexitime	*YES*	*Final stage*	
Conflict of interest	*YES*	*awaiting feedback*	Pending adoption by EDPS of specific guidelines
Anti-harassment procedures	*NO*	*preparatory work*	Procedures being developed in IMI
Administrative inquiries and disciplinary proceedings	*NO*	*preparatory work*	Procedures being developed in IMI
Video surveillance	*NO*	*not applicable*	IMI is not the controller of the data

Access to documents

During 2013 IMI continued to promote transparency and access to information and documents through the IMI Infodesk (see Section 4.2). IMI also implemented the guidance regarding access to data related to IMI projects.

5.6 Internal control strategy and environment

IMI implements a clearly defined framework of 16 Internal Control Standards (ICS) designed to maintain an efficient and effective internal control system that corresponds to IMI'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 2013, 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 behaviour, and sound management. These are embedded across IMI's administrative, support and grant management systems 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 (including a mid-year formal self-assessment) the progress made towards achieving compliance with and effectiveness of the internal controls system. In addition, at the end of 2013, an assessment of the compliance with 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's mission and objectives were also systematically identified, assessed and managed through the annual risk assessment exercise (RAE).

The 2013 RAE identified 14 corporate risk areas which were recorded in the IMI 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 taken during the year to strengthen internal controls and focus on the prioritised standards included:

- the implementation of a new policy on conflict of interest and an operating procedure concerning the selection of independent experts (ICS 8);
- new measures to enhance the quality of accounting information through new procedures on reimbursement, negotiation, acceptance of periodic reports and payments, year-end financial closure and financial *ex post* audits (ICS 13);
- the establishment of an internal scorecard to better monitor performance and report on achievements (ICS12/ICS 9);
- more emphasis on fraud prevention and detection (ICS 2).

Ex post control of operational expenditure has continued to play an important role in the overall internal control framework. By the end of 2013, 70 audits of beneficiaries had been finalised since the launch of the first such audits in November 2011. In addition, the first three audits of EFPIA participants were concluded during 2013 (for more information, see Section 6.2). Errors detected through these audits are progressively corrected and followed up, and when found to be systematic in nature, also extended to unaudited claims from the same participant. Preventive measures are also in place to reduce the risk of errors from occurring in the first place, particularly through ongoing training and guidance for participants as well as through rigorous *ex ante* procedures.

In conclusion, IMI's internal control system can be considered having reached an advanced level of maturity and is working as intended, given also the particular nature and limited size of the organisation. Within this context, the efficiency and effectiveness of internal control systems will be further enhanced in 2014 as part of a process of continuous improvement, as highlighted in the Annual Implementation Plan 2014.

6. ELEMENTS LEADING TO THE DECLARATION OF ASSURANCE

6.1 Background

IMI, as a European Union body, is required to include in its Annual Activity Report a structured assessment of the effectiveness of internal controls and on other elements supporting the 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, regularity and sound financial management 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.

6.2 Assessment by management

Implementation of operational and administrative budgets

The budgets for 2013 were adopted by the Governing Board together with the corresponding Annual Implementation Plan on 21 December 2012.

Operational budget

At the end of 2013, 54 operational payments were made for a total of €121.5 million. Budget execution was therefore 99.4% (100.0% in 2012).

During the first five months of the year, IMI JU experienced a significant delay in the receipt of the annual financial contribution from the European Commission to cover the year's running and operational costs. This led to a cash shortfall for IMI JU and delayed payments for both pre-financing and interim payments. The first instalment of €65.0 million from the European Commission was transferred to IMI JU on 28 May 2013.

The cash shortfall had a direct impact on the average time to pay for pre-financing payments. In 2013, it took on average 18 days to process these payments (5 days in 2012). Similarly, the average time to pay for cost claims increased from 60 days in 2012 to 66 days in 2013. The situation also led to three late payments in 2013 generating late interest costs.

Budget year	No. payments	Average delay for report submission from the projects after reporting deadline* a)	Average suspension period (days) b)	Average time to pay (days) c)	Average processing time after report submission (days) b) + c)	% of payments on time	% beyond time limit
2011	16	28	62	54	117	94	6
2012	26	16	65	60	125	96	4
2013	33	14	44	66	110	91	9

*after the 60 contractual days for submission

Each payment represents the end of a complex validation procedure that consists 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 and for audit findings). As expected, a significantly larger number of payments were made in 2013 when compared to the previous year (from 26 in 2012 to 35 in 2013 – an increase of 34.6%), with the receipt of the first claims from an additional 12 projects from Call 3 and Call 4.

Despite the increase in the number of projects and participants' claims to be validated by IMI and the challenging situation experienced with the cash shortfall in the first half of the year, the average processing time (from the date of report submission to the IMI bank execution date for the payment of the cost claims) actually decreased from 125 days in 2012 to 110 days in 2013. This is the result of a number of proactive initiatives IMI took in the past two years to facilitate and streamline the process for project participants and IMI staff, including:

- the publication of guidance and the organisation of workshops for participants on the applicable financial rules and the correct completion of the financial statements;
- the simplification of internal workflows and key documents;
- the development and enhancement of IMI's core business application SOFIA to automate and further support project-related processes.

These measures were also particularly critical in view of the increasing workload related to the processing and payment of cost claims.

As a result, shorter average timelines were registered in 2013 in all critical stages of the process, including a reduction in the time needed for projects to submit reports after each reporting period; shorter average suspension periods; and overall less time for IMI to review and process for payments throughout 2013.

Administrative budget (running costs)

As of 31 December 2013, payments were made for a total of €5.9 million, resulting in a budget execution of 69.6% (as compared to 60.2% in 2012).

Time to pay has continued to improve when compared to 2011 and 2012**.** The table below only shows administrative payments with maximum time limits.

Maximum payment time limit	% paid on time			% paid beyond time limit			Average time to pay (days)		
Year	**2011**	**2012**	**2013**	**2011**	**2012**	**2013**	**2011**	**2012**	**2013**
30 days	51	85	92	49	15	8	39	17	15
45 days	60	90	92	40	10	8	44	23	19
60 days	71	84	100	29	16	0	47	25	14
All[16]	N/A	N/A	92.5	N/A	N/A	7.5	N/A	N/A	18

[16] Since January 2013, IMI has had to comply with the payment time limits set out in the new Financial Regulation.

Control systems

IMI'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 primarily at preventing errors from entering the process and also detecting and correcting errors in case these occur.

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, certificates on the financial statements. The operational and financial agents perform initiation and verification tasks. As FP7 reporting is based on self-declarations, at the moment the payment is authorised, IMI is not able to fully ensure that the amount paid is accurate and in compliance with the applicable legal and contractual provisions. This can only be achieved through *ex post* audits carried out at the beneficiaries' premises, after the costs have been incurred and declared (see below).

Internal controls are also embedded in the Call and grant award process, including the eligibility screening of the EoIs and the FPPs; the selection of experts; the ethical reviews of the proposals performed by independent external experts; the controls to ensure conformity with IMI rules, procedures and checks carried out during the negotiation; and grant preparation and signature processes.

In 2013, independent observers compiled four reports on the publication of IMI Calls, the selection of independent experts and the evaluations of the 7th Call (Stage 2), 8th Call (Stages 1 and 2) and 9th Call (Stage 1). They list their observations and also make recommendations for further fine-tuning of the processes. The independent observers concluded that for these evaluations:

- these processes were all according to the established procedures and regulations and there were no violations of the rules of the published evaluation guidelines;
- the evaluators were of high quality, possessed the relevant expertise for each of the topics 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 processes were well organised and managed from the initial publication and promotion of the Calls and the organisation of submissions to the evaluation of proposals;
- the evaluation of the proposals was exhaustive, fair, impartial 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;
- further improvements from previous Calls recommended by independent observers had been implemented.

Furthermore, an appeal procedure provides applicants with the possibility of formally filing a complaint if they think that there were shortcomings in the handling of their proposal during the evaluation. No appeal requests were submitted in 2013 and this provides a further indication of the robustness of the grant award process and the effectiveness of the internal controls.

IMI also actively monitors the progress of the funded projects through the systematic review of technical reports and through interim reviews of each project. In 2013, six interim reviews were held and these had positive conclusions on the early achievements of Call 2 projects (see section 2.1 for more information).

Ex post controls: audit and corrective actions

Ex post audits are used extensively by IMI to independently measure and assess, on a multi-annual basis, the legality and regularity of interim (and eventually) final payments made to beneficiaries. Findings from the *ex post* audits are carefully analysed by the Executive Office and used for recovery and corrective actions, as well as to reinforce and fine-tune the preventive measures put in place by the Executive Office to minimise the occurrence of errors in cost claims submitted by beneficiaries.

Ex post audits are outsourced to external audit firms as the lean structure of IMI does not allow for the setting up of an internal team of auditors for these purposes. Nevertheless, IMI staff remain responsible for the management of *ex post* audits, namely:

- the selection of audits;
- coordination with the EC;
- the preparation of the audit input files;
- contract management and the monitoring of the external audit firms' progress and deliverables (regular follow up of the audit status, interaction with audit firms on technical questions and quality checks of audit reports);
- the analysis of detected errors and the implementation of audit results.

Important changes and improvements were made to the *ex post* audit process in 2013, including:

- the creation of a new position of Ex post Audit and Finance Officer (see Section 5.2) to dedicate more time and resources to the above activities;
- the introduction of additional quality review stages to further improve the quality of the reporting in the audit reports;
- the approval in October 2013 of a comprehensive standard operating procedure for the operational planning and management of outsourced financial audits of beneficiaries as well as the main processes and procedures relating to the follow-up of audits.

These initiatives will be continued in 2014, *inter alia* with the updating of the model audit report and other continuous improvement measures, to improve the efficiency and effectiveness of IMI's *ex post* audit process.

Beneficiaries

The main legality and regularity indicators for payments made to beneficiaries, as defined in the *Ex post* Audit Strategy approved by the Governing Board in December 2010, are the representative and residual error rates detected by *ex post* audits:

- The ***representative error rate*** is the error rate resulting from the representative audits. It provides a reasonable estimate of the level of error in the population relating to the accepted IMI JU contributions on completion of the audits, but does not take into account the corrections and follow-up undertaken by IMI. It is calculated as the average error rate (AER) according to the following formula:

$$AER\% = \frac{\sum(err)}{n} = RepER\%$$

  Where:

  $\sum(err)$ = sum of all individual error rates of the sample (in %). Only errors in favour of the JU (i.e. overstated amounts) are taken into consideration.

  n = sample size (i.e. number of audited financial statements)

- The ***residual error rate*** is the level of error remaining in the population after deducting corrections and recoveries made by IMI. This includes the extension of audit results to non-audited financial statements of the audited beneficiaries to correct systematic errors. The formula for the residual error rate is:

$$ResER\% = \frac{(RepER\% * (P-A) - (RepERsys\% * E)}{P}$$

Where:

ResER% = residual error rate, expressed as a percentage.

RepER% = representative error rate, or error rate detected in the representative sample, in the form of the Average Error Rate, expressed as a percentage and calculated as described above (AER%).

RepERsys% = systematic portion of the RepER% (the RepER% is composed of complementary portions reflecting the proportion of systematic and non-systematic errors detected) expressed as a percentage.

P = total amount in euros of the auditable population relating to accepted IMI JU contribution.

A = total value of audited IMI JU contribution, expressed in euros.

E = total non-audited amounts of IMI JU contributions of all audited beneficiaries. This will consist of the total JU's share, expressed in euros, of all non-audited cost statements received for all audited beneficiaries.

The calculation of the error rates is performed on a point-in-time basis, i.e. all the figures are provided as of a certain date.

In addition, 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. For this purpose, the weighted average residual error rate for the entire cumulative period covered by *ex post* audits during the execution of the IMI programme will be applied once sufficient audits from each representative sample have been concluded.

Periodic representative samples of beneficiaries to be audited have been extracted each year since 2011. The methodology for selecting the representative sample is established in the *Ex Post* Audit Strategy. A combination of the largest beneficiaries and randomly selected entities are included in each sample. The first three samples covered payments to beneficiaries made between 22 December 2010 (when the first and only interim payment to an IMI project was made in 2010) and 23 October 2013 (cut-off date of the last extracted sample).

The following table gives an overview of the status as at 31 December 2013.

Representative samples	Number of *ex post* audits			
	Selected	Launched	Ongoing	Finalised
1st Rep. Sample (Q4 2011)	60	60	4	56
2nd Rep. Sample (Q4 2012)	40	34	20	14
3rd Rep. Sample (Q4 2013)	35	0	0	0
Total	135	94	24	70

135 different beneficiaries participating in Call 1, 2 and 3 projects have so far been selected for *ex post* audit. This represents more than 40% of all beneficiaries participating in these projects. The initial broad coverage of beneficiaries is in line with the current strategy approved by the Governing Board.

A total of 70 IMI *ex post* audits had been concluded by the end of 2013 and are used as a basis for determining the error rates in this Annual Activity Report:

- 56 of the 60 audits from the first representative sample (93.3%) were concluded between Q3 2012 and Q2 2013. The remaining four audits from this sample were extended in scope in 2013 due to important additional information being provided by the beneficiary during the report drafting stage.
- 14 of the 40 audits from the second representative sample (35.0%) launched in February and March 2013 were finalised by the end of the year. As for the remaining 26 audits:
  - 20 are ongoing and are at different stages of implementation. Results cannot as yet be used for the calculation of the error rate. Seven of these audits were launched later in the year (four engagements in June and three in October) after the closure of audits with the same beneficiaries by the EC and/or the European Court of Auditors (ECA).
  - Two audits from this sample were on hold as all external audit firms available through the IMI JU framework contract for external audit services reported a conflict of interest with the beneficiaries in question. These audits will now be outsourced in 2014 to other contractors using alternative European Commission framework contracts for audit services to which IMI JU has access for cases like this.
  - Four audits from this sample were still on hold at the end of 2013 due to recently-closed or ongoing audits by the EC with the same beneficiaries, and close coordination is being maintained with audit teams of the relevant EC services.

The 35 planned audits resulting from the 3rd representative sample were selected in December 2013 from an audit population of payments made between December 2012 and October 2013. The audits have been assigned to the external audit firms and the first set of these engagements will be launched in the first quarter of 2014, with results expected at the end of the year.

Representative and Residual Error Rates as at 31 December 2013

First Representative Sample
The average error rate (AER) resulting from the 56 concluded audits of the first representative sample was estimated at 5.8 % as at 31 December 2013.

The residual error rate (ResER), after corrections on the audited claims are made (but at this stage prudently excluding the impact of corrected systematic errors on non-audited amounts of all audited participants until the extension of audit results is undertaken in 2014), was estimated at 3.6% as at 31 December 2013.

When analysing these results, three elements need to be taken into consideration:

- The 56 audits cover a substantial 37.3% of the accepted IMI JU's contribution of the audit population.
- The audits in this first sample were by design focused in most cases on new or unaudited beneficiaries under the EU research programmes. In fact, the majority of detected errors clearly arose from misunderstandings of the rules or a lack of attention to the detail of the provisions of the Grant Agreements by these beneficiaries.
- Several concrete preventive actions have since been undertaken to mitigate as much as possible the risk of these errors since the validation and payment of these claims in 2010 and 2011 (see Section 6.4 below).

Second Representative Sample

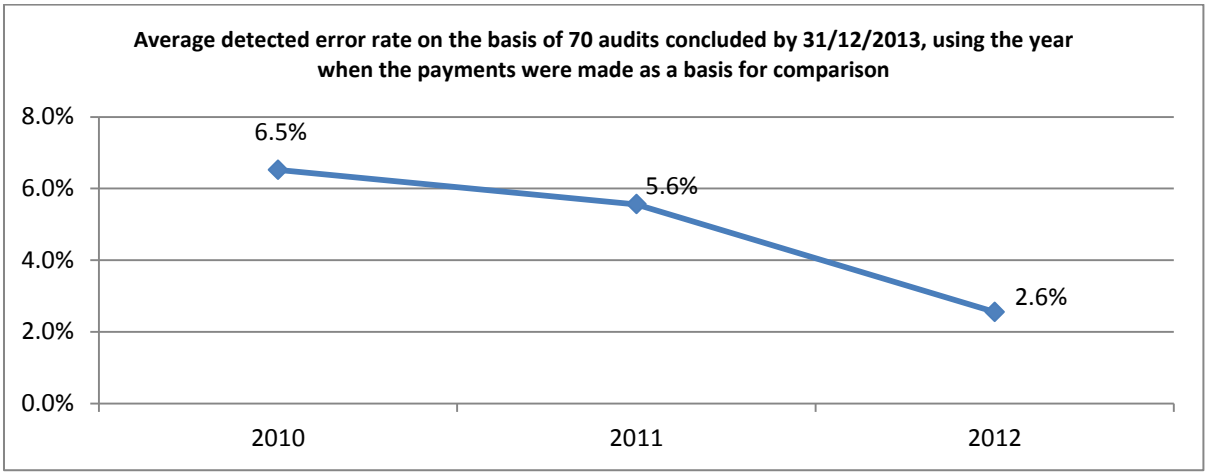
The 14 audits from the 2012 sample which were finalised by December 2013 register a significantly lower representative error rate than that recorded from the first representative sample. The error rate on the basis of these audit reports was estimated at 2.3% as at 31 December 2013. This estimate will continue to evolve with the completion of the remaining audits in the second representative sample.

The residual error rate (ResER) will be calculated after further analysis is carried out on these results and the corrective and recovery actions are launched in 2014.

The initial error rate from these first 14 audits, nonetheless, already shows a very encouraging early indication that the error rate is being reduced over time as envisaged in the *Ex Post* Audit Strategy.

Further analysis of detected error rate levels using the year when the payments were made as a basis for comparison

With a substantial number of audits having already been carried out on the first interim payments made to beneficiaries in the initial years of IMI (i.e. covering the financial years 2010, 2011 and 2012), the following chart shows the gradual but clearly steady reduction in error rate over time since the first interim payment of 22 December 2010.



Implementation of audit results

IMI is very advanced in concluding the recovery and offsetting against subsequent claims of the same beneficiaries of the unduly paid IMI JU funds on the basis of concluded audits from the first representative sample. The vast majority of financial errors identified in these audits where adjustments were needed were relatively small sums (less than €5 000 in favour of IMI JU), and therefore in most cases the decision was taken to efficiently offset the amounts against the next payments to the beneficiaries concerned. There are no open controversial issues with these beneficiaries and this will duly lead to a 100% correction by the end of the process.

The table below provides an overview on the implementation of *ex post* audit results from the first representative sample in favour of IMI JU as at 31 December 2013:

Status as at 31/12/2013	Amount (EUR)	%
Negative adjustments in IMI JU contribution	251 102.27	
Implemented	170 347.00	67.84
Recoveries - not yet cashed	68 382.21	27.23
To be offset:		
Reports currently under analysis	7 520.61	3.00
Reports due in January 2014	3 150.56	1.25
Reports due in February 2014	1 701.89	0.68

On the basis of these audits, in 2014, the process will also start for extending the systematic errors identified in the first representative sample to unaudited IMI JU claims by the same beneficiary for the same project and also for other projects in which the beneficiary is a participant.

In addition, the same corrective actions (implementation of audit result and extension of audit findings) will also be taken on the first audit results from the second representative samples which were received in December 2013.

A balanced and risk-based approach to ex post control

IMI remains committed to managing its funding to beneficiaries through a trust-based approach whilst ensuring sufficient control and accountability. The risk-based preventive and corrective actions already taken by IMI provide a sufficient basis for sound financial management and the gradual reduction of the risk of error in interim payments to beneficiaries on a multi-annual basis.

With many projects only starting to generate expenditure, particularly in the case of projects from Call 3 onwards, the full impact of IMI's actions can only be seen in the longer term, once more projects submit cost claims and *ex post* audits cover a greater part of the total population of beneficiaries.

EFPIA Companies

In addition to the *ex post* audits covering the IMI JU share of the funding to beneficiaries, 2013 also saw IMI conduct the first in a series of *ex post* reviews and audits on the declared in kind contributions by EFPIA companies participating in IMI projects following the reporting of the first declarations of in kind contributions in 2012

These companies do not receive any IMI funding, but contribute in kind to the projects in which they participate and benefit from. The purpose of the IMI audits is to independently measure and assess, on a sample basis and using a risk-based approach, the legality and regularity of the in kind contributions accepted by IMI.

Each exercise consisted of two key elements.

1. A review of the in kind methodology used by the EFPIA company to declare in kind contributions for all the IMI projects in which it participates, applying agreed-upon procedures to confirm the factual basis of the responses and descriptions provided in the submitted certificate on in kind contribution methodology. On this basis, the auditors conclude whether:

a) the approach and basis of the actual calculations were as originally described in the accepted methodology;
b) there were mathematical errors or other inconsistencies in the actual calculations made relating to the direct personnel full time equivalent (FTE) daily cost rate;
c) the in kind methodology was consistently applied by the EFPIA company across all research and business activities and in accordance with its usual accounting and management principles and practices;
d) the basis of the methodology and calculation is consistent with Article II.13.4 of the Grant Agreement and excludes prescribed ineligible costs.

2. A financial audit of a sample of in kind contributions declared in the Financial Statements submitted by EFPIA companies to IMI in order to assess and present an opinion on whether these meet the conditions of the Grant Agreement.

By the end of 2013, the first three ex post selected reviews and audits of EFPIA companies were finalised. and with the following outcomes:

- For two of the audited companies, the auditors reported no exceptions, based on the agreed-upon procedures, in their review of the submitted in kind methodology.

- For the other EFPIA company, the auditors reported specific one-off human errors in the calculations made, leading to significant understatement of the FTE rate and the resulting in kind contributions declared in the projects. In addition, for this case, the auditors identified two cost statements not yet approved and eligible under Clause 13 of the Grant Agreement in relation to time recorded in the US.

- With regard to the audit of sampled in kind declarations, in the case of one EFPIA company, the auditors found errors of a systematic nature, of both additional

allowable amounts and disallowances. The impact of this was a significant increase in the allowable amount that could be declared by the EFPIA company.

- For the other two companies, the auditors identified a few isolated errors, none of which were systematic or had a major impact on the declared amounts of in kind contributions, leading to adjustments in the total declared contributions.

  The calculated individual error rates for these three companies, on the basis of the audited declared contributions, were a negative adjustment of 3.52%, and two positive adjustments of 0.02% and 39.89%..
- All three companies accepted the findings and adjustments of the auditors and have already adjusted their claimed contributions or are in the process of doing so in the next reporting periods. In addition, one of the audits also led to the revision of the certificate on in kind methodology being updated and re-submitted for acceptance by IMI.

- The auditors also made recommendations for improving internal controls and for ensuring that the contractual obligation concerning the type and level of evidence kept on time-recording by staff working on IMI projects is sufficiently addressed.

In addition to the above three finalised audits, a new on-the-spot review of applied in kind methodology and audit of a sample of declared contributions was launched by IMI in the third quarter of 2013 and this exercise is expected to be finalised in 2014.

This approach will also be continued with other sampled EFPIA companies in order to obtain, on a multi-annual basis and over the lifetime of IMI, sufficient risk-based coverage of declared in-kind contributions.

Collectively the first four EFPIA companies selected for an IMI ex post exercise account for a significant 23% of all committed in-kind contributions in IMI projects launched so far.

In addition, at the end of 2013, two further EFPIA ex post exercises were being prepared for launch in the first half of 2014. These two companies account for a further 24% of all committed in-kind contributions in IMI projects launched so far.

Fraud prevention and detection

Since its inception, IMI has ensured that procedures to fight against fraud at all stages of the management process are applied across the organisation. In October 2008, the Governing Board adopted a decision concerning the terms for internal investigations in relation to the prevention of fraud, corruption and any illegal activity detrimental to the European Community's interests.

Anti-fraud measures are embedded in various *ex ante* and *ex post* controls for prevention and detection purposes, and a policy on sensitive posts is in place. The Executive Office has also collaborated closely with the European Commission on this matter over the years, and its staff has participated actively in training on fraud awareness, ethics, integrity and good conduct. In 2013, management gave prioritisation to the internal control standard on ethical values, and a policy on conflicts of interest was developed and implemented during the year.

Moreover, IMI has also started the process of developing a consolidated Anti-Fraud Strategy for the whole organisation. The main purpose of this strategy will be to translate the strategic anti-fraud priorities into concrete operational measures addressing risks that are particularly relevant for the operations managed by IMI. It is expected that the Strategy will be finalised in early 2014.

6.3 Results from audits and the second interim evaluation of IMI during the reporting year

Second Interim Evaluation of IMI

The second interim review was carried out in 2013 by an independent expert group appointed by the EC. The expert panel was highly positive on the effectiveness, efficiency and quality of research and on the progress of IMI towards achieving its set objectives. The experts also reported on the considerable achievements and acquired strengths of IMI since the first interim evaluation and highlighted areas where more attention can be given in order to maximise the impact of IMI. These recommendations focused on communication activities, the measurement of the socio-economic impact of IMI, opportunities for increased engagement from a wider range of industry stakeholders, the possibility of more flexible funding mechanisms to ensure the sustainability of current and future projects; finding ways of reducing bureaucracy and ensuring that IMI has the optimal organisational structure for the tasks ahead, and on the Commission's proposals for IMI 2 under Horizon 2020. IMI is implementing the relevant actions arising from these recommendations.

Internal Audit

In 2013, the Internal Audit Service of the European Commission (IAS) carried out two risk assessments at IMI, one on the common IT infrastructure shared among five JUs located in same building in Brussels and another on IMI's own applications. The reports on these two risk assessments were finalised in November 2013.

On the common IT infrastructure, the IAS risk assessment concluded that the five JUs showed a good level of control of all the risks in the area of IT management except for two risk areas, namely that implemented security management measures do not necessarily correspond with the business needs, and that specific contracts with IT service providers do not give adequate details about the procedures and controls the contractors have to follow. The JUs will take the necessary joint mitigating measures to address these risks.

With regard to the IMI applications, the IAS risk assessment concluded that IMI also showed a good level of controls for all the risks in the area of applications except for the need for better descriptions in the contracts on the minimum project controls IMI expects from IT service providers.
The IAS nonetheless also concluded that adequate project management controls are applied in practice and that the issue is to better enhance the descriptions in the contracts. IMI has in the meantime addressed this risk and introduced detailed clauses on project management controls in its new contracts with service providers.

In the fourth quarter of 2013, the IAS also launched an internal audit on project monitoring and the reporting of operational performance at IMI. The main objective of the audit was to assess whether the JU has set up effective and efficient systems to monitor projects and to report on operational performance. The audit resulted in three recommendations, none of which were flagged as 'critical'. Two of the recommendations were classified as 'very important' and the other as 'important'.

The IAS acknowledged in the report the considerable efforts of IMI to put in place KPIs and the challenges faced within the pioneering context in which IMI operates. The IAS recommend that objective setting and performance measurement and reporting be further developed by IMI by creating a more structured link in the Annual Implementation Plan to strategic objectives and by defining more clearly related objectives, quantitative targets and criteria for measuring and reporting progress and achievements. The auditors also make recommendations on how to strengthen and enhance the internal practices, tools and procedures applied by IMI for project monitoring and reporting.

The final audit report was received in February 2014 and IMI will use the conclusions and recommendations of the auditors to draw up a plan to implement the accepted actions for improvement.

During 2013, the Internal Audit Manager of IMI, who also acts as the Internal Audit Capability (IAC) supported management through consultancy activities related to governance, internal control, *ex post* audits and risk management issues. The Internal Audit Manager also coordinated the various visits of the ECA and the IAS, providing additional support to the auditors in the conduct of their work.

External audit

In its report on the 2012 accounts issued in November 2013, the European Court of Auditors (ECA) provided a 'clean opinion' on the reliability of the accounts.

On the legality and the regularity of the transactions underlying the accounts, the Court considered all transactions to be, in all material respects, legal and regular, except for a qualification on the basis of the preliminary error rate detected *ex post* by IMI's own audits on a sample of intermediate payments made to Call 1 beneficiaries in the years prior to the one under review (that is, 2010 and 2011). At the time of the ECA audit, IMI was in the process of taking corrective and recovery actions and had also launched additional audits to cover more recent claims validated between July 2011 and November 2012.

Furthermore, in its opinion, the Court also concluded that IMI JU's *ex post* audit strategy was a key tool for IMI JU for assessing the legality and regularity of such payments.

Several preventive and corrective actions have since been taken by IMI to mitigate the risk of errors in financial statements submitted by beneficiaries. More information on these measures can be found in the sections on financial operations (section 5.1), on *ex post* controls and recoveries (section 6.2) as well and the analysis and action plan (section 6.5).

Without calling into question its opinions as outlined above, the ECA also provided in its report on the financial year 2012 comments on budgetary and financial management. These issues have been superseded by later developments and the actions taken by IMI in 2013. The Court commented on:

- the implementation of the budget in terms of both commitment and payment appropriations (see the financial tables and graphs in section 5.1 on the achievements in 2013 and previous years);
- the degree of utilisation of the total EC contribution for IMI at the end of 2012 (refer to the most recent strategic achievements in section 1);
- IMI's adequate and comprehensive internal control systems and the areas where further work was being done at that time (an update on internal controls is presented in sections 5.6, 6.2 and Annex C);
- the internal audit of the IAS in 2012 and the actions of IMI to address the auditors' recommendations (reported in 6.4 below);
- the information to be available for the monitoring report that is regularly produced for FP7 (see section 5.3 on the automatic export to CORDA);
- the implementation of recommendations resulting from the validation of the accounting system of 2012 (refer to Annex C).

6.4 Audits from previous years

Follow-up of the 2011 reservation

The Declaration of Assurance for the 2012 Annual Activity Report was qualified for the first time with one reservation concerning the rate of the residual errors with regard to the accuracy of cost claims submitted by IMI project participants. This reservation was made on the basis of the findings from the first IMI *ex post* audits concluded in 2012 on payments made to beneficiaries in 2010 and 2011 and on the conclusion that it was not possible to state with certainty that the residual error rate would fall below the materiality threshold of 2% at the end the IMI programme.

The following steps were taken by IMI in 2013 in line with the action plan set out in the 2012 Annual Activity Report.

- The continued systematic launch of *ex post* audits of beneficiaries and EFPIA participants together with the resulting corrective and recovery actions (see section 6.2 above).

- The improvement of checklists and internal procedures for the validation and acceptance of cost claims in 2012 (see overview in Annex C). These are periodically reviewed and updated in line with the internal control standards and the principal of continuous improvement.

- Training actions in 2013, through guidance and workshops, for beneficiaries and EFPIA participants on the provisions of the IMI model Grant Agreement and the most common errors. Actions to raise the awareness included the publication of updated IMI Financial Guidelines in June 2013 (first issued in January 2012) and the organisation of four financial workshops for participants throughout the year (following the successful launch of the first workshops in 2012). Both measures will continue to be conducted and updated.

- Monitoring of the financial impact of identified errors, which might be lower, over the multi-annual period (see section 6.2 above and Annex B).

Follow-up of the European Court of Auditors' comments from previous years

All recommendations from the ECA from the report on the 2011 Accounts issued in November 2012 were fully addressed by IMI between 2012 and 2013. These concerned:

- the ongoing implementation of the action plan to mitigate the risk of errors in financial statements submitted by beneficiaries (details provided above and in section 6.5);
- significant improvements in the implementation of the budget in terms of both commitment and payment appropriations (see the financial tables and graphs in section 5.1 on the achievements in 2013 and previous years) and more clarity in the subsequent Governing Board decision on the approval of carry-overs;
- the timely launch of Calls for Proposals and the full utilisation of the total EC contribution for IMI by end of 2013 (refer to the most recent strategic achievements in section 1);
- the continued strengthening of internal controls and follow-up actions (an update on internal controls is presented in sections 5.6, 6.2 and Annex C);
- the work and role of the IAS as IMI's Internal Auditor (described in section 6.3),
- the continued formalisation of IT policies and systems (reported in section 5.3), and
- the introduction of a reservation in the Declaration of Assurance to reflect the limited results of ex-post controls (documented in section 6.5, 6.6 and 7).

Follow-up of the internal audit recommendations of 2012

During 2012, the IAS carried out its first internal audit assurance engagement at IMI. The audit covered the negotiation, Grant Agreement preparations and pre-financing processes of IMI JU and resulted in 11 recommendations, none of which were flagged as 'critical'. Three of the recommendations were classified as 'very important' and the others as 'important'.

The IAS recommendations were namely to:

1. develop and implement a comprehensive policy to manage potential conflicts of interests of staff involved in the negotiation process;
2. to formalise and implement a documented procedure and guidelines covering all aspects of the negotiation process;
3. to develop SOFIA further in order to manage the technical negotiation as well as allow an accurate online information trail of changes made to financial and legal data by the project participants.

All recommendations were accepted by IMI and were implemented between 2012 and 2013.

In the third quarter of 2013, IAS also validated and closed the implementation of 10 of these 11 recommendations; the remaining action will be closed by the IAS after they have conducted an on-the-spot verification of the supporting evidence.

6.5 Reservations

For claims submitted by beneficiaries:

- The representative error rate resulting from 56 audits (65 cost claims accepted in 2010 and 2011) finalised from the first representative sample (93.3% completed) is 5.8%. The estimated residual error rate based on these concluded audit results is 3.6%.

- The initial error rate resulting from 14 audits (19 cost claims accepted in 2011 and 2012) finalised in December 2013 from the second representative sample (35.0% completed) is 2.3%. The residual error rate will be calculated once more results from other audits are received and implemented.

The representative and residual error rates will continue to develop as more audits are closed and more corrections and recoveries are undertaken.

Taking into account the 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'.

With regard to the declared in kind contributions, it is still early in the *ex post* audit process to draw aggregate conclusions on the basis of the first risk-based sample of three audits of EFPIA participants.

For these reasons, IMI JU maintains the reservation it introduced last year for its research programme.

Action plan to address the reservation

The reduction of errors will continue to 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.
- Monitoring and fine-tuning of *ex ante* control procedures to optimise the 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.
- Training actions through guidance and workshops for beneficiaries and EFPIA participants on IMI's 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.
Domain	IMI JU projects.
Activity and amount	Payment appropriations related to intermediate payments made to beneficiaries in 2013: €59.4 million. Estimated in kind contribution by EFPIA companies accrued under operational expenditure in 2013 : €106.2 million
Reason for the reservation	At the end of 2013 it is not possible to state with certainty that the residual error rate of the level of the 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 the control objective is set to be achieved in the future, it is therefore not sufficient to assess the effectiveness of controls only by looking at the error rate determined during the year under review. The analysis must also include an assessment of whether: • the scope and results of the audits carried out until the end of the reporting year were sufficient and adequate to meet the multi-annual control strategy goals; • the preventive and remedial measures in place are adequately effective in order lead to the expected reduction in the target error rate by the end of the programme.

Quantification of the impact	In the case of beneficiaries, the maximum impact is calculated on the basis of the best available information by multiplying the estimated residual error rate of 3.6% in favour of IMI JU (currently based on the more complete audit results of the first representative sample) by the amount of intermediate payments made to them in 2013. The estimated impact on interim payments made to beneficiaries in 2013 is €2.1 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 on the basis of the first three audits of EFPIA 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 for this issue 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 certificates on the financial statements, respectively. Within these parameters, IMI JU's remedial action is carried out through *ex ante* controls, *ex post* audits, and the systematic correction of detected errors, as well as through ongoing 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 monitoring and fine-tuning of *ex ante* control procedures to optimise the balance between on one hand the effective detection and correction of errors before acceptance of cost claims and on the other hand the avoidance of undue complexity and delays in the processing time needed to pay beneficiaries and accept declarations of in kind contributions from EFPIA companies; • initiatives to pre-empt and stem the occurrence of errors in financial statements and certificates on the financial statements 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 first audit results on cost claims received from beneficiaries of Call 1 and Call 2 projects.

6.6 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.

7. STATEMENT OF REASONABLE ASSURANCE

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 findings 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 projects.

Signed in Brussels, on 14 February 2014

Michel Goldman, MD, PhD
Executive Director

ANNEX A – FINANCIAL INFORMATION

In accordance with the Financial Rules of the IMI JU art. 41, the Annual Activity Report shall include financial information for the year under review. This Annex provides a detailed overview of the Budget and its execution in 2013.

BUDGET

Budget of IMI JU is divided in three titles:

- Title I covers staff expenditure such as salaries, training, costs associated with recruitment procedures and staff well-being;
- Title II covers the costs associated with functioning of IMI JU such as renting of premises, IT needs, expenses related to external communication, expert fees and costs of ex-post audits;
- Title III covers operational activities of IMI JU.

The 2013 budget was approved by the Governing Board on 21 December 2012 and adjustments were made based on the Decision of the Governing Board on carry over amounts of 4 February 2013.

On 2 December 2013, the Governing Board approved an amending budget 2013. The following changes were introduced:

- Cancelled commitment appropriations were re-entered in the budget in order to use available appropriations for Calls for proposals launched in 2013;
- Payment appropriation for Title III was lowered following the cut of the EU contribution for 2013 operational payments by the budgetary authority;
- Correction of bank interest was made for both payment and commitment appropriation.

Budget 2013 (in EUR)		
	Commitment appropriation	*Payment appropriation*
Original budget	226,945,440	134,974,655
Amending budget No 1	255,715,919	130,558,622

Budget transfers

No budget transfer between Titles was done during 2013.

Five budget transfers between chapters were authorised out of which three were formalised during the amending budget. Two budget transfers made after the adoption of amending budget led to the following changes:

Chapter	Amending Budget No 1/2013	Budget transfer	Budget after transfers
Chapter 11	4,131,000	(-) 16,000	4,115,000
Chapter 14	200,000	(+) 16,000	216,000
Chapter 26	500,000	(-) 25,873	474,127
Chapter 28	800,000	(+) 25,873	825,873

Twenty six budget transfers were made between different budget lines of the same Chapter without any impact on voted budget.

Budget execution

Details on budget execution are reported in section 5.1.

REVENUE

IMI JU's revenue for the year:

Source of revenue	Amount (in EUR)	
	2013	2012
EU Contribution from European Commission	125,829,159.00	97,783,960.00
Contribution from EFPIA	2,742,987.80	4,067,578.15
Bank interest	95,796.81	474,655.28
Miscellaneous income	100,112.92	
TOTAL	128,768,056.53	102,326,193.43

Overview of EFPIA contribution to IMI JU running costs

Year	Payments from EFPIA	50% of payments executed C1+C4	50% of payments executed C8	Balance 31/12/2013
2008		171,974.04	n/a	
2009	711,167.90	397,989.50	n/a	
2010	2,126,460.00	1,408,297.53	164,906.28	
2011	1,660,162.00	2,221,660.11	440,540.59	
2012	4,067,578.15	2,830,223.22	312,764.58	
2013	2,742,987.80	2,925,226.85	411,704.20	
Total	11,308,355.85	9,955,371.25	1,329,915.65	*(23,068.95)

*The amount due to IMI will be paid by EFPIA together with the first instalment 2014

EXPENDITURE

Administrative expenditure (Title I and Title II)

Title I

In 2013 IMI JU had 29 temporary agents and 7 contract agents. Following expenditure is reported under Title I: salaries, insurance, taxes, allowances, training costs, mission costs, medical service fees, entertainment and representation.

Title II

Other administrative expenditure is reported under Title II including:

- rent and related charges;
- development of IT tools (SOFIA, DORA, etc.);
- ABAC fees;
- purchase, rent and maintenance of equipment;
- purchase of software;
- postage and telecommunications fees;
- office supply;

- costs of formal meetings, workshops, call evaluations and interim reviews including renting of facilities and payments of experts;
- costs of ex-post audits;
- studies, etc.

Procurement

The majority of IMI JU's tendering needs are in the field of external communication, IT and ex-post audit services. The tender and contract management is being simplified as far as possible through the use of multiannual framework contracts. IMI JU also cooperates with other Joint Undertakings in tendering services in order to avoid duplication of administrative work. Where possible, IMI JU is party to European Commission's framework contracts to reduce administrative burden created by proprietary contract management.
In 2013, IMI mainly relied on these existing contracts for its procurement needs. No major new procurement procedures were launched under IMI's administrative budget in 2013. The only larger procurement procedure was carried out for a service contract for consultancy services to set up a platform for stakeholder involvement to optimise project outcomes. This contract was concluded against IMI's operational budget.

Administrative expenditure per Chapter

Chapter	Administrative expenditure 2013							
	Budget 2013	Budget Amend. 1	Budget transfer	Budget after transfer	Execution Commitment appropriation		Execution Payment appropriation	
	EUR	EUR	EUR	EUR	EUR	%	EUR	%
11 - Staff in active employment	4,131,000	4,131,000	(-) 16,000	4,115,000	3,434,239.40	83.46	3,434,239.40	83.46
12 - Misc. expenditure on staff recruitment	20,000	20,000		20,000	3,007.06	15.04	3,007.06	15.04
13 - Missions and duty travel	160,000	160,000		160,000	150,734.21	94.21	141,684.21	88.55
14 - Sociomedical structure	200,000	200,000	(+) 16,000	216,000	189,331.78	87.65	139,787.57	64.72
17 - Entertainment and representation	30,000	30,000		30,000	4,433.32	14.78	4,183.32	13.94
TOTAL TITLE 1	**4,541,000**	**4,541,000**		**4,541,000**	**3,781,745.77**	**83.28**	**3,722,901.56**	**81.98**
20 - Office building and associated costs	510,000	455,000		455,000	356,996.38	78.46	356,996.38	78.46
21 - Information technology purchases	550,000	630,000		630,000	627,791.67	99.65	445,130.30	70.66
22 - Office equipment (movable property)	110,000	72,000		72,000	21,490.02	29.85	2,693.84	3.74
23 - Current administrative expenditure	100,000	113,000		113,000	93,843.78	83.05	81,588.00	72.20
24 - Telecommunication and postal expenses	70,000	70,000		70,000	51,277.04	73.25	23,341.47	33.34
25 - Expenditure on formal meetings	150,000	150,000		150,000	110,249.04	73.50	107,575.78	71.72
26 - Exp. In connection with oper. Activities	500,000	500,000	(-) 25,873	474,127	295,597.79	62.35	277,178.14	58.46
27 - External communication	500,000	500,000		500,000	405,354.65	81.07	268,985.44	53.80
28 - Service contracts (studies, audits)	800,000	800,000	(+) 25,873	825,873	825,873.07	100.00	63,131.50	7.64
29 - Expert contracts and evaluations	569,000	569,000		569,000	548,966.28	96.48	499,505.95	87.79
TOTAL TITLE 2	**3,859,000**	**3,859,000**		**3,859,000**	**3,337,439.72**	**86.48**	**2,126,126.80**	**55.10**
TOTAL RUNNING COSTS	**8,400,000**	**8,400,000**		**8,400,000**	**7,119,185.49**	**84.75**	**5,849,028.36**	**69.63**

Administrative budget was executed applying principles of sound financial management. As an example, IMI planned to improve working conditions in an open space for its staff which would require some works and purchase of furniture. For this activity, budget was foreseen under Chapter 22. These plans were postponed taking into consideration the proposal of IMI2 with estimated start date in 2014.
Meetings were mostly organised in Brussels or in parallel with other meetings which considerably lowered costs of formal meetings (Chapter 25), workshops (Chapter 26) and events (Chapter 27).
For Title I, it was expected that the indexation of salaries (2011) will have to be paid at the end of 2013. The information that the indexation will not be paid in 2013 came only the last days of December when it was too late to use the reserved funds for other purposes.
It is important to note that the EU part of unused appropriations for running costs will be made available for operational activities under 2014 budget.

Report on C1

Running costs	Budget (PA/CA)	Committed	Not used	Paid	To be carried forward (RAL)	To be carried over to Title III C2 (50%-EC)*
Title I	4,541,000	3,781,745.77	759,254.23	3,722,901.56	58,844.21	379,627.12
Title II	3,859,000	3,337,439.72	521,560.28	2,126,126.80	1,220,915.53	260,780.14
Total	8,400,000	7,119,185.49	1,280,814.51	5,849,028.36	1,279,759.74	640,407.26

*The amount transferred from Title I & II to Title III and carried over to 2014 following decision of the Governing Board

Report on C8

	Carried forward RAL from 2012	Paid in 2013	To be cancelled	To be carried over to Title III C2 (50%-EC)*
Title I	115,491.69	71,384.45	44,107.24	22,053.62
Title II	1,104,798.03	752,023.94	352,774.09	176,387.05
TOTAL	1,220,289.72	823,408.39	396,881.33	198,440.67

*the amount transferred to Title III and carried over to 2014 following decision of the Governing Board.

Report on C4

	C4 2013	Paid in 2013	To be carried forward to 2014
Title I	2,234.00	0	2,234.00
Title II	15,810.88	1,425.33	14,385.55
TOTAL	18,044.88	1,425.33	16,619.55

Operational expenditure (Title III)

Operational expenditure on Title III covers all the expenses linked to the Research Agenda of IMI JU. In 2013, intermediate payments for Call 1, 2, 3 and 4 projects have been made as well as pre-financing for projects of Call 7, Call 8 and one project of Call 6. These payments consumed 99.43% of the payment appropriation available for 2013.

Commitment appropriation was fully consumed by launching Call 9, Call 10, Call 11 and ENSO Call 2013 (global commitments) and one individual commitment for consultancy service to set up a platform for stakeholder involvement to optimise IMI projects' outcomes (€ 200,000).

Report on C1

Research Title III	Budget	Amending Budget No 1	Committed	Not used	Paid	**To be carried over
Commitments	*196,379,206	*197,311,368	197,311,368	0	n/a	0
Payments	*126,150,000	*121,733,967	n/a	266,547.55	121,467,419.45	266,547.55

*Including budgeted bank interest

** The amount carried over to 2014 following decision of the Governing Board

Report on C2

Research Title III	Budget	Amending Budget No 1	Committed	Not used	Paid	*To be carried over
Commitments	22,166,234	50,004,551	50,004,551	0	n/a	0
Payments	424,655	424,655	n/a	424,655	0	424,655.00

* The amount carried over to 2014 following decision of the Governing Board

Report on C4

	C4 2013	Committed in 2013	To be carried forward to 2014
Title III	16,823.34	0	16,823.34

Report on C8 - carried forward contractual obligations (on-going projects/calls)

Title III Commitment Appropriation	RAL carried forward to 2014
Call 1	15,389,481.05
Call 2	30,044,211.47
Call 3	65,890,685.04
Call 4	57,499,181.33
Call 5	58,793,232.30
Call 6	74,812,972,73
Call 7	6,399,872.00
Call 8	84,980,808.00
Call 9	63,120,000.00
Call 10	6,100,000.00
Call 11	171,424,773.00
ENSO 2013	6,471,146.00
Service contract	200,000.00
Total	**641,126,362.92**

Overview of appropriations carried over to 2014

Title	Commitment appropriation	Comment
Title I & II → Title III	640,407	Non-used EU contribution in 2013
Title I & II → Title III	198,441	Appropriation cancelled in 2013
Title III	42,055	Bank interest – Q4 2013
TOTAL	**880,903**	

Title	Payment appropriation	Comment
Title III	266,547	Non-consumed appropriation 2013 – C1
Title III	424,655	Non-consumed appropriation 2013 – C2
Title III	42,055	Bank interest – Q4 2013
TOTAL	**733,257**	

BUDGET OUTTURN ACCOUNT

	2013	2012
Revenue	EUR	EUR
EU contribution – European Commission DG RTD	125,829,159.00	97,783,960.00
EFPIA contribution for running costs	2,742,987.80	4,067,578.15
Bank interest	95,796.81	474,655.28
Interest on pre-financing	54,072.68	52,864.52
Miscellaneous income	100,112.92	
Total revenue (a)	**128,822,129.21**	**102,379,057.95**
Expenditure	EUR	EUR
Personnel expenses – Title I	**3,794,286.01**	**3,718,444.28**
Payments on current year appropriations (C1)	3,722,901.56	3,677,389.78
Payments on previous year appropriations (C8)	71,384.45	41,054.50
Administrative expenses – Title II	**2,879,576.07**	**2,567,531.31**
Payments on current year appropriations (C1) + (C4)	2,127,552.13	1,983,056.66
Payments on previous year appropriations (C8)	752,023.94	584,474.65
Operational expenses – Title III	**121,467,419.45**	**103,809,163.00**
Payments on current year appropriations (C1)	121,467,419.45	93,133,960.00
Payments on previous year appropriations (C2)	0	10,675,203.00
Total expenditure (b)	**128,141,281.53**	**110,095,138.59**
Outturn for the financial year (a-b)	**680,847.68**	**-7,716,080.64**
Cancellation of unused appropriations	(+) 396,881.33	(+) 160,656.06
Appropriations carried over/forward (Title I and II)	(-) 2,135,227.22	(-) 2,560,589.67
Appropriations carried over (Title III)	(-) 424,655.00	(-) 424,655.28
Balance of the outturn account for the financial year	**-1,482,153.21**	**-10,540,669.53**

ANNEX B - MATERIALITY CRITERIA

The Executive Director assessed the significance of any weaknesses or risks that could lead to a formal reservation in the annual declaration of assurance. This annex provides an explanation of the materiality threshold that was applied as a basis for this assessment.

The control objective is to ensure that the residual error rate of payments made to beneficiaries, i.e. the level of errors which remain undetected and uncorrected, does not exceed 2% by the end of the research programme. 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;

- *in quantitative terms*, the potential financial impact is taken into account.

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, therefore, taken into account:

- Due to its multiannual nature, the effectiveness of IMI'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 regarding beneficiaries have been detected and corrected.

- As the control objective is set to be achieved in the future, it is therefore not sufficient to assess the effectiveness of controls only by looking at the error rate determined during the year under review. The analysis must also include an assessment of whether (1) the scope and results of the audits carried out until the end of the reporting year were sufficient and adequate to meet the multi-annual control strategy goals; and (2) whether the preventive and remedial measures in place are being deemed to be adequately effective in order lead to the expected reduction in the error rate by the end of the programme.

ANNEX C - INTERNAL CONTROL FOR BUDGET IMPLEMENTATION

Key figures

Details on budget execution and time to pay for administrative and operational expenditures are provided in sections 5.1 and 6.2.

Management and control systems: stages and main actors

- IMI applies the simple financial circuit model in the Accrual Based Accounting (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 financial rules.

- The Executive Director acts as Authorising Officer, with authority being delegated to the Head of Administration and Finance and, when necessary as backup, to another member of staff. In accordance with its financial rules, IMI 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 an Internal Auditor (the 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 projects is based on a two-stage evaluation process which includes a public Call for proposals, official rules of participation, eligibility screening of the EoIs and FPPs; ethical reviews of the proposals performed by independent external experts; and controls to ensure conformity with IMI rules as well as procedures and checks carried out during the negotiation, grant preparation and signature processes. Each key stage is endorsed by a decision of the Governing Board.

- In the case of the selection of experts, individuals are chosen on the basis of a list of appropriate experts according to their specific expertise. The experts are appointed for the duration of each specific Call process. A Scientific Officer ensures that the proposed experts have the necessary expertise and prepares a dossier with the required information to support the decision of the Executive Director. IMI has a documented standard operating procedure and controls for the selection of experts.

- 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; 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 established thresholds of the estimated value of the contract.

Communication and information

- *Internally*: The main internal mechanisms for communication and the dissemination of information are senior management briefings and updates to the Governing Board, 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 sessions 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 have already been accepted by the EC 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 carried out and validates the expenditure.

- Since 2011, interim reviews have also been systematically used to complement the detective and corrective controls. In 2013, six interim reviews were organised.

Corrective controls and audit

- *Ex post* audits are a key element of corrective controls. IMI follows the JUs' *ex post* audit strategy which was approved by the IMI Governing Board following harmonisation with the corresponding FP7 strategy.

- 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 can carry out on the spot checks and/or audits of beneficiaries. In addition, IMI 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, and 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 of beneficiaries were concluded in 2012 and new audits are continuously being launched to cover new cost claims. In parallel, follow-up corrective actions are taken to recover amounts found to have been paid in excess. Systematic errors detected on the audited contracts are also extended and corrected in the relevant non-audited claims. This ensures that a substantial share of funding is largely free from systematic errors.
- All audit results are implemented by the authorising officer and errors detected are 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, and further strengthening of *ex ante* controls are also being implemented.

- In addition, in 2013, the first sample of three independent *ex post* reviews of the accepted in kind methodologies of EFPIA companies together with audits of a sample of declared in kind contribution were concluded. This approach is being continued with other sampled EFPIA companies particularly the largest contributors of in kind contributions to IMI projects.

Anti-fraud measures

Anti-fraud measures are embedded in various *ex ante* and *ex post* controls for prevention and detection purposes. In addition, in 2014, IMI will build on the Anti-Fraud Strategy of the European Commission and experience acquired by Commission services to develop its own Anti-Fraud Strategy in line with guidance from OLAF (the European Anti-Fraud Office) and good practices applied across the European Commission's research family. In 2013, the initial work for the preparation of this strategy was started and consultations were held with the European Commission. The main purpose of this strategy will be to translate the strategic anti-fraud priorities into concrete operational measures addressing risks that are particularly relevant for the operations managed by IMI.

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 the 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 rigorous reporting and registration of exceptions to internal policies and standard operating procedures and processes that have been assessed and accepted by management. In 2013, 13 exceptions were registered by management. These related to processes and workflows concerning grant management (2 registered exceptions), call coordination (1), financial management (5), contract management (5) and ex-post audit (1).

- Management at all levels supervises the activities they are responsible for and keeps track of main issues identified. A system of checklists and routing sheets document the processes and the work carried out. Activities involving potentially critical risks (e.g. aspects of legality, regularity and operational performance) are also adequately documented and, when necessary, also discussed and addressed during regular management or team meetings.

- The effectiveness and efficiency of management supervision is also systematically evaluated during each annual risk assessment exercise and by other planned or ad hoc examinations, assessments, audits and checks carried out by the ICC and the IAC.

- As from 2012, independent verifications and follow-up examinations on the implementation of recommendations have also been carried out by the IAS on IMI's processes. These can be in the form of an audit assurance engagement or as a performance audit.

- Two in-depth and comprehensive exercises were carried out in 2011 and 2012 by the Accounting Officer to validate the system of underlying processes supporting the accounting system. Moreover, the Accounting Officer can launch at any time additional validations, particularly of new or modified processes or procedures that are assessed as having a significant impact on reliability of the accounting system,

- Independent observers are also engaged by IMI to monitor each evaluation of EoIs or FPPs. Their role is to report on the degree of compliance with the established rules, the extent to which proceedings were fair, exhaustive and transparent, as well as on the level of organisation and the quality of the evaluations. In their report they also propose recommendations for further improvement and fine-tuning of the processes. These reports are made public and identified actions are followed up and implemented by IM in subsequent evaluations. In 2013, there were four independent observers' reports.

- *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.

- In parallel, the ECA carries out financial and compliance audits of IMI 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.

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. Issues and risks (e.g. on Call management status) are flagged and followed up. Additional systematic monitoring and tracking is also undertaken by management, the ICC and the IAC on prioritised areas of activity or concern. Critical strategic or governance issues are also monitored and followed up in Governing Board meetings.

- In addition, throughout the year, metrics, indicators and qualitative evaluations on the scientific achievements and results of IMI 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 and budget execution.

- An internal audit was also launched in the fourth quarter of 2013 by the IAS to assess IMI's performance monitoring and reporting systems. The conclusions and recommendations of this audit are expected in 2014 and these will used by management to refine and improve the overall approach and the underlying processes for measuring and monitoring performance.

- Moreover, two external interim reviews by independent panels of experts were carried out on behalf of the European Commission in 2010 and 2013 to assess the effectiveness, efficiency and quality of research generated through IMI, and to evaluate the progress of IMI towards the objectives set and the level of implementation of recommendations from the first interim evaluation.

High-level management reporting

- The Annual Implementation Plan includes planned actions, initiatives and priorities relative to the implementation of the budget.

- The Executive Director reports to the Governing Board on progress and achievements through regular briefings and communications as well as during at least two meeting of the Board which are held every year.

- In addition, the Annual Activity Report outlines the activities, achievements and progress made during the year, including issues related to budget implementation.

ANNEX D – MEDIA COVERAGE

The following list sets out some media highlights from 2013. Articles appearing in national media in the EU are arranged by country. A more exhaustive list can be found on the Media Coverage page of the IMI website.

European

- European Files, December 2013
  IMI: Delivering results for patients
- MedNous, 23 December 2013
  Genetic variants affect cognition
- Science Business, 12 December 2013
  Health in Horizon 2020 – A move towards personalised healthcare
- PharmaNews, 12 December 2013
  IMI launches €371 million call with focus on Alzheimer's, arthritis, cancer, and more
- European Biotechnology News, 11 December 2013
  First adaptive Alzheimer trials
- European Biotechnology News, 15 August 2013
  A Bioeconomy PPP – the next generation in collaboration
- Euronews, 25 June 2013
  Developing a treatment for autism
- EurActiv, 13 March 2013
  EU body may provide 'solution' to antibiotics resistance threat, says UK medical chief
- European Files, February-March 2013
  IMI – Towards a new ecosystem for healthcare in Europe

International

- Wall Street Journal, 30 December 2013
  Researchers Aim to Speed Cures to Patients
- BioCentury, 13 December 2013
  IMI launching project for adaptive Alzheimer's trial
- Scrip, 11 December 2013
  IMI to revolutionize the hunt for Alzheimer's drugs as part of €371m call
- BioCentury, 27 November 2013
  Stakeholders launch pan-Europe vaccine monitoring project
- Scrip, 29 October 2013
  IMI offers €12.2m for better ways of testing effectiveness of flu vaccines
- FierceBiotech, 15 July 2013
  Europe eyes social media and mobile for data on bad drug reactions
- Science, 12 July 2013
  E.U. Commission Beefs up Research Partnerships with Industry
- Scrip, 21 April 2013
  INTERVIEW: Goldman's dreams of competitive collaboration as IMI 2 considered

- Fierce Biotech, 7 February 2013
  €196 million pan-European drug discovery platform launched
- Reuters, 7 February 2013
  Drugmakers, academics pool R&D in $265 mln EU project
- BioCentury, 24 January 2013
  IMI's collaborative chemistry

Belgium

- Belga Agency, 2 December 2013
  Europees project wil system ontwikkelen om veiligheid vaccins te kunnen onderzoeken (European project wants to develop system in order to be able to research vaccine safety)
- RTBF, 14 May 2013
  Sur les traces de l'autisme génétique (Investigating genetic autism)
- La Dernière Heure, 21 March 2013
  Une pandémie d'ici peu! (A pandemic coming soon!)
- De Standaard, 8 February 2013
  Europese farmareuzen delen onderzoek (European pharma giants share research)

Bulgaria

- Meditsinski Digest, 28 July 2013
  Increasing antibiotic resistance, fewer antibiotics under development

Czech Republic

- Zdravotnické noviny, 16 December 2013
  Inovativní farmaceutické společnosti nabízejí českým vědcům pomocnou ruku (Innovative pharmaceutical companies offer Czech scientists a helping hand)
- Medical Tribune, 20 May 2013
  Krátce ze světa farmacie (Short world of pharmacy)
- Medical Tribune, 11 February 2013
  IMI – cesta k partnerství při výzkumu i realizaci (IMI - the path to partnership in research and implementation)

Denmark

- MedWatch, 11 December 2013
  Trecifret millionbeløb bag IMI-satsning på Alzheimers (Three-digit million figure behind IMI focus on Alzheimer's)

Germany

- Focus, 20 December 2013
  Werden künftig Stammzellen am Fließband produziert? (Will stem cells be made on a production line in the future?)
- Die Welt, 19 December 2013
  Geschäft mit der Hoffnung bei Stammzellforschung (Promising business in stem cell research
- Ärzte Zeitung, 11 December 2013
  Personalisierte Medizin rückt in den Vordergrund (Personalised medicine comes to the fore)

- Ärzte Zeitung, 4 October 2013
  EU gibt Innovationen Schub (EU gives innovations a boost)
- Arzt Aspekte, 25 September 2013
  Schmerztherapie: so früh wie möglich – um Veränderungen des Gehirns vorzubeugen (Pain treatment: as early as possible – to prevent changes in the brain)
- Deutsche Welle – Spectrum, 4 March 2013
  Make drugs not war

Estonia

- Eesti Päevaleht, 23 May 2013
  Euroopa Liit koondab joud ajuhaiguste vastu (The European Union joined forces on brain disease)

Ireland

- Medical Independent, 6 June 2013
  AD pre-diagnosis window crucial
- Medical Independent, 23 May 2013
  Paternal age may have autism link
- Independent, 11 March 2013
  Resistance to antibiotics risks health 'catastrophe' to rank with terrorism and climate change

Greece

- EKT, 29 July 2013
  Περισσότερα από 22 δισ. ευρώ επενδύουν η ΕΕ και η ευρωπαϊκή βιομηχανία στην έρευνα και την καινοτομία (More than 22 billion invested by the EU and European industry in research and innovation)
- Pharma Market Journal, 20 February 2013
  Ανθεκτικότητα στα αντιβιοτικά: Συνεργασία 5 φαρμακευτικών εταιριών στις έρευνες (Antibiotic resistance: 5 pharmaceutical companies in research)

Spain

- La Voz de Galicia, 23 December 2013
  Los medicamentos que nos cambiarán la vida (The medicines that will change our lives)
- Diario Medico, 27 May 2013
  Los emprendedores son esenciales (Entrepreneurs are essential)

France

- Europe Nouvelles, 23 December 2013
  Les variantes génétiques liées à la schizophrénie ont un impact chez les porteurs sains (Genetic variants link to schizophrenia have an impact in healthy carriers)
- Les Echos, 2 April 2013
  Un plan européen de 195 millions d'euros pour inventer de nouveaux antibiotiques (A EUR
- 195 million European plan to invent new antibiotics)

Italy

- Agora Magazine, 2 December 2013
  Nasce ADVANCE, progetto europeo per il monitoraggio dei benefici e rischi dei vaccine
  (ADVANCE, European project for vaccines benefits and risks monitoring, was created)
- Corriere Della Sera, 26 November 2013
  Vaccini, progetto europeo per monitorare benefici e rischi

Latvia

- Latvijas Avīze, 7 June 2013
  Postošais Alcheimers joprojām mīkla zinātniekiem (Devastating Alzheimer's is still an enigma for scientists)
- Latvijas Avīze, 31 May 2013
  ES kā galvenos izvirza pētījumus un inovācijas neirozinātnēs (The EU supports neuroscience research and innovation)

Lithuania

- Lietuvos Rytas, 6 December 2013
  Vaistų gamintojams kryptį rodo mokslas (Pharmaceutical manufacturers' direction of science)

Hungary

- HaziPatika.com, 13 June 2013
  A jövő gyógyszereit ma fejlesztik (The future of medicines being developed today)

Netherlands

- De Telegraaf, 26 November 2013
  Effect vaccinatie sneller in kaart (Effects of vaccination mapped faster)
- De Volkskrant, 7 February 2013
  Bundeling kennis voor nieuwe medicijnen (Bundling knowledge for new medicines)

Poland

- Gazeta dla Lekarzy, May 2013
  Innovative Medicine Initiative Stakeholder Forum

Slovakia

- Quark, 2 April 2013
  Spolupraca je všetko (Cooperation is everything)
- Pravda, 5 March 2013
  Univerzita Komenského prispieva k špičkovému vzdelávaniu o liekoch (University contributes to excellent medicines education)

Finland

- Talouselämä, 11 March 2013
  Globaali aikapommi uhkaa terveydenhoidossa - "samanlainen kansakunnan uhka kuin terrorismikin" - Global time bomb threatening to health care - "similar to the nation as the threat of terrorism"

Sweden

- SverigesRadio - Kropp & Själ, 29 October 2013
  Bakteriekriget (Bacterial war)

United Kingdom

- Nature, 16 December 2013
  Man versus microbe: warfare at its worst
- ITV, 10 December 2013
  Dementia replaces cancer as disease people fear most
- Financial Times, 6 December 2013
  Science: High-tech drug research gives us a fuller picture
- Financial Times, 17 October 2013
  Doctor prescribes boost for biomedicine in EU
- Financial Times, 12 August 2013
  Pharmaceuticals: Back to the lab
- Financial Times, 21 April 2013
  Healing the UK pharma industry
- Chemistry World, 13 March 2013
  Antibiotic resistance is a 'ticking time bomb'
- The Guardian, 11 March 2013
  New wave of 'superbugs' poses dire threat, says chief medical officer
- BBC, 11 March 2013
  Antibiotics resistance 'as big a risk as terrorism' - medical chief
- Scottish Government, 7 February 2013
  Lanarkshire and Dundee in £100M life science project
- Nature, 7 February 2013
  Europe bets on drug discovery
- BBC, 7 February 2013
  Scottish consortium wins £100m drug research contract
- Nature Biotechnology, 7 February 2013
  Industry backs biocatalysis for greener manufacturing
- Nature Biotechnology, January 2013
  Banking iPS cells

ANNEX E - TABLE OF ONGOING IMI PROJECTS AS AT 31 DECEMBER 2013

Project acronym	Full project title	Website	Subject area
ABIRISK	Anti-biopharmaceutical immunization: prediction and analysis of clinical relevance to minimize the risk	www.abirisk.eu	drug safety
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe		vaccines
AETIONOMY	Organising mechanistic knowledge about neurodegenerative diseases for the improvement of drug development and therapy		Alzheimer's disease and Parkinson's disease
BioVacSafe	Biomarkers For enhanced vaccine safety	www.biovacsafe.eu	vaccines
BTCure	Be the cure	www.btcure.eu	rheumatoid arthritis
CHEM21	Chemical manufacturing methods for the 21st century pharmaceutical industries	www.chem21.eu	green chemistry
COMBACTE	Combatting bacterial resistance in Europe	www.combacte.com	antimicrobial resistance
COMPACT	Collaboration on the optimisation of macromolecular pharmaceutical access to cellular targets	www.compact-research.org	drug delivery
DDMoRe	Drug disease model resources	www.ddmore.eu	knowledge management
DIRECT	Diabetes research on patient stratification	www.direct-diabetes.org	diabetes
EBiSC	European bank for induced pluripotent stem cells		stem cells
EHR4CR	Electronic health record systems for clinical research	www.ehr4cr.eu	knowledge management
EMIF	European medical information framework	www.emif.eu	knowledge management, Alzheimer's disease, metabolic syndromes
EMTRAIN	European medicines research training network	www.emtrain.eu	education and training
ENABLE	European Gram negative antibacterial engine		antimicrobial resistance
eTOX	Integrating bioinformatics and chemoinformatics approaches for the development of expert systems allowing the *in silico* prediction of toxicities	www.e-tox.net	knowledge management, drug safety
eTRIKS	Delivering European translational information & knowledge management services	www.etriks.org	knowledge management
Eu2P	European programme in pharmacovigilance and pharmacoepidemiology	www.eu2p.org	education and training
EU-AIMS	European autism interventions - a multicentre study for developing new medications	www.eu-aims.eu	autism

Project acronym	Full project title	Website	Subject area
ELF	European lead factory	www.europeanleadfactory.eu	drug discovery
EUPATI	European patients' academy on therapeutic innovation	www.patientsacademy.eu	education and training
Europain	Understanding chronic pain and improving its treatment	www.imieuropain.org	chronic pain
GetReal	Incorporating real-life clinical data into drug development		relative effectiveness
IMIDIA	Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes	www.imidia.org	diabetes
K4DD	Kinetics for drug discovery	www.k4dd.eu	drug discovery
MARCAR	Biomarkers and molecular tumor classification for non-genotoxic carcinogenesis	www.imi-marcar.eu	safety, cancer
MIP-DILI	Mechanism-based integrated systems for the prediction of drug-induced liver injury	www.mip-dili.eu	drug safety
NEWMEDS	Novel methods leading to new medications in depression and schizophrenia	www.newmeds-europe.com	schizophrenia, depression
OncoTrack	Methods for systematic next generation oncology biomarker development	www.oncotrack.eu	cancer
Open PHACTS	The open pharmacological concepts triple store	www.openphacts.org	knowledge management
OrBiTo	Oral biopharmaceutics tools	www.orbitoproject.eu	drug delivery
Pharma-Cog	Prediction of cognitive properties of new drug candidates for neurodegenerative diseases in the early clinical development	www.alzheimer-europe.org/Research/PharmaCog	Alzheimer's disease
PharmaTrain	Pharmaceutical medicine training programme	www.pharmatrain.eu	education and training
PRECISESADS	Molecular reclassification to find clinically useful biomarkers for systemic autoimmune diseases		rheumatoid arthritis and lupus
PREDECT	New models for preclinical evaluation of drug efficacy in common solid tumours	www.predect.eu	cancer
PreDiCT-TB	Model-based preclinical development of anti-tuberculosis drug combinations	www.predict-tb.eu	tuberculosis
PROactive	Physical activity as a crucial patient reported outcome in COPD	www.proactivecopd.com	chronic obstructive pulmonary disease (COPD)
PROTECT	Pharmacoepidemiolocal research on outcomes of therapeutics by a European consortium	www.imi-protect.eu	pharmacovigilance
QuIC-ConCePT	Quantitative imaging in cancer: connecting cellular processes with therapy	www.quic-concept.eu	cancer
RAPP-ID	Development of rapid point-of-care test platforms for infectious diseases	www.rapp-id.eu	infectious diseases

Project acronym	Full project title	Website	Subject area
SafeSciMET	European modular education and training programme in safety sciences for medicines	www.safescimet.eu	education and training
SAFE-T	Safer and faster evidence-based translation	www.imi-safe-t.eu	drug safety
StemBANCC	Stem cells for biological assays of novel drugs and predictive toxicology	www.stembancc.org	stem cells
SUMMIT	Surrogate markers for vascular micro- and macrovascular hard endpoints for innovative diabetes tools	www.imi-summit.eu	diabetes
TRANSLOCATION	Molecular basis of the outer membrane permeability	www.translocation.eu	antimicrobial resistance
U-BIOPRED	Unbiased biomarkers for the prediction of respiratory disease outcomes	www.ubiopred.eu	asthma

List of acronyms

Acronym	Meaning
3D	three-dimensional
ABAC	Accrual Based Accounting
ABPI	Association of the British Pharmaceutical Industry
AchEi	acetylcholine esterase inhibitor
AD	Alzheimer's disease
ADR	adverse drug reaction
AER	average error rate
API	active pharmaceutical ingredient
ASD	autism spectrum disorder
ASL-FMRI	arterial spin labelling functional magnetic resonance imaging
ATLA	Alternatives to Laboratory Animals
BIT	Booking of IT material application
BLA	beta-lactamase inhibitor
BRIDG	Biomedical Research Integrated Domain Group
CAD	Carcinogenicity Assessment Document
CAMD	Coalition Against Major Diseases
CDA	confidential disclosure agreement
CDASH	Clinical Data Acquisition Standards Harmonization
CDISC	Clinical Data Interchange Standards Consortium
CFAST	Coalition for Accelerating Standards and Therapies
CFS	Certificate of Financial Statement
CHMP	Committee for Medicinal Products for Human Use
CNS	central nervous system
CNV	copy number variation
COPD	chronic obstructive pulmonary disease
CORDA	Common Research Data Warehouse
COST	European Cooperation in Science and Technology
C-Path	Critical Path Institute
CPD	continuing professional development
CPTR	Critical Path to TB Drug Regimens
CSF	cerebrospinal fluid
CTMM	Center for Translational Molecular Medicine
DG	Directorate-General
DIA	Drug Information Association
DIKI	drug-induced kidney injury
DILI	drug-induced liver injury
DIVI	drug-induced vascular injury
DN	diabetes neuropathy
DORA	Document Registry Application
DPO	data protection officer
E&T	education and training

Acronym	Meaning
EACPT	European Association for Clinical Pharmacology and Therapeutics
EAPM	European Alliance for Personalised Medicine
EASD	European Association for the Study of Diabetes
EC	European Commission
ECA	European Court of Auditors
eCDR	electronic Career Development Report application
eCORDA	External Common Research Data Warehouse
EDPS	European Data Protection Supervisor
EEG	electroencephalograph
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHR	electronic health record
EMA	European Medicines Agency
ENSO	Exploring New Scientific Opportunities
EoI	Expression of Interest
ERA	European Research Area
EU	European Union
FCH	Fuel Cells and Hydrogen
FDA	Food and Drug Administration
FP7	Seventh Framework Programme
FPP	Full Project Proposal
FTE	full time equivalent
GEMM	genetically-engineered mouse model
GMP	good manufacturing practice
GWAS	genome-wide association study
HL7	Health Level Seven International
HR	human resources
HTS	high throughput screening
IAC	Internal Audit Capability
IAS	Internal Audit Service of the European Commission
ICC	Internal Control Coordinator
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICI	International Congress of Immunology
ICS	Internal Control Standards
ICT	Information and communication technology
IHC	immunohistochemistry
ILG	Industry Liaison Group
IMI	Innovative Medicines Initiative
IP	intellectual property
ISA	Information System for Absences
ISO	International Organization for Standardization
IT	information technology
ITI-PF&S	innovative therapeutic interventions against physical frailty and sarcopenia
IVC	International Venture Club

Acronym	Meaning
JAMA	Journal of the American Medical Association
JDRF	Juvenile Diabetes Research Foundation
JTI	Joint Technology Initiative
JU	Joint Undertaking
KPI	key performance indicator
KU Leuven	Katholieke Universiteit Leuven
LSE	London School of Economics
MAPP	medicines adaptive pathways to patients
MCI	mild cognitive impairment
MDL	modelling description language
MEP	Member of the European Parliament
MoU	memorandum of understanding
MRC	Medical Research Council
MRI	magnetic resonance imaging
NCATS	National Center for Advancing Translational Sciences
ND4BB	New Drugs for Bad Bugs
NFAT	Nuclear Factor of Activated T-Cells
NGC	non-genotoxic carcinogen
NIA-AA	National Institute on Aging–Alzheimer's Association
NIH	National Institutes of Health
OLAF	European Anti-Fraud Office
PDX	patient-derived xenograph
PET	positron emission tomography
PharmML	pharmacometrics markup language
phMRI	pharmacological magnetic resonance imaging
PM²	Project Management Methodology
PMDA	Pharmaceuticals and Medical Devices Agency
POCT	point of care test
PPP	public-private partnership
PR	public relations
PRO	patient-reported outcome
PRRE	Private Remote Research Environment
PSTC	Predictive Safety Testing Consortium
Q&A	question and answer
R&D	research and development
RA	rheumatoid arthritis
RAE	risk assessment exercise
RepER	representative error rate
ResER	residual error rate
SDTM	Study Data Tabulation Model
SLE	systemic lupus erythematosus
SME	small and medium-sized enterprise
SOFIA	Submission of Information Application
SRA	Strategic Research Agenda

Acronym	Meaning
SRG	States Representatives Group
SSRI	selective serotonin reuptake inhibitor
SWP	Safety Working Party
TB	tuberculosis
TMA	tissue microarray
TraIT	Translational Research Information Technology
UML	unified modelling language
US	United States
UVB	ultraviolet B
VC	venture capital
VCF	variant call format
ZDF	Zucker diabetic fatty

Innovative Medicines Initiative

IMI JU Governing Board
Analysis and Assessment of the Innovative Medicines Joint Undertaking
Annual Activity Report 2013 (IMI JU AAR)

Legal Basis

Article 41 (2) of the IMI Financial Rules states that 'by no later than 15 June each year, the Governing Board shall send the budgetary authority and the Court of Auditors an analysis and assessment of the authorizing officer's annual report on the previous financial year. This analysis and assessment shall be included in the Annual Activity Report of the IMI Joint Undertaking, in accordance with the provisions of Article 18 of the Statutes'.

Analysis

The Innovative Medicines Initiative Annual Activity Report 2013 (Authorising Officer's report) was presented to the IMI JU Governing Board in March 2014 and it is planned to have it approved by the Governing Board in June 2014.

The Governing Board is of the opinion that the IMI JU AAR 2013 covers the main achievements of the IMI JU in 2013 in relation to the objectives set; clearly identifies the risks associated with the IMI JU operations; duly reports on the use made of the IMI JU resources provided; and indicates the efficiency and effectiveness of the IMI JU internal control system.

The Governing Board recognizes the progress made by the IMU JU towards achieving the objectives set for year 2013 and notes in particular that:

- The Annual Implementation Plan 2013 was approved on 22 December 2012.
- With the launch of the last three Calls for Proposals under IMI 1 and the kick-off of 6 new projects, IMI continued to implement key strategic objectives of its Scientific Research Agenda and IMI committed entire of its available budget. This has been possible thanks to efficient collaboration between EC and EFPIA with the support from IMI SC and SRG and the entire JU office.
- Continued analysis of projects deliverables indicates outstanding scientific performance with uptake of results in research processes, regulatory and clinical practice. The bibliometric analysis of IMI projects demonstrated impact factor higher than world and EU 's average confirming scientific excellence.
- The second Interim Evaluation of IMI performed by independent experts documented the added value of IMI for the European Union. The expert panel was positive on the effectiveness, efficiency and quality of research and on the progress of IMI towards its objectives.

Innovative Medicines Initiative (IMI)
Postal mail: IMI JU, TO 56, Office 6/5 1049 Brussels
Visiting address: Avenue de la Toison d'Or, 56-60, 1060 Brussels
tel: +32 (0)2-221 81 81 – fax: +32 (0)2-221 81 74
www.imi.europa.eu

- Communication activities have been enhanced in particular towards scientific audiences, patient organisation and other possible applicants.
- In 2013 IMI increased its focus on fostering cross-project interactions and collaboration as well as creating new relationships between multiple stakeholders, particularly with regards to promoting collaboration beyond IMI and Europe to achieve global impact.
- The execution of 2nd Call projects was adequately followed up, including ex-ante and ex-post financial and scientific verifications. All 6 interim reviews expected in 2013 took place.
- In 2013, IMI JU finalised 3 ex post reviews and audits (risk-based audits) on the declared in-kind contribution of 3 EFPIA companies.
- 70 ex-post audits of beneficiaries were finalised by the end of 2013.
- IMI's IT project management tool (SOFIA) was further developed to better support all Call processes. Since the third quarter of 2013 SOFIA is integrated with EC IT architecture for reporting on Call and project data, which is now available in Common Research Data warehouse (CORDA).
- Simplification of call, application and reporting processes was put in place and implemented as of the 4th Call. Time to grant has improved (more than 400 days for call 3 to less than 150 days for Call 6).
- In 2013, the budget execution improved slightly compared to 2012, with 95.5% execution in commitment appropriations and 97.52% in payment appropriations.
- The authorised maximum ceiling of 36 staff members was reached on 1 July 2012. Following the departure of staff members 4 new staff members joined IMI during 2013 (3 project officers and 1 administrative assistant).
- IMI continued to promote SME participation in IMI projects. The SME involvement in IMI projects (Call 1 to 8) represents 15.2% and receiving 18.4 % of the IMI JU funding.
- IMI JU enhanced communication activities and coverage in specialized/scientific press and in newer EU Member States and it focused on promoting IMI's successes.

Most of the key objectives were achieved in the expected time frame in a satisfactory manner.

During 2013 the monitoring tools were fully operational and the IMI JU AAR 2013 provides information on the effectiveness of the internal controls implemented and on the main results of monitoring and supervision controls.

Based on the information provided, the key objectives set up for 2013 have been met in compliance with legality, regularity and sound financial management.

The technical and operational information provided in the report reflects the situation at the end of 2013 in a realistic way.

As recommendations for improvements, IMI should work further on the communication strategy to reach different groups with targeted messages, thus addressing the lack of visibility of IMI among specific groups within the scientific, healthcare and patient community.

The KPIs should be further developed to better measure and reflect Innovative Medicines Initiative's overall objectives. There is also a need for the long-term strategy to better evaluate the general impact of IMI on the biopharmaceutical industry, the healthcare system and the European economy.

Further work on sustainability of projects and uptake of results from IMI projects should also be undertaken.

Assessment

The declaration of the Executive Director's and the IMI Annual Activity Report 2013 gives a fair assessment (clear, unambiguous, congruous) of operational and financial management in relation to the achievement of objectives, and the legality and regularity of the financial operations of the IMI JU in the year 2013.

However, the reservation concerning the rate of residual errors with regard to the accuracy of cost claims submitted by participants of IMI JU projects should be noted.

Therefore, the IMI JU Governing Board hereby adopts this assessment of the IMI Annual Activity Report 2013 of the authorizing officer. This assessment will be included into the IMI Annual Activity Report 2013.

Done at Brussels, on ..... 10 June 2014

For the Governing Board of the Innovative Medicines Initiative

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Roch Doliveux

Chair of the Governing Board