Annual Activity Report 2014

Annex 1 to IMI2 JU Governing Board Decision No IMI2-GB-DEC-2015-32
Document approved by the IMI2 JU Governing Board on 23.07.2015
Last update: 16.07.2015
Document reference: IMI2/INT/2014-04923

Contents

Foreword

2014 was yet another fruitful period for the Innovative Medicines Initiative Joint Undertaking (IMI JU). It marked the kick-off of IMI 2 JU under the Horizon 2020 framework.

Building on the success of IMI 1 JU, the IMI 2 JU programme aims at providing European citizens with more efficient and effective medicines and treatments. Cost savings will ease the burden on public healthcare systems and greater coordination across industry sectors will result in more reliable and faster clinical trials, and better regulation. IMI 2 JU research and innovation efforts will also open new commercial possibilities based on new services and products. The research, industry and societal sectors involved in IMI 2 JU programmes will benefit from the cooperation and knowledge-sharing which take place in these projects.

IMI 2 JU was swiftly implemented with the launch of four Calls for proposals in key areas such as diabetes, neurodegeneration, and vaccines. It also marked the launch of the Ebola+ programme and the implementation of the last Calls under IMI 1 JU. By the year end, IMI JU had a portfolio of almost 59 projects, with many of them producing impressive results, as shown in this report.

I would like to pay tribute to Professor Michel Goldman under whose leadership IMI JU has become a recognised worldwide model of public-private partnership (PPP) in healthcare. I would also like to highlight the efficient collaboration between the European Commission services and the European Federation of Pharmaceutical Industries and Associations (EFPIA), with the essential support of the IMI JU Scientific Committee and the IMI JU States Representatives Group (SRG). Furthermore, tribute should be paid to the group of more than 7 000 scientists who contribute every day to IMI JU's reputation as a European flagship for pharmaceutical research. With its efficient and highly motivated staff, the IMI JU Programme Office remains fully committed to continuing its mission of facilitator to achieve the ambitious goals set for IMI 2 JU, which should result in concrete improvements in the standard of care across the European Union (EU).

Irene Norstedt

Acting Executive Director

1 ACHIEVING IMI JU'S STRATEGIC OBJECTIVES

1.1 Assessment of project achievements

An extensive analysis of achievements from IMI JU's ongoing projects has been performed using progress reports, interim reviews, and scientific publications coming from the projects. These achievements support the following messages that have been and will continue to be conveyed to IMI JU's relevant audiences:

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

Key Performance Indicators – 2014 results

Key Strategic Focus	Selected Key Performance Indicator (KPI)	2014 Target	Result
Portfolio	**KPI 1:** Target number of priority areas defined in IMI 2 JU's Annual Scientific Priorities for 2014 that are addressed by IMI 2 JU Call for proposals launched in 2014	≥4 priority areas from IMI 2 JU's Annual Scientific Priorities for 2014	6 priority areas were addressed in IMI 2 JU Calls 1-4
Scientific Output	**KPI 2:** Target estimated percentage of IMI JU projects that are assessed by the Programme Office as having achieved 100% of pre-set deliverables by the last reviewed reporting period by the end of the year	≥80% of IMI JU projects	10% of projects achieved 100% of pre-set deliverables Average deliverable completion is 80% for 40 reporting projects
	KPI 3: Target estimated average number of IMI JU publications per EUR 10 million of total IMI JU funding requested by the projects	≥20 publications	60 publications per EUR 10 million of total IMI JU funding requested by the projects 1 134 publications in total
	KPI 4: Target to measure extent to which IMI JU's estimated average impact factor of journals in which IMI JU publications have been published is higher than the EU average	≥10% higher than EU average	6.09 – IMI average impact factor vs. 3.26 – EU average impact factor
	KPI 5: Target to measure extent to which IMI JU's estimated citation impact of IMI JU publications is higher than the EU average	≥20% higher than EU average	2.19 – IMI JU citation impact vs. 1.10 EU citation impact > 99% higher

Key Strategic Focus	Selected Key Performance Indicator (KPI)	2014 Target	Result
	KPI 6: Target to measure the extent to which IMI JU's bibliometric results compare with those of other international funding bodies	Not applicable in 2014	2.59 – IMI JU citation impact vs. 2.17 – FNIH vs. 2.09 – MRC vs.1.95 – Wellcome Trust [1]
Impact on regulatory framework and standardisation	**KPI 7:** Target to measure the number of scientific advices and qualified opinions initiated with the European Medicines Agency (EMA) and Food and Drugs Administration (FDA) by IMI JU projects	≥ 5	10 qualification advices obtained
	KPI 8: Target to measure the number of regulatory guidelines derived from IMI JU projects	For KPI 8 and KPI 9, the methodology for capturing information and the baseline data for establishing the targets is being determined in 2014-2015	Not available
	KPI 9: Target to measure new standards and best practices derived from IMI JU projects	No target has been set for 2014. Baseline data was collected in October 2014 via a survey. The result is cumulative for all IMI projects.	33
Business development and sustainability	**KPI 10:** Target to measure the average number of patent applications filed and/or awarded to those IMI JU projects which have been reimbursed at least for the third year of implementation	≥2 patent applications per EUR 10 million of costs accepted and reimbursed by IMI JU	12 patents filed 3.2 patents per EUR 10 million of costs accepted and reimbursed by IMI JU
	KPI 11: Target to measure impact on competitiveness	The methodology for capturing this information from industry and other sources and the baseline data for establishing the target will be determined in 2015	
	KPI 12: Target to measure the number of spin-off companies or foundations created as a result of IMI JU projects	25% of finalised projects	8 from on-going projects
SME participation	**KPI 13:** Target percentage of participants in signed grant agreements that are SMEs	≥20%	16%
	KPI 14: Target percentage of overall budget for projects that has been allocated to SMEs	≥20%	15.8%
Patient participation	**KPI 15:** Target percentage of projects involving patient organisations as consortium partners, members of Advisory Boards, Ethical Advisory Boards or on consultancy basis for topics of relevance	100%	60% as reported via survey conducted in 2013, Data collection for update is ongoing

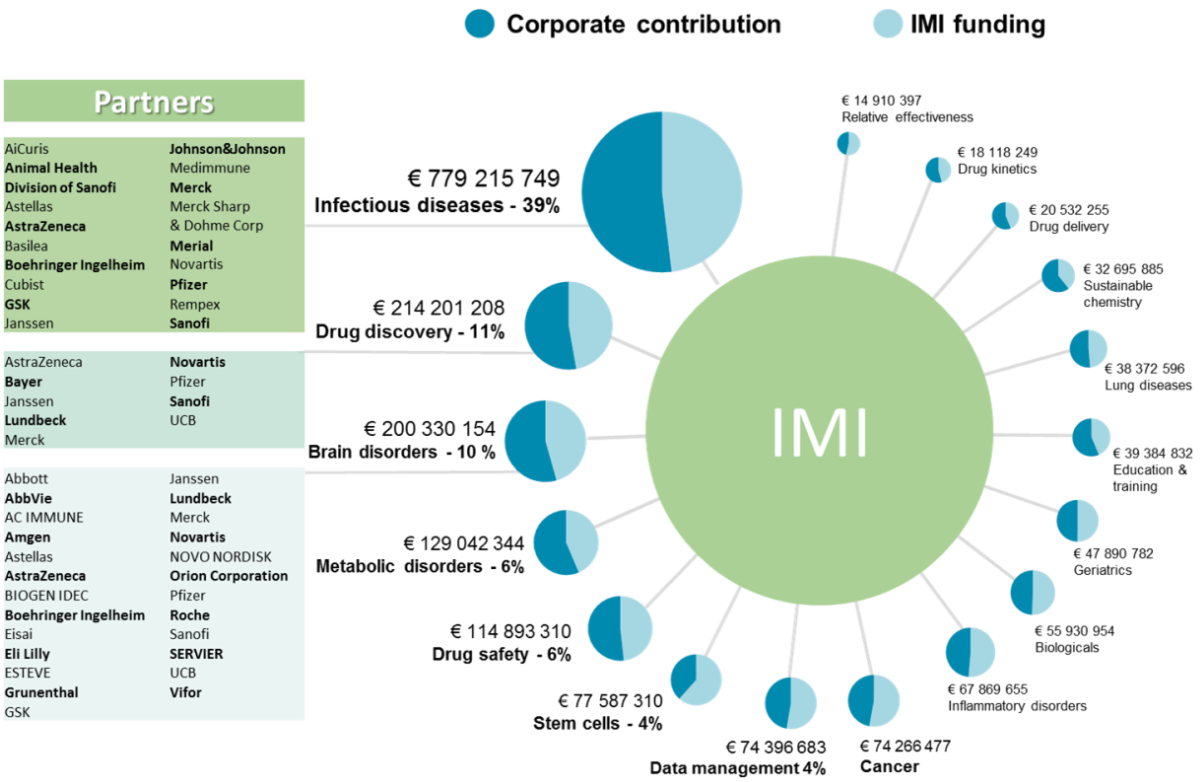
[1] Results from Thomson Reuters report from December 2014

Key Strategic Focus	Selected Key Performance Indicator (KPI)	2014 Target	Result
	KPI 16: Target to measure impact for patients	The methodology for capturing this information and baseline data for establishing the target will be determined with the European Commission in 2015	
Socio-economic impact	**KPI 17:** Target to measure the estimated number of reported jobs created since the start of IMI JU and that can be considered as directly related to the IMI JU programme	≥ 1 500	2 272 (based on PM declared in DoW)
	KPI 18: Target to measure additional impact on healthcare systems	The methodology for capturing the information and the baseline data for establishing the target will be determined in 2015	
Information, communication and dissemination	**KPI 19:** Target number of average monthly visitors to the IMI JU website	≥10 000	13 035
	KPI 20: Target to measure the performance of communication activities	The methodology for capturing the information and the baseline data for establishing the target will be determined in 2015	
Efficiency of the IMI Programme Office	**KPI 21:** Target timeframe for time to grant (TTG) of 240 days	≤240 days	123 days
	KPI 22: Annual budget execution target for commitment appropriations of running costs	≥95%	84.1%
	KPI 23: Annual budget execution target for commitment appropriations of operational costs	≥95%	92.7%
	KPI 24: Annual budget execution target for payment appropriations of operational costs	≥95%	74.1%
	KPI 25: Annual average time to pay (TTP) target for pre-financing payments to beneficiaries	≤30 days	7 days
	KPI 26: Annual **a**verage TTP target for interim payments to beneficiaries	≤90 days	71 days

1.2 Implementation of the Strategic Research Agenda

In 2014 IMI JU concluded its first phase with a total of 59 projects (as at 31.12.2014, 54 grant agreements had been signed and 5 were still under finalisation). A key mission and one of the main achievements of IMI JU has been to facilitate the mobilisation of stakeholders and the creation of the networks behind these projects. It is estimated that these projects currently involve more than 7 000 scientists.

The IMI JU portfolio of projects already signed or in the pipeline[2] reflects the implementation of the IMI JU Scientific Research Agenda (SRA) and comprehensively covers the full spectrum of the research & development (R&D) value chain as well as many key disease and interest areas[3].



2014 also marked the launch of the next phase of IMI JU - IMI 2 JU, with a larger budget of EUR 3.276 billion and an enlarged participation for all health sector industries, as well as to other relevant non-industrial actors, such as associated partners, who can be partners at an organisational or individual project level.

IMI 2 JU objectives are:

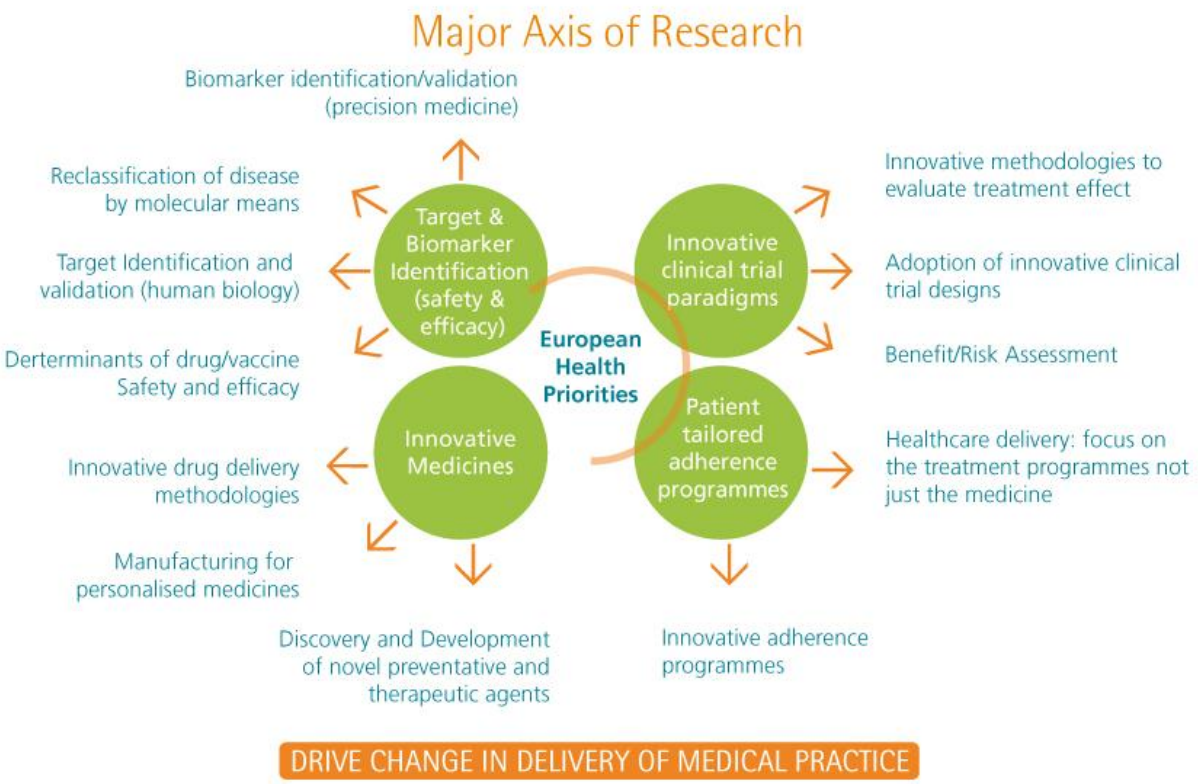
- to increase the success rate in clinical trials of priority medicines identified by the World Health Organisation(WHO);
- where possible, to reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;
- to develop new therapies for diseases for which there is a high unmet need, such as Alzheimer's disease and limited market incentives, such as antimicrobial resistance;
- to develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;

[2] This data is based on projects with signed grant agreements and those for which grant agreements are under preparation.

[3] The 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.

- to reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;
- to improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.

The activities of IMI 2 JU are defined by its Strategic Research Agenda[4] and will follow four major axes of research as indicated below:



IMI 2 JU officially started on 9 July 2014 and in 2014 launched four Calls for proposals, including the first Ebola+ Call for proposals, under a fast track one-stage procedure. The Ebola+ programme was created in response to the ongoing Ebola outbreak in western Africa.

1.3 IMI JU project output assessment

1.3.1 Bibliometric outputs

One of the traditional ways of measuring scientific output is via bibliometrics, which analyse how many scientific papers have been produced by a given group (in this case, IMI JU projects), what journals they were published in, and how often they have been cited by other researchers in subsequent publications. IMI JU conducts these analyses with the assistance of Thomson Reuters. The latest data is based on publications resulting from IMI JU projects up to 31 December 2014.

1134 PUBLICATIONS

9359 CITATIONS

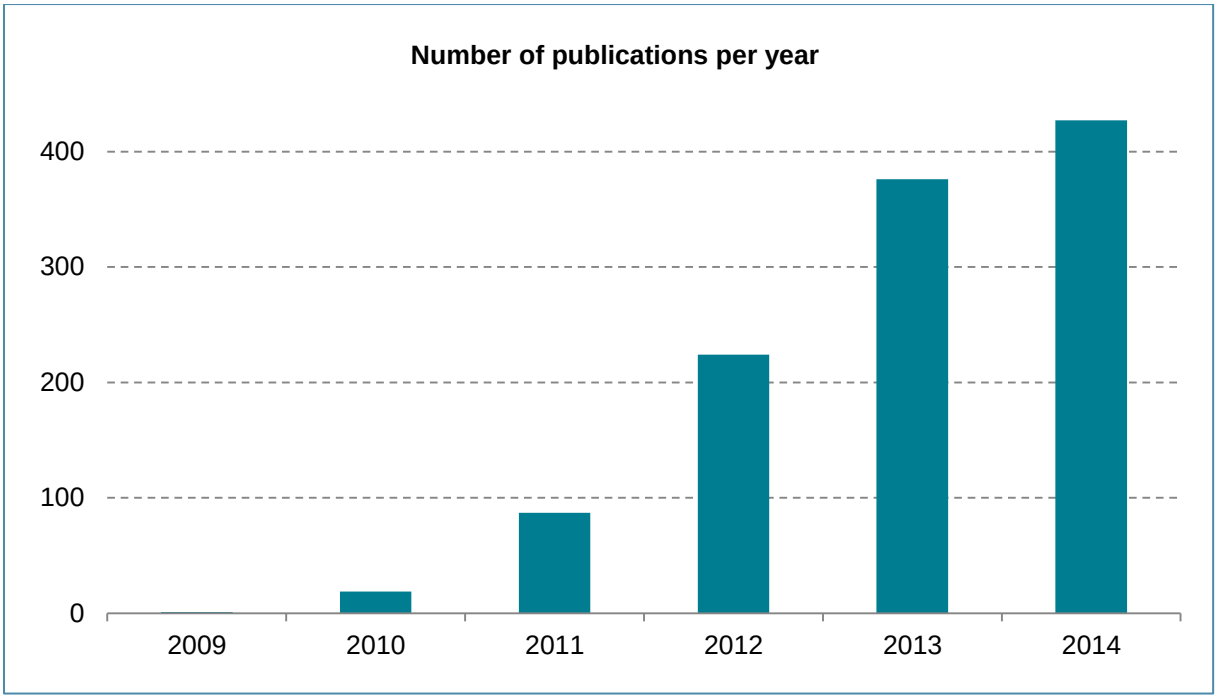
2.19 CITATION IMPACT vs. 1.10 EU average

24% HIGHLY CITED

[4] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_SRA_March2014.pdf

The results show that the overall volume of IMI JU project research output has increased rapidly since 2009 and the output continues to increase, as illustrated below. By 31 December 2014, IMI JU projects had produced 1 134 publications, half of which were published in 2013 and 2014.

It is expected that publication output will continue to rise as the number of active projects increases and those projects yield results for publication.

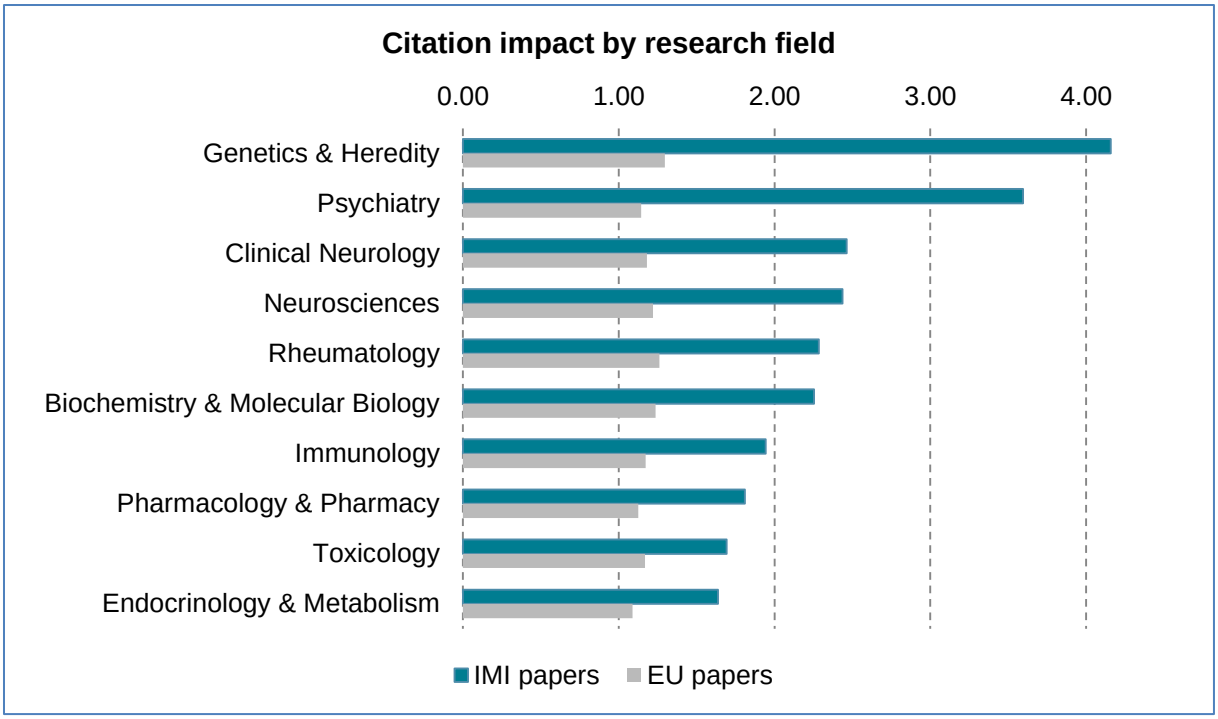


Source: Thomson Reuters analysis, 2015

IMI JU project publications have been found in a total of 473 journals, and 74% 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% of papers from IMI JU 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 6.09.

The citation impact of papers associated with IMI JU projects is internationally influential, with an average citation impact average of 2.19 for the five-year period from 2010 to 2014 (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 JU research has not only been maintained but has increased while output has grown. The EU's average citation impact relative to world baseline for the same four year period in similar research fields was 1.10.

IMI JU project research that is published in the fields of genetics and heredity, psychiatry, clinical neurology and neurosciences 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 '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, 2015

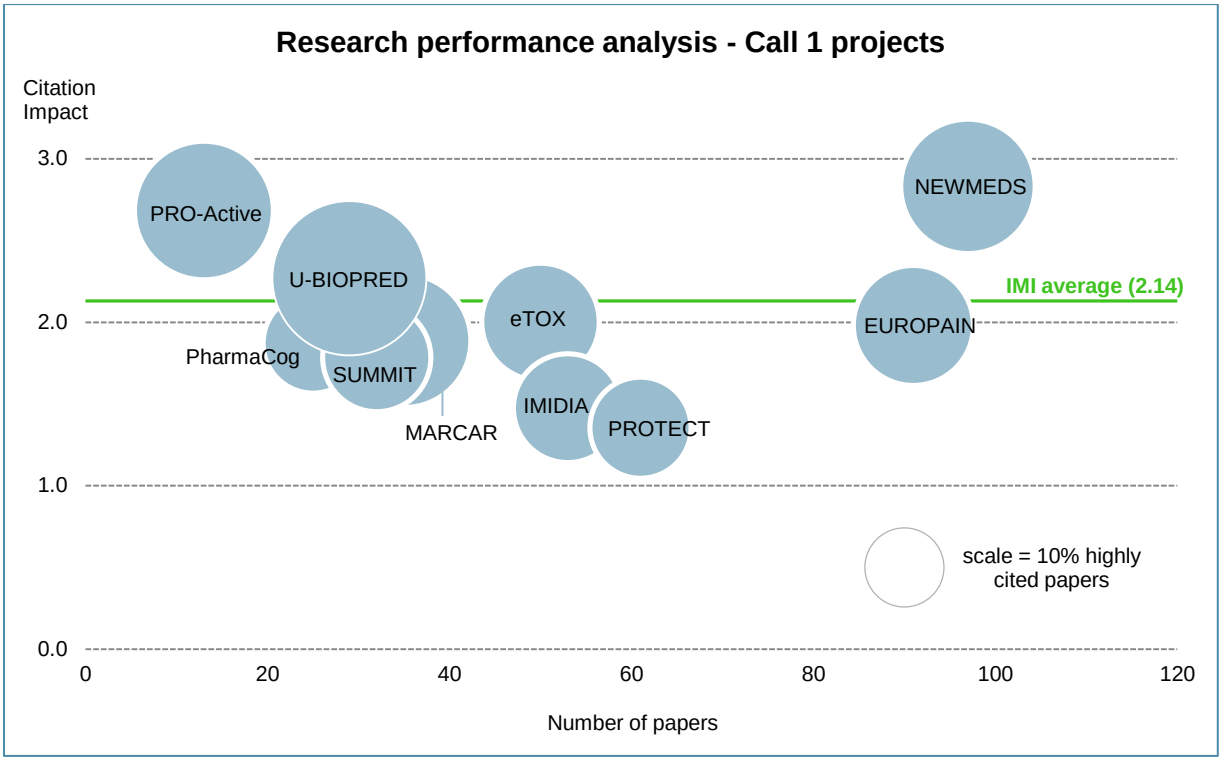
The number of papers, four-year average citation impact and share of highly-cited papers were analysed in order to compare the research performance of individual projects. Projects from IMI 1 JU Calls 1 to 4 with at least 10 publications during the time period 2010-2014 were included.

The most prolific projects Among projects from IMI 1 JU Call 1 in terms of publication outputs are EUROPAIN and NEWMEDS with more than 90 publications each. NEWMEDS is also the project with the highest average citation impact (2.83), followed by PRO-Active (2.68) and U-BIOPRED (2.27). U-BIOPRED is also the project with the highest percentile of highly cited papers (38%).

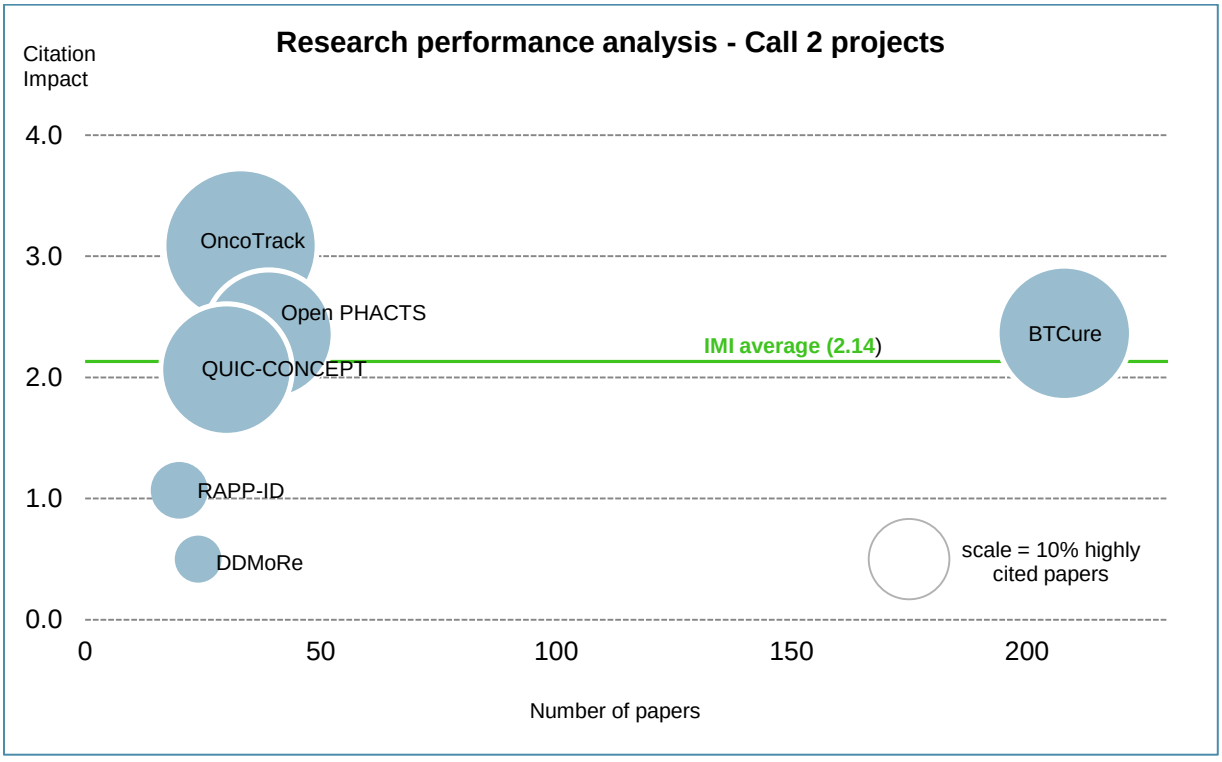
Overall so far, the most prolific project for output among projects from IMI 1 JU Call 2 is BTCure with 208 publications. The most highly cited project from this Call is OncoTrack (3.09), followed by BTCure (2.36) and OpenPHACTS (2.35).

The most prolific project among projects from IMI 1 JU Call 3 is EU-AIMS with 72 publications. This project is also most highly cited among all IMI JU projects with citation impact more than three times the world average (3.37), followed by DIRECT (3.15) and BioVacSafe (3.00).

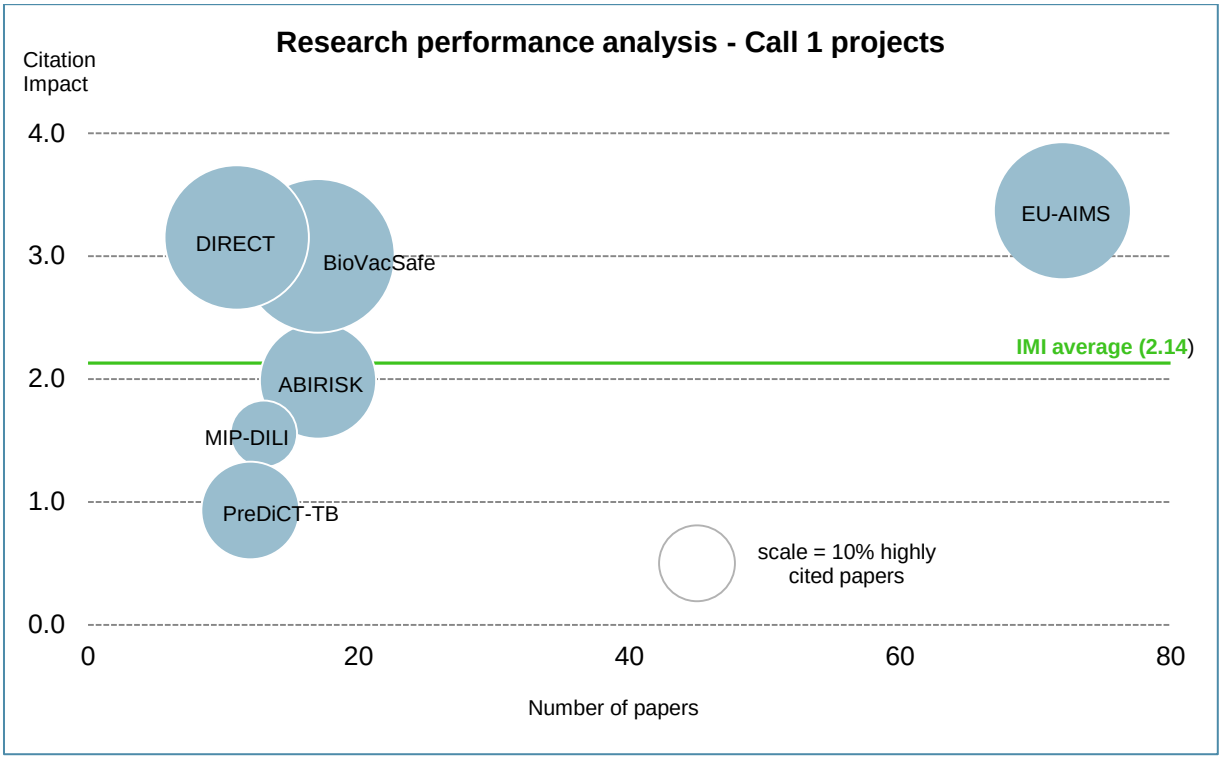
Projects from IMI 1 JU Call 4 are starting to accumulate publications. ORBITO has the most highly cited publications so far from this Call with citation impact at three times the world average (3.14).



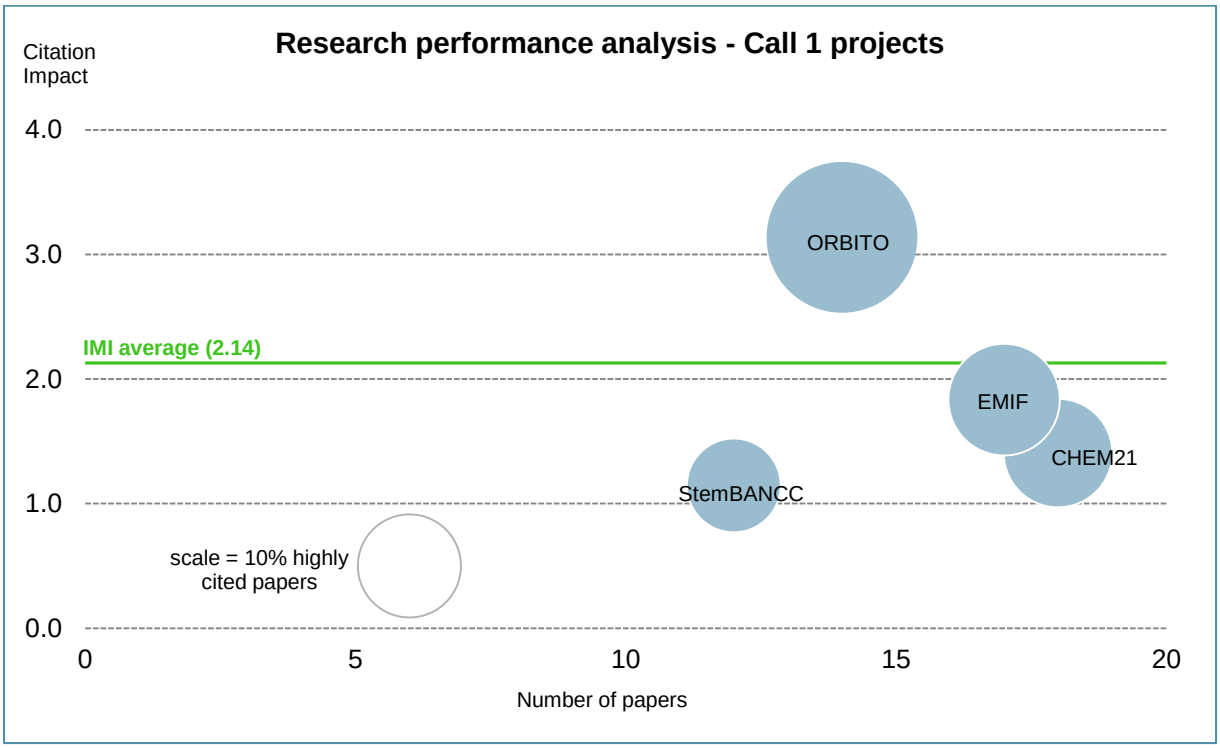
Source: Thomson Reuters analysis, 2015



Source: Thomson Reuters analysis, 2015



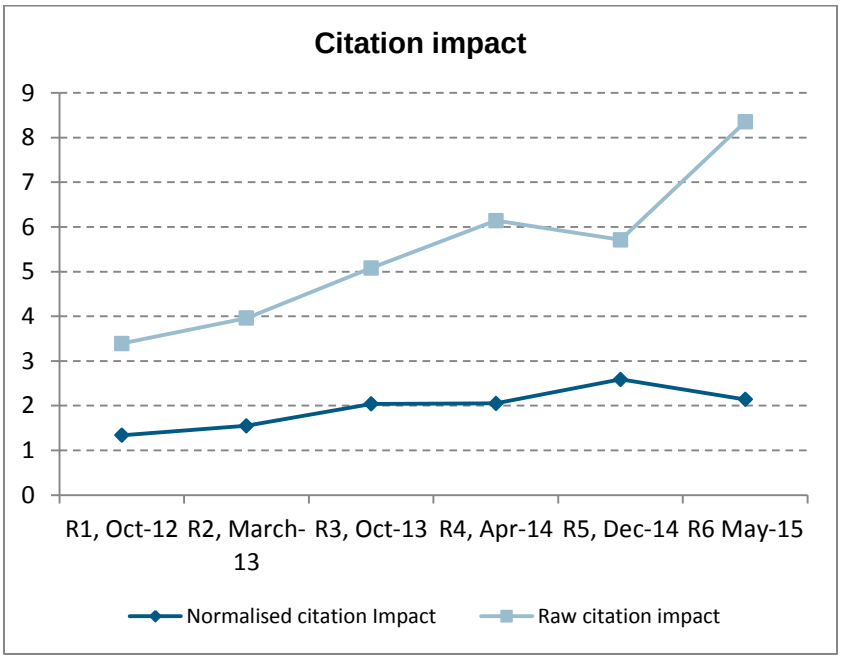
Source: Thomson Reuters analysis, 2015

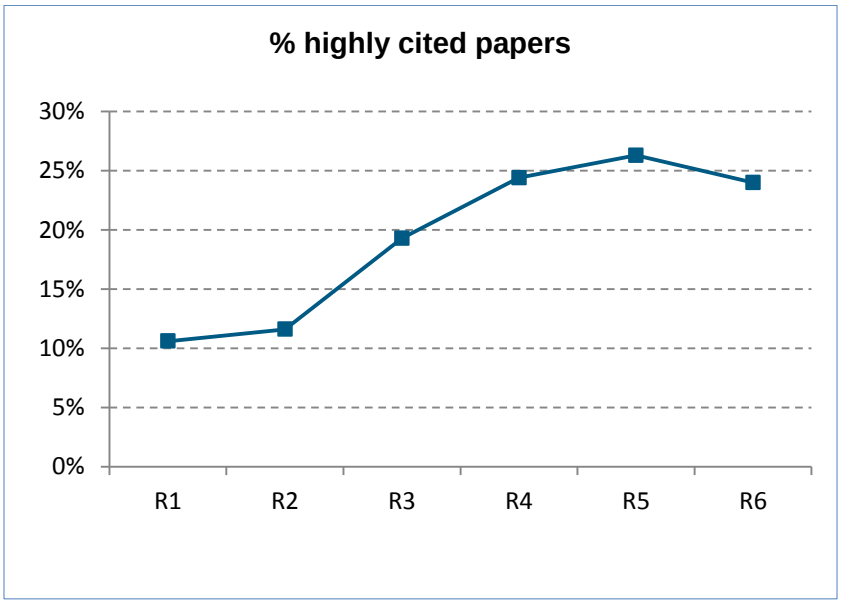


Source: Thomson Reuters analysis, 2015

Trends in the normalised citation impact and raw citation impact are analysed and presented in the graphs below.

The normalised citation impact is adjusted to take account of differences between research fields, whereas the raw citation impact does not take these into account. This demonstrates that the quality of IMI JU's work published by projects has increased significantly since the first report (R1) in October 2012, using citation impacts as an index, as well as the percentage of highly-cited papers.





1.3.2 Research and development related outputs

The R&D related outputs resulting from IMI JU's projects have been classified according to the following nine categories:

- identification and validation of new drug targets and novel hit and lead discovery;
- establishment of robust, validated tools for preclinical drug development;
- development of biomarkers and tools predictive of clinical outcomes (efficacy and safety);
- clinical trials - improved design and process;
- 'big data' solutions to leverage knowledge;
- implementation of data standards;
- impact on regulatory framework;
- implementation of project results inside industry;
- education and training for a new generation of R&D scientists.

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

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

- the table below lists the new developments that have taken place in 2014;
- earlier achievements are listed in the Annual Activity Reports 2012 and 2013.

Project	Area	Results description
Identification and validation of new drug targets and novel hit and lead discovery Listed achievements contribute to a better understanding of how disease biology is 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 and unique compound collections enabling the identification of new potent molecules that might lead to novel medicines for rare or neglected diseases.		
European Lead Factory	drug discovery	Delivered first results in the form of 4 'qualified hit lists' – lists of up to 50 compounds identified as showing activity against a drug target.
		Thanks to the access to one of the partners in European Lead Factory (ELF), the Netherlands Cancer Institute had fast-forwarded its oncology drug discovery work 'by several years'.
		As the first non-ELF partner, the Netherlands Translational Research Centre received a qualified hit list report in early November 2014. NTRC is also the first SME participating with a target programme in the European Lead Factory. They are now running a second programme hoping for access to unique and tractable chemotypes.
		ELF partner Edelris has synthesized 10 000 molecules. Together with academic partners, the University of Leeds and the Technical University of Denmark, they have set up a robust and efficient platform to steadily deliver a daily average of 50 innovative compounds of high 3D character. The teams are now embarking on the next 10 000 molecules.

		Library status at December 2014: 290 selected ideas/ 98 validated; 38 187 compounds from public ideas; 326 486 compounds from private partners.
		Recruitment of targets at December 2014: 58 EFPIA target programmes planned; 78 public target proposals received; 34 public target proposals accepted.
EMIF	knowledge management	Identification of family history of type 2 diabetes as a significant risk factor of both becoming overweight or obese and of having greater susceptibility to the negative consequences of increasing body fat.
ENABLE	infectious diseases	Novel antibiotic hit molecules are progressing towards the clinic. Currently ongoing 2 hit-to-lead programmes and one lead-to-clinical candidate programme.
EU-AIMS	autism	Identification, by using human iPS cells and transgenic animal models, of new gene pathways in animals and humans, and of mechanisms that may explain how genetic and environmental factors of autism interact.
NEWMEDS	schizophrenia depression	Significant contribution to the unravelling of the pharmacology of NMDA-Receptor antagonists and the neurobiological basis of schizophrenia symptoms to support the development of new antipsychotic drugs.
PREDICT-TB	tuberculosis	Major progress in completing the first truly systematic review of historical and modern first-line regimens against tuberculosis. This achievement will in future clearly define the target space for preclinical systems and highlight important gaps in existing evidence of clinical efficacy.
SUMMIT	diabetes cardiovascular complications	Completed a dynamic Bayesian molecular network model of type 1 diabetes (T1D) complications to guide future drug discovery.
		Identified a genetic region that is associated both with cardiovascular risk and biomarker levels suggesting a novel pathway for those complications in type 2 diabetes (T2D).
		A patent has been filed on biomarkers panels predictive of diabetes nephropathy progression.
		Using the unique SUMMIT database of aggregated GWAS scans on >10 000 individuals several novel genome-wide significant associations of genetic *loci* with metabolic biomarkers have been discovered. These have been independently replicated in up to 12 467 individuals.

Project	Area	Results description
Establishment of robust validated models and tools for drug discovery & development Listed achievements contribute to speeding up the development of new medicines by providing improved tools that more precisely predict whether any given candidate molecule will be effective in patients before they have progressed into clinical development. The tools include unique *in vitro* or animal models that reproduce the patient reality more closely, using non-invasive imaging techniques, as well as computer models that allow efficacy prediction without the need to expose the patients and animals to test compounds.		
STEMBANCC	stem cells	Produced and distributed first reference iPS cells.
		Established and patented the podocyte differentiation protocol.
		Generated nociceptive neurons and optimized protocol to generate cortical glutamatergic and mid-brain dopaminergic neurons. The project led to material transfer agreement/s (MTAs) between many consortium participants. Several training sessions have been organised between partners.
EBiSC	stem cells	Standard operating procedures were established for the procurement of biological specimens, the generation of human stem cells and their characterisation & qualification for prior to bio-banking.
		Around 400 cell lines have been deposited and are available in the IPS centre participating consortium to the central facility. Lines include healthy donors, autism spectrum disorder, long QT Syndrome, Huntington's, Alzheimer's, *Retinitis pigmentosa*, chronic granulomatous disease, acquired aplastic anaemia.
EU-AIMS	autism	Developed a new protocol to collect, freeze and bank a large number of samples from patients and healthy individuals for future production of iPS cells.
		Successful characterisation by endophenotypes of several animal models of autism (including NLGN3, CNTNAP2, and SHANK3 mutations) using multimodal MRI, showing for the first time distinct changes in neural activity in brain regions consistently related to autism-associated behavioural deficits.
		Several new mice and rat transgenic models for example, NRXN1and NLGN3 have been produced on a harmonised genetic background and are made available to the consortium via a common repository.
		Establishment and validation of a set of reproducible behavioural assays (including touch screen tests) to assess in rodents behavioural aspects relevant to the autism phenotype.
EUROPAIN	chronic pain	Development and pharmacological validation of four new translational animal pain models.

		Development of a human hypersensitivity model based on total sleep deprivation (TSD).
		Use of *in vivo* electrophysiology of peripheral nerve using microneurography to obtain objective measures of spontaneous pain in humans, (both experimental models and in patients) and in animal models.
		Validation of RNA-seq as a transcriptomics method more efficient, faster, and cheaper than current gold standard microarrays.
		Generation of transgenic mice with SCN9a mutation causing a persistent pain state in humans.
		Across laboratories validation of the burrowing deficit and of the elevated maze models as validated endpoints for assessing spontaneous pain behaviour in rodents.
		Fully comprehensive characterisation of inflammatory pain model induced by UVB irradiation in both rodents and human volunteers.
IMIDIA	diabetes	Standardised protocol for preparation of human islets.
NEWMEDS	schizophrenia depression	Validation of the circuit-based approach, linking imaging and electrophysiology and demonstration that some circuits represent weak points in psychiatric disorders.
		Development and validation of PCP-induced deficits in murine nest building activity as an ethological rodent behaviour to mimic negative-like symptoms of schizophrenia.
		Full phenotypic characterization of a mouse model that recapitulates cardinal features of the 15q13.3 microdeletion syndrome.
		Validation of cross-species neurochemical imaging using PET and micro-PET with a focus on transmitter release and modulation.
		Produced a user-friendly machine learning package purpose-built for application to drug discovery and demonstrated its utility in studying the spatiotemporal profile of *in vivo* cerebral blood flow changes following intra-nasal Oxytocin in humans.
PHARMACOG	Alzheimer's	Accomplished a systematic evaluation of the *in vitro*, *ex vivo* and *in vivo* PK/PD relationship of each of the four available gold standard Alzheimer's symptomatic drugs in order to recommend clinically-relevant, translational doses for future preclinical studies.
		Pharmacological validation of sleep deprivation (SD)-induced memory impairment in young and old octodons.
		Development of neuroimaging biomarkers as surrogate outcomes homologous in animals and humans.

PREDICT-TB	tuberculosis	Practical implementation of novel approaches to design and analysis of *in vivo* PK and PD experiments by cross-institutional teams of experimentalists and modellers. These initial experiments have demonstrated the informational and ethical advances that can be achieved using this approach.
		Successful development of a number of key enabling technologies, particularly expanded applications of the 16s rRNA assays, novel reporter strains for key mycobacterial functions *in vitro*, microfluidic devices supporting dynamic exposures of multiple drugs and small format CT systems for *in vivo* imaging.
PROactive	COPD	Developed an innovative conceptual framework on the physical activity as experienced by patients.
SUMMIT	diabetes cardiovascular complications	Successfully applied novel PET-markers to study atherosclerotic plaque inflammation, and intervention effects on atherosclerotic plaque inflammation in preclinical *in vivo* models.
U-BIOPRED	asthma	Established a validated clinical rhinovirus challenge model for asthma exacerbation. First part of the virus challenge study, the Safety/Dose escalation component, is almost complete and the second part which is the main virus challenge biomarker study is under preparation.

Project	Area	Results description
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 patients, 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 techniques 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.		
EMIF	knowledge management	Identified by a systematic metabolomics approach in a longitudinal clinical study, alterations of serum metabolites that are either reversible or not reversible in obese children before and after weight loss due to lifestyle intervention.
		Identified 10 plasma proteins strongly associated with disease severity and disease progression from the results of the largest to date (n =1148) multicentre validation study of plasma biomarkers predictive of conversion from mild cognitive impairment to Alzheimer's disease.
EU AIMS	autism	Development and extensive validation (including test-retest reliability) of a set of reliable fMRI tests for core cognitive deficit domains of autism (theory of mind, executive function, social. non-social reward processing, emotion processing). SOP for analysis delivered to partners.
		Developed guidelines and best practices for electrophysiological data collection, analysis and reporting in autism.
		Identification of a list of biomarkers which are used in the clinical studies to gather data for their qualification for stratification of autism patients.
		To facilitate validation of EU AIMS biomarker methodologies by external replication, the Foundation for the National Institute of Health (fNIH) required applicants to include some of its eye-tracking and EEG tasks in one of their recent funding Calls.
NEWMEDS	schizophrenia depression	Demonstrated that C-reactive protein (CRP), a commonly available marker of systemic inflammation, predicts differential response to SSRI vs. noradrenergic antidepressants, suggesting that easily obtained demographic, clinical variables and biomarkers can predict response to antidepressants with clinically meaningful effect size.

Project	Area	Results description
		Demonstration of reliable (test-retest), standardised set of fMRI tests for early phase drug development, including evidence for heritability (familiarity) of these robust readouts, enabling use in imaging genetics.
		Demonstration of dose-dependent copy number variation effect in human structural MRI.
		Validation of 11C-ORM-13070 as a PET tracer for α2C-adrenoceptors in the human brain.
		Identification of plasticity markers in joint EEG-fMRI paradigms and extraction of robust EEG parameters linked to these.
PHARMACOG	Alzheimer's disease	WP5 European ADNI study: 147 mildly cognitively impaired patients have completed baseline evaluation with the PHARMACOG biomarker matrix. 101 patients are still participating and 9 patients have completed the study entirely.
PROactive	COPD	Five clinical trials of various types initiated led by academic or industry partners using the PROactive Patient Reported Outcomes' tools (either the PRO for daily use and/or the PRO for clinical visits). These trials include pharmacological interventions as well as physical activity coaching interventions and pulmonary rehabilitation interventions) will generate the necessary data for the validation of the PRO tools.
SUMMIT	diabetes	Identified new biomarkers of tissue-remodelling demonstrating significant association with both cardiovascular disease and atherosclerosis burden in T2D.
		Novel findings in a prospective study implicate elevated renin plasma levels as a potential biomarker for development of vascular complications in T2D.
		The development of a novel Optical Coherence Tomography (OCT) method and successful standardization of different OCT devices allowed for standardisation in multi-centre clinical trials and the identification of association between regional differences in macula thickness and retinopathy.
		The novel ultrasound-based plaque structure analysis (UPSA) has been fully validated. The UPSA has been used in at least two new Swedish prospective cohort studies.

Project	Area	Results description
SAFE-T	safety	Diagnostic criteria of renal tubular injury and progression of or adaptation to drug-induced hepatocellular injury may be modified based on readouts of new safety biomarkers.
		Demonstrated that a panel of 20 selected biomarkers discriminates healthy volunteers from patients with vascular injury. In addition, the biomarker panel can be used to discriminate patients in the acute and dormant stages of disease.
MARCAR	safety	New molecular pathologies for drug exposure and tumour phenotypes have been identified by the project.
RAPP-ID	infectious diseases	Some first-stage diagnostic prototypes and semi-integrated chips ready for further testing, iteration and continued integration. Efforts will focus on a breath based rapid influenza test, a bacterial community-acquired-lower respiratory tract infections (CA-LRTI) test and a molecular ventilated acquired pneumonia (VAP test).
BTCure	rheumatoid arthritis	BTCure has defined new subsets of rheumatoid arthritis patients based on the analysed biomarkers.
		Thanks to the scientific evidence delivered by the BTCure, life style factors are now taken into account when predicting rheumatoid arthritis treatment outcome.
QuIC-ConCePT	cancer	Multicentre protocols have been developed for implementation of the FLT and ADC imaging biomarkers. This is being done partly in collaboration with US partner (QIBA PDF) under a memorandum of understanding.
		The project is finalising the imaging biomarker roadmap.
U-BIOPRED	asthma	Completed the clinical cross-sectional and longitudinal studies (1 029 study participants across 4 adult and 4 paediatric cohorts) with closure of longitudinal visits of the severe asthma study participants in the asthma cohorts returning for their visit (in total 517) and exacerbation visits, CT scans and telemonitoring data captured in the adult asthma cohorts. These are the largest most well-characterised severe asthma adult and paediatric cohorts. These datasets will help define bio-clinical phenotypes of severe asthma as well as generating the final ‘handprint’.
		Biobank completed by the addition of longitudinal and exacerbation samples. Sample numbers for U-BIOPRED (e.g. blood, sputum, breath samples, brushing and biopsy samples from the bronchoscopies) are >100 000 aliquots including those that have been created from processing samples for analysis.

Project	Area	Results description
ABIRISK	bio-pharmaceuticals	Developed a set of terms and definitions for describing and interpreting unwanted immunogenicity of biopharmaceuticals.
COMPACT	drug delivery	Research tools have been developed that enable qualitative and semi-quantitative monitoring of therapeutic peptides and proteins delivery into the cell.
DIRECT	diabetes	GLP-1 assay development successfully achieved and first interim analysis performed on 27 samples.
		The first draft list of biomarker candidates for proteomic and metabolomic analysis has been completed.

Project	Area	Results description
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 utilising of healthcare records or creating well-characterised patient registries, to focus clinical trials on more precisely characterised patient population.		
EMIF	knowledge management	27 AD cohorts have been fully fingerprinted and have been made available in the EMIF browser.
EUROPAIN	chronic pain	Insight on factors influencing the placebo response in randomized clinical trials (RCTs) by meta-analysis of placebo data of nine 12-week parallel randomized double-blinded RCTs on chronic nociceptive pain.
		A breast cancer treatment specific functional outcome assessment tool has been validated based on deeper understanding of its specific mechanisms and of the important role of surgical technique for the development of persistent postoperative pain.
		Demonstration that hypersensitive patients with neuropathic pain and remaining nociceptor function are more prone to respond to treatment than patients with pronounced loss of function.
EU AIMS	autism	Creation of a clinical research network in autism which currently consists of 75 sites spread across 37 European countries and covering nearly 15 000 patient visits per year.
		Started recruitment and deep phenotypical assessment of the EU-AIMS Longitudinal European Autism Project (LEAP), including approximately N=400 participants with autism and N=250 control participants aged 6-30 years.
		Started a new study with patients with Phelan McDermid Syndrome (SHANK 3 deletion) applying a similar protocol as in the other EU AIMS clinical research studies and in alignment with ongoing US PMS networks.
		Started the EU-AIMS Infant at risk study that prospectively investigates 300 infants at high genetic risk (by virtue of having an older sibling with autism) and 100 low-risk infants at 5, 9, 12, 24 to 36 months including testing with an extensive phenotyping battery.
		Signed legal agreements with several other autism consortia world-wide to facilitate data sharing, pooling and replication. This includes the Chinese Key 973 program (Nanjing), the Australian Cooperative Research Centres (CRC) and the Province of Ontario Neurodevelopmental Disorders (PONDS) network.

		Recruited 188 ‘healthy control’ carriers of copy number variations (or point mutations) in regions or genes linked to autism, schizophrenia and other neurodevelopmental disorders. These individuals will be fully phenotyped using an extensive battery of neurocognitive test, questionnaires and structural and functional MRI in alignment with phenotyping in the Longitudinal European Autism Project (LEAP).
		Determination by magnetic resonance imaging (MRI) scans of both healthy adults and adults with high-functioning autism that autism affects different parts of the brain in males and females. The findings suggest that researchers should stratify their results by gender and avoid assuming that results found in males also apply to females.
BTCure	rheumatoid arthritis	Developed biomarkers for patient stratification in rheumatoid arthritis to define which patients to include in clinical studies.
		BTCure has led to new clinical practice in early rheumatoid arthritis, including personalised therapy and lifestyle advice.
EH4CR	knowledge management	Implementation of platform services for patient identification and recruitment helping streamline clinical research.
ND4BB - COMBACTE	antibiotics	Setting up of 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). More than 300 clinical sites in 37 countries already candidates for joining CLIN-Net. Training programme developed for both CLIN-NET (GCP) and LAB-NET. First participants finished the web-based GCP training and obtained CLIN-NET GCP accredited certificate. Site/Laboratory capability survey prepared and rolled-out.
		First patient was randomised and dosed at a Belgian site for the phase 2 trial with MEDI4893, a monoclonal antibody from MedImmune/ AstraZeneca. A total of 462 patients are expected to be enrolled across approximately 80 sites in Europe. Study protocol, site selection, regulatory approval, and initiating study sites have been completed.
NEWMEDS	schizophrenia depression	Developed the DUPCHECK tool which is a web-based tool to screen for duplicate patients in clinical trials within and across studies, sponsors and therapeutic areas. Even a small number of duplicate patients can lead to a negative or failed trial and enrolling duplicate patients could result in an adverse event being attributed to the wrong trial. DUPCHECK provides a solution for this problem.
		Developed a new proof of concept trial design combining pharmacological and cognitive interventions that is robust and feasible, with high power through repeated measures.

		Companies have agreed for research use of the NEWMEDS database of 25 900 patients from antipsychotic RCTs and 12 217 patients from antidepressant RCTs beyond the end of the NEWMEDS project.
BioVacSafe	vaccines	New clinical trial designed based on the project results.
DDMORE	knowledge management	Developed clinical trial simulator (2nd release) and model-based adaptive trial optimal design tool (1st release).

Project	Area	Results description
‘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.		
eTOX	knowledge management safety	Developed a new ontology for histopathological findings. The project has also defined and applied standards for the development, documentation and assessment of the predictive models developed. The data extraction methodology and flows for pre-competitive sharing can be leveraged as best practice by other initiatives.
		Collaboration was established between the eTOX consortium and the EFPIA working group aiming at using the eTOX database for sharing of data from pre-clinical studies.
ORBITO	drug delivery	Delivered the first version of the Orbito database with historical pharmacokinetics data and associated meta data, including 86 compounds, whereof a majority represents modern drug development, with *in vivo* data sets from almost 500 studies.
EHR4CR	knowledge management	Contributed strongly to the development of a data reuse code, led by Sanofi, originally for EHR4CR but now broadened to IMI-wide promotion as best practice.
EMIF	knowledge management	Developed data hierarchies for Alzheimer’s disease cohorts – leveraged by the IMI project EPAD and the UK Dementia Platform.
		Data upload in tranSMART completed for the first 5 AD cohorts, including full curation and harmonisation of individual patient data to create a single integrated virtual cohort.
		Developed a methodology and a software able to aggregate information for monitoring the productivity, efficiency of digital medical imaging, and some metrics of patient’s safety, to allow benchmarking and quality assurance in medical institutions and medical imaging centres.
		Developed an ontology-based medical imaging archive that provides a generic, dynamic and standard architecture to interrogate the repository and improves searching results without any changes in the software implementation.

eTRIKS	knowledge management	To date 35 deployments of tranSMART are known including 5 in pharmaceutical companies creating a powerful network of open bioinformatics nodes. Developers from eTRIKS contributed significantly to the development of the fully open source tranSMART1.1 eliminating expensive license fees. eTRIKS also established a public version of the platform eTRIKS1.1.1 allowing exploratory analyses of open access data from 22 subject-level translational studies and aggregated summary results from 1 400 Gene Expression Atlas studies.
		Contributed to the release of a new version of the 'tranSMART' translational research data warehouse. 5 distinct software branches were consolidated to enable critical functionality required for supporting IMI JU projects, including Oncotrack and ABIRISK. Several new data types, enhanced user experience and extended programmatic access to tranSMART are among the key features delivered.
		Established tailor made engagement models that differentiates in the level of partnership (from high level service partnerships to light support). This flexible model has allowed eTRIKS to positively impact a growing number of clients.
		eTRIKS extended the analytic capabilities offered to clients by integrating the XNAT (imaging) and Galaxy (omics) tools with the eTRIKS platform.
DDMoRe	knowledge management	Developed and released to public a drug/disease model library containing 13 drug/disease reference models fully expressed in the human (MDL) and machine readable (PharmML) modelling language standards. It allows the re-use of pharmacokinetic drug /disease models and simulate outcome in the context of new data parameters thus informing quantitative decision making.
		Developed first automated translator from the human readable standard (MDL) to the machine readable code (PharmML), and execution with a key modelling and simulation software (Monolix). The translator was deployed within the framework and accessed using the DDMoRe R package, permitting the development of complex pharmcometric workflows.
Open PHACTS	knowledge management	Launched a new version of its drug discovery platform ensuring the long-term financial and technical viability of the infrastructure created so far.

		The Open PHACTS Discovery Platform now also covers data pertaining to tissue expression and diseases. The Open PHACTS datasets are highly heterogeneous covering many types of quantitative experimental data measurements to diverse annotations about proteins and chemicals. There are over 3 billion triples from 12 different data sets. Additionally, the data entities are mapped to a wide variety of identifiers from other data sources. It contains over 100 million mappings to 49 different datasets. The scientific facts on compounds, targets, pathways, tissues, and diseases from multiple public data sources allow medicinal chemists and computational scientists easy access to this wide variety of information from a single entry point.
PHARMACOG	Alzheimer's	Established Pharmacog-xnat, a neuroscience imaging repository to be used to consolidate MRI & PET imaging files into a centralized database system. It also has the capability of storing associated information such as that coming out of EEG sessions, neuropsychological assessments, biological analysis and demographics questionnaires.
UBIOPRED	asthma	All clinical data sets are being curated and uploaded into upload into tranSMART (eTRIKS) with the process for the baseline data almost complete and with the longitudinal data cleaning ongoing. It is novel for studies of this type and no other cohort study of this size has had this level of quality control implemented.
PREDICT TB	tuberculosis	Completion and initial evaluation by external partners of a draft data-sharing framework for individual patient data comprehensively addressing key issues including data standards, privacy and re-use. This initiative is leading the field in crystallising a practical and viable approach to long-term sharing and curation of clinical trial data in TB.

Project	Area	Results description
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	Published the 'Standards Starter Pack' based on Clinical Data Interchange Standards Consortium (CDISC) standards to accelerate the incorporation of new data into eTRIKS and to promote cross study data use. Published appropriate use guidelines for patient data to be applied to eTRIKS engagements.
BioVacSafe	vaccines	All clinical data are collected with CDSIC standards.
Safe-T	drug safety	Clinical data is mapped to CDISC standards during the data management process.
EMIF	Alzheimer's disease	Preparing suggested extensions to CDISC for the AD cohorts.
PreDiCT-TB	tuberculosis	The PreDiCT-TB clinical trials database is mapping datasets to CDISC standards and has offered additional data items for inclusion in the TB-specific standard.
EHR4CR	knowledge management	CDISC is a partner in the consortium, and has worked closely with the semantic interoperability work package. CDISC standards have been used within the semantic broker.
eTOX	knowledge management safety	Working towards compatibility between eTOX and SEND. Some standards developed within eTOX are shared now with CDISC.
IMIDIA	diabetes	Implementing System Biology Data format (RDF) at SIB compatible with CDISC.
U-BIOPRED	asthma	The project is formally connected to CDISC via eTRIKS and has taken the CDISC standards into account.
OncoTrack	cancer	CDISC standards are used in the collaboration with eTRIKS.
BTCure	rheumatoid arthritis	Created standards for sharing of data and samples between the groups. Their Standard Operating Procedures (SOPs) will be published soon.
DDMoRe	knowledge management	Annotations of the models stored in the DDMoRe model repository will be using the CDISC controlled terminology.
AETIONOMY	Alzheimer's disease	Is developing the NDD-CTO, the clinical trial ontology for neurodegenerative disease trials, which comprises CDISC concepts and links to CDISC.

PRECISESADS		Will use CDISC SDTM to store clinical data collected through the e-CRF hosted by SERVIER.
EUROPAIN	chronic pain	Development of a European certification process that sets the gold standard for quantitative sensory testing (QST) to be used in clinical trials for new chronic pain therapies across the EU.
DIRECT	diabetes	The infrastructure of the data warehouse has further been developed and additional tools for data mining and modelling have been installed.
		Validated standard operating procedures for the preparation of prospective study samples have been delivered.

Project	Area	Results description
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 procedure on the patient reported tools (PRO) completed at EMA.
EU-AIMS	Autism	Qualification advice procedure completed from the EMA for the biomarker approaches and methodologies used in the Longitudinal European Autism Project. Also informal discussions between EU-AIMS and the NIMH and FDA have started.
eTOX	drug safety	Discussions with EMA about potential future use of the eTOX system and system compatibility with the CDISC SEND initiative. Initiation of a regulatory dialogue regarding qualification of *in silico* models through EMA's Innovation Task Force (ITF).
MARCAR	cancer	The project may contribute to the enhancement of preclinical carcinogenicity testing strategies in the context of recently proposed changes to the ICH S1 guidance on Rodent Carcinogenicity Testing of Pharmaceuticals.
Safe-T	drug safety	Scientific advice has been obtained twice from EMA and FDA during the project working towards a final submission for qualification.
DDMORE	knowledge management	DDMoRe and the International Society of Pharmacometrics jointly commented on EMA Policy 0070 ‘Publication and access to clinical-trial data' identifying key aspects of data that will allow relevant and proper modelling analyses to benefit patients.
		In June 2014 members of the modelling review group met with EMA at the Population Approach Group in Europe (PAGE) meeting 2014. A first interest in the generic qualification procedure was raised. The EMA advised their point of view on the plan which provided useful insights on how to best engage with them and to utilise project outputs.
MIP-DILI	safety	The project has started an informal dialogue with regulators to discuss the overall MIP-DILI strategy to obtain guidance on how to obtain regulatory acceptance of testing strategies and use for human risk assessment of liver injury.

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.

Project	Area	Results description
European Lead Factory	drug discovery	Partner pharmaceutical company UCB stated that access to the 300 000 joint European compound collection of ELF had provided them with a list of 'highly interesting' compounds that would allow it to take a fresh look at a particularly challenging drug target. They publicised this result in an ELF press release.
IMIDIA	diabetes	ß-cell lines are licensed to multiple industry partners.
DDMORE	knowledge management	9 EFPIA partners are involved in building the new models for the DDMoRe repository. 5 EFPIA partners are receptive to implementing the model repository, the interoperability framework or both.
eTRIKS	knowledge management	TranSMART 1.2 platform is being deployed by several commercial entities. Pfizer expects deployment in February 2015 and Sanofi plans deployment in 2015. Data curation suppliers including Thomson Reuters and Rancho Biosciences are deploying Version 1.2 on behalf of their customers.
EUROPAIN	chronic pain	Burrowing deficit and hypersensitivity pain models, electrophysiology–threshold tracking, and microneurography methods developed by the consortium have been implemented by the industrial partners for internal R&D projects.
eTOX	knowledge management safety	Prototypes of eTOXsys have been deployed in participating EFPIA companies.
		The unprecedented levels of data sharing between public and private partners in the project has resulted in the launch of a rich preclinical database (eTOXdb) and a new *in silico* toxicology prediction system (eTOXsys), which will significantly improve the capability to predict the safety of new medicines and play a direct role in reducing attrition rates.
PREDICT TB	tuberculosis	Successful technology transfer of some novel technology systems developed by public partners and their embedding in in-house activities of industry partners.
PROactive	COPD	Patient reported outcomes (PRO) developed in the project are being used in several EFPIA trials.
PREDECT	cancer	Protocols to prepare and use cancer slices and some three-dimensional models have been incorporated in pre-clinical studies.

Open PHACTS	knowledge management	The Open PHACTS Discovery Platform is now available permanently open and is being used by academia as well as EFPIA, e.g. Janssen, GlaxoSmithKline (GSK) or Roche.
		In June 2014, the Open PHACTS Foundation announced its first three members – GSK, Janssen and Roche. A core developer team is now responsible for maintaining and enhancing the Open PHACTS Application Programming Interface (API).
OncoTrack	cancer	Xenograft tumour models established by the partner EPO GmbH are being used in drug screening activities by one or more of the EFPIA partners of OncoTrack.
QuIC-ConCePT	cancer	PTtheranostics has been formed to create a sustainable platform for Radiomics (partly developed under QuIC-ConCePT).
BTCure	rheumatoid arthritis	Several clinical trials are on-going with patients included based on BTCure's development of biomarkers in early RA.
SAFE-T	safety	Assays measuring newly qualified safety biomarkers will be commercialised by some consortium beneficiaries and may be made available also for clinical practice in the future.
OrBiTo	drug delivery	Access to all EFPIA partners to project databases which can aid internal development decisions.
Chem21	chemistry	Optimised the process of direct fluorination of cytosine by elemental fluorine on a small scale and now Sanofi is exploring industrialisation of this process for the production of flucytosine for the treatment of fungal infections.
		Developed a range of synthetic biology tools (biocatalysts, promoters etc.) for assembly into pharma manufacturing Synthetic Biology methodologies.
EHR4CR	knowledge management	The EHR4CR platform components and services are being taken up by an SME partner on behalf of the consortium for commercial exploitation. As a result, an early adoption of EHR4CR value-added solutions by pharmaceutical industry (and contract research organisations (CROs) is expected.
		The project will provide new business opportunities to many stakeholders, including service providers and CROs who will be able to expand their business portfolios from respectively providing and adopting EHR4CR value-added solutions.

Project	Area	Results description
Education and Training (E&T) for new generation R&D scientists IMI education and training (E&T) programmes are meant to address the gaps in the required biomedical research and development expertise by training new generations of highly qualified individuals that strengthens the position of the European scientific community in the global drug research arena.		
EMTRAIN	E&T networking	Competency profiles and competency portfolios are being introduced in the biomedical science community. The IMI Education and Training Quality Standards have been developed, published and implemented in the on-course® database.
		The IMI JU's education and training projects launched their new pan-European framework for continuing professional development in the biomedical sciences. The LifeTrain framework will enable biomedical professionals to work collaboratively across disciplines and national boundaries. Furthermore, LifeTrain's unique collaborative approach aims to provide the critical mass to make a major contribution to strengthen the skills and competencies of European biomedical professionals in a rapidly changing environment.
		The online course portal on-course® now contains information on over 6 000 courses in its catalogue. The 6 000 courses featured on the site today include Master's courses, PhDs, and short courses taught in organisations across Europe as well as over the internet.
SafeSciMET	E&T in Safety Sciences	A third cycle of the SafeSciMET curriculum is to be launched. The project launched also a 'blended learning' pilot course to reduce the length of the face-to-face elements of the course and accommodate requests from partners using the EU2P *e*Learning platform.
Eu2P	E&T in pharmaco-vigilance and pharmaco-epidemiology	Flexible and personalised, fully online *e*Learning programme at Certificate-, Masters- and PhD-levels through partnership of seven European Universities, the EMA and French Health Authority, and 15 pharmaceutical companies. The programme covers medicines risk identification and quantification, medicines and public health, medicines risk communication, medicines benefit assessment, and regulatory processes. There are currently 58 participants on courses, of whom 41 are currently following the 2-year program. Student enrolment has doubled from the first to the second operational year. To date 160 training areas are offered. The number of Eu2P Master's trainees has more than doubled in two years. The Eu2P online training programme in regulatory science is becoming more popular.

EUPATI	E&T	Meaningful involvement of patients in EUPAT's industry-led Medicines R&D workshop on 23 July 2014 led to the foundation of working groups that will assess, drive forward, and guide systematic and practical patient involvement in industry-led medicines R&D. Case studies and a report have been published. EUPATI achievements so far include the development of a EUPATI network of 1 000 members from 53 countries which includes a wide mix of healthcare professionals, patients, caregivers, public relations and communications specialists, industry and academic representatives. EUPATI has developed an IT Platform called 'How Medicines are Developed', and integrated its IT infrastructure with social media. The project has started translating e-based materials into several languages.
		The EUPATI Patient Expert Training course was successfully launched and enrolled 300 applicants onto the Expert Academy Training course. 55 trainees are now participating in this course which started in October 2014. EUPATI launched a second round of recruitment for the Expert Academy training course.
		Successful launch of the EUPATI National Platforms in the United Kingdom, Ireland, Spain, Switzerland and Luxembourg.
EUROPAIN	chronic pain	The consortium reviewed their work in the context of the EU Directive 2010/63/EU on the protection of animals used for scientific purposes and developed guidance for other pain researchers on the required classification of severity of experiments.
		Developed training and accreditation in clinical methodology for quantitative sensory testing.
Chem21	chemistry	Further developed a green chemistry metrics tool for evaluating chemical reagents used in manufacturing in terms of cost, impact on environment, safety of use, and scarcity. This tool is already used for the education and training of chemists.
DDMORE	knowledge management	Model development environment from the project was utilised to deliver a set of training courses on model informed anti-diabetic drug development.
IMI-TRAIN	E&T in pharmaceutical medicine	The IMI JU's education and training projects launched their new pan-European framework for continuing professional development (CPD) in the biomedical sciences. The LifeTrain framework will enable biomedical professionals to work collaboratively across disciplines and national boundaries. Furthermore, LifeTrain's unique collaborative approach aims to provide the critical mass to make a major contribution to strengthen the skills and competencies of European biomedical professionals in a rapidly changing environment.

1.3.3 Business-related outputs

In early IMI JU Calls, sustainability was not specifically mentioned and was in most cases not part of the objectives of the project. As projects are nearing their final stage, they all investigate their sustainability. Several have identified innovative business solutions for sustaining the added value of the project after the IMI-JU funded project duration.

For example, the Education & Training project Pharmatrain has created the PharmaTrain Federation, a legal entity that succeeds the IMI 1 JU project and is managing and developing the assets created during the original five-year project duration.

In 2013, the knowledge management project Open PHACTS created a not-for-profit legal entity in the form of the Open PHACTS Foundation. The Foundation is now fully responsible for operating and developing the infrastructure resulting from the IMI 1 JU Open PHACTS, and the business model is based on membership fees from a range of organisation types. By the end of 2014, the Open PHACTS Foundation had four paying members – GlaxoSmithKline, Janssen, Lilly and Roche. In addition the Open PHACTS Foundation is partnering in the Big Data Europe project, (a H2020 project no. 644564) building on the expertise acquired during the project.

In 2014 EHR4CR followed a similar path. The European Institute for Innovation through health data is in the final stages of being established. The Institute is a not for profit company providing services to its registered members who are data providers, data users, service providers and publicly available for clinical research or the eHealth community. It is funded by license fees, subscription fees, certification fees, and membership fees. The income is invested to improve services & to fund further research.

Other knowledge management projects have also been productive. ETRIKS has set up a structure to provide data curation and hosting services. A 'Radiomics' tool partly developed in the oncology project QuIC-ConCePT has been successfully translated into a sustainable platform through the formation of PTtheranostics.

IMI 1 JU Oncology project ONCOTRACK has founded a spin-off organisation under the name CPO Cellular Phenomics & Oncology Berlin-Buch GmbH to conduct the biological and pharmacological testing of new therapeutics and diagnostics in preclinical models.

Many more projects are currently investigating options to make their output sustainable.

During 2014, the Centre for the Advancement of Sustainable Medical Innovation (CASMI), a partnership between Oxford University and University College London, analysed how outputs of IMI JU projects could be maximised and further exploited and whether a stakeholder platform should be designed for this purpose.

It was considered that the CASMI analysis should focus on the concept of medicines adaptive pathways to patients (MAPPs), and that a small number of projects should be selected as case studies for such an analysis. The CASMI study found that the projects DIRECT, EH4CR, PROTECT and SAFE-T will all create assets of potential value in the MAPPs scenario, provided there is effective engagement with key stakeholders from among relevant regulators, Health Technology Assessment (HTA) agencies, payers, ethics review bodies, and relevant channels are used for public and patient involvement. Specific recommendations were made, both for immediate action and future planning, along the following lines:

- broader and deeper stakeholder engagement at the project level
- cross-fertilization of lessons and approaches to maximise impact
- creation of a future stakeholder platform and process.

1.4 Stakeholder engagement

IMI JU 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[5] below shows the total number of participations by different stakeholders.

1.4.1 SME involvement

Throughout 2014, IMI JU continued to promote the participation of SMEs in IMI projects and offer support to SMEs interested in applying. This has been primarily through an SME-dedicated contact person, via the SME webpage, and through interactions with Europe-wide umbrella organisations.

By the end of 2014 SMEs accounted for 16% of all beneficiaries (169 out of 1 059 participations in total). The SMEs involved in IMI JU projects received 15.8% of the total IMI JU budget.

The IMI Programme 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, particularly other EU instruments.

Another approach has been to engage with venture capitalists (VCs) private finance organisations and to facilitate dialogue between these and IMI JU's SMEs already involved in IMI JU projects. An SME funding meeting called 'Investing in excellence' was held on 18 February 2014 in Brussels. SMEs involved in IMI JU projects and previous IMI 1 JU Calls for proposals were able to interact with VCs, pharmaceutical company investors, and business development professionals with the aim of identifying other sources of financial support and helping the SMEs prepare for future investor interactions. It is envisaged to hold a follow up meeting in 2015.

Overview of the SMEs participation in IMI per year

	2011	2012	2013	2014
%Participation	13%	16.1%	15.2%	16%
%Budget)	13%	18.9%	18.5%	15.8%

[5] 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.

1.4.2 Patient involvement

Patients and the lay community are key IMI JU stakeholders. IMI JU-funded research is 'patient-centric' and IMI JU provide 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 and will continue to do so.

It has always been clear that patients have an essential role to play in IMI JU's activities, and over the years the IMI Programme Office has taken more active steps to engage with patients and promote patient involvement in its projects and activities. These include:

- The inclusion of a patient representative in the IMI JU Scientific Committee since its creation;
- Regular involvement of patients and patient representatives as speakers and panellists in IMI JU events;
- The inclusion of sections dedicated to patient involvement in Call topic texts for relevant projects. This has already been implemented in IMI 1 JU Calls 9 to 11 and IMI 2 JU Calls 1 to 5.
- Efforts to facilitate patient involvement in IMI JU projects including a brief guide for potential applicants with advice for on how to ensure meaningful patient involvement. This has been published on IMI JU website for IMI 2 JU Calls 3 and 4.
- Patient focus meetings held annually. The event in Spring 2014 focused on diabetes, with the objective to identify research and development gaps in diabetes research from the perspective of patient needs and challenges.

IMI JU has several projects which have particularly strong patient involvement.

- EUPATI is developing training materials and courses to help patients engage more effectively in medical research and development;
- U-BIOPRED is paving the way for more personalised treatments for severe asthma. As well as taking part in the project's clinical study, patients have advised the project on ethical, scientific, and communication issues;
- PROactive is developing methods to incorporate the impact of chronic obstructive pulmonary disease (COPD) on patients' daily lives into drug development;
- Patient organisation Alzheimer Europe is an active partner Pharma-Cog, EMIF, AETIONOMY and EPAD;
- EU-AIMS is paving the way for new treatments for autism spectrum disorder. US-based patient advocacy group Autism Speaks is a partner in the project and is contributing EUR 1 million to its work;
- Diabetes charity and patient organisation JDRF has contributed to IMIDIA and SUMMIT projects and is now an associate partner in IMI 2 JU as it is contributing to the IMI 2 JU Call 1 project on type 1 diabetes;
- GetReal aims at developing a framework for assessing how and when to apply real world data and data analytical techniques in drug development. This is aimed at enriching decision-making by regulatory authorities and HTA bodies. The project involves all relevant key stakeholders, including a patient organisation, the International Alliance of Patients' Organisations (IAPO). IAPO provides the patients' perspective on the development of tools, methods and frameworks and support dissemination and outreach to patient' organisations where relevant;
- DIRECT launched a survey to gather patients' views about personalised medicine.

In addition, it is worth noting that IMI JU is strongly supported by a number of key opinion leaders among patients and in the patient advocacy community.

1.5 Interactions and involvement with regulatory authorities/health technology assessment bodies

As many IMI JU projects focus on building new science-based evidence that is needed to support informed decisions by regulatory agencies, early engagement with regulators is paramount.

The effective collaboration between IMI JU and the regulatory agencies, particularly the EMA and FDA, continued in 2014 particularly through:

- EMA input to the definition of IMI JU priorities, proposed IMI JU Call topics and projects' outputs through its membership in the IMI JU Scientific Committee;
- EMA involvement in the activities of several consortia, either as full partner or as member of their advisory boards. Several IMI JU projects have also FDA representatives on their advisory boards;
- Use by IMI JU consortia of the existing regulatory process/procedures such as the EMA qualification advice of novel methodologies for drug development and briefing meetings for input to the project plan. In this respect, IMI JU continuously encourages consortia to take advantage of possible ways to engage early dialogue with regulators.

Interactions cumulate with the yearly workshop at which IMI JU, the EMA and the FDA hold a strategic discussion of topics of common interest. In 2014, the fourth Regulatory Summit was hosted by Centre for Drug Evaluation and Research (CDER) and the FDA at their offices. This meeting, also attended by representatives of the Pharmaceuticals and Medical Devices Agency (PMDA) and Health Canada, was an opportunity to discuss challenges/gaps and identify potential opportunities for improvement. Actions addressed included defining a clear path for development and acceptance of biomarkers/drug development tools, establishing communication among partners early and often to enhance efficiency in the processes. The actions resulting from this Summit will be followed up in 2015 and their progress will be monitored during the regular IMI JU/EFPIA/EMA/FDA teleconferences.

With projects looking at the whole value-chain, engagement with HTAs/payers is becoming increasingly important. Collaboration between IMI JU and HTA bodies is already in place, notably through a representative of National Institute for Health and Care Excellence (NICE) on the IMI JU Scientific Committee, and through participation in IMI JU consortia such as the IMI 1 JU Call 8 project GetReal.

Based on this experience, IMI JU has now taken steps during 2014 to include a provision requesting applicants to elaborate in their proposal plans for interaction with regulatory agencies/HTAs with relevant milestones and appropriate resource allocation when relevant in the IMI JU Call topic texts.

Finally, a growing interest in the application of adaptive pathways to enable patients to have timely access to novel medicines is being observed. In April 2014, the EMA, Massachusetts Institute of Technology's (MIT) NEWDIGS (New Drug Development ParadIGmS), EFPIA and IMI JU co-organised a multi-stakeholder meeting to discuss new adaptive pathways for drug licensing and patient access. With the strong emphasis of looking at enablers for the implementation of MAPPs in IMI 2 JU, a Coordination and Support action was launched in December 2014 to establish an enabling platform with relevant stakeholders for the coordination of MAPPs-related activities within IMI 2 JU. This allows effective collaboration with regulatory agencies, health technology assessment bodies and payers which will expand further through this platform.

1.6 Measures of collaboration – the added value of PPPs

1.6.1 Collaboration measured based on bibliometric data

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 JU projects with the aim of having an impact on the productivity and success of the projects. Now IMI JU wants to know how well those stakeholders are working together.

How collaborative are IMI JU projects?

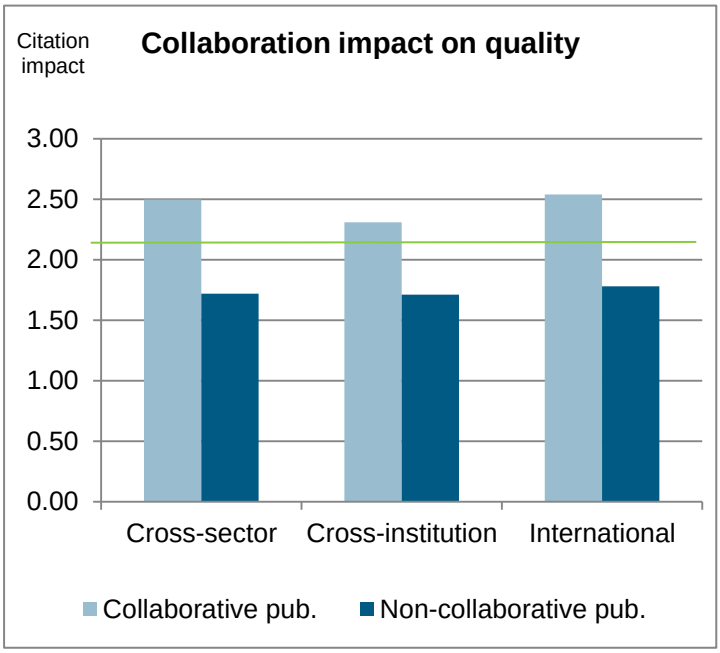
International research collaboration is a rapidly growing element of research activity.[7] In addition, international collaboration has been shown to be associated with an increase in the number of citations received by research papers, although this may vary across countries.[8] Co-authorship is likely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

Collaboration **BETWEEN PUBLIC AND PRIVATE**
60%
of IMI publications

Collaboration **BETWEEN INSTITUTIONS**
79%
of IMI publications

INTERNATIONAL collaboration
53%
of IMI publications

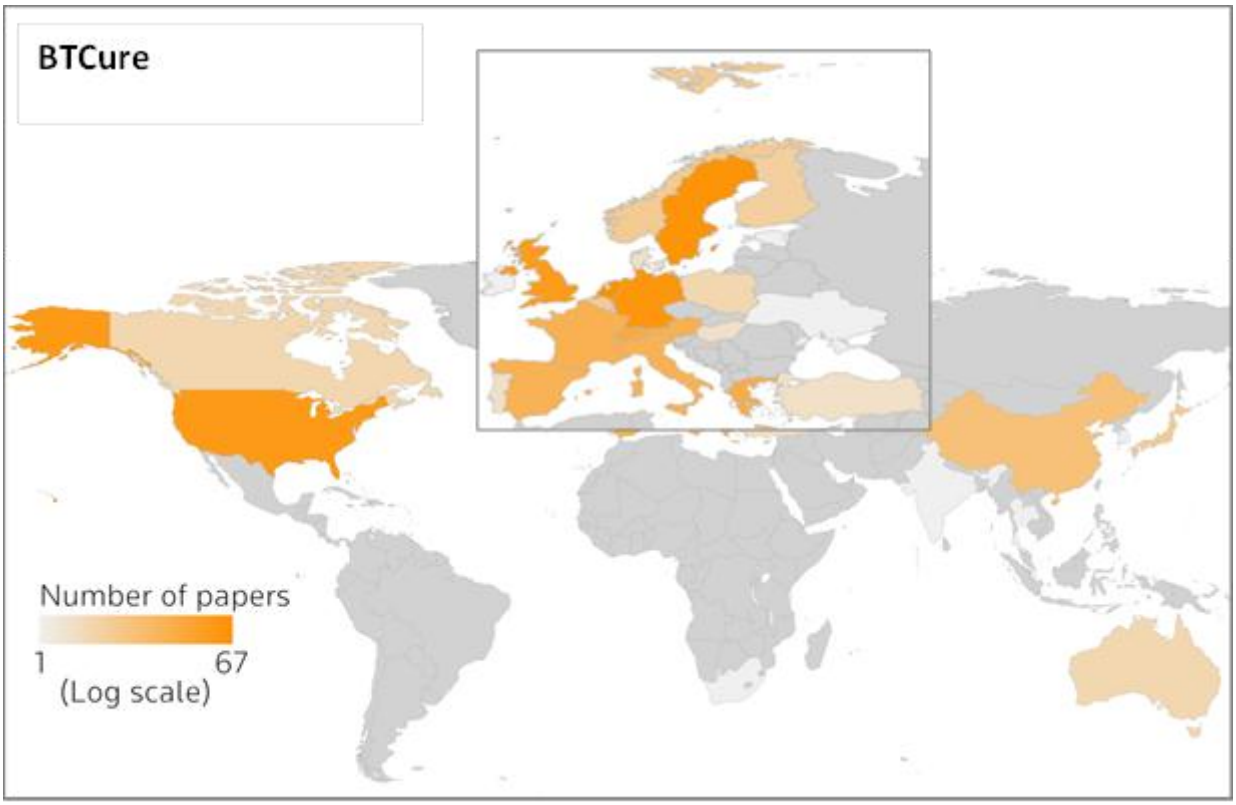
- The data shows that IMI JU project research is collaborative at the sector, institution and country level. Well over half (60%) of all IMI project papers have been published by researchers affiliated with different sectors (such as researchers with academia publishing together with researchers from industry or SMEs). More than three quarters (79%) of IMI JU project papers involve collaboration between different institutions. Half (53%) of all IMI JU project papers are internationally collaborative.
- The collaborative IMI JU publications are internationally influential, with a citation impact well over twice the world average (1.0). Within IMI JU project research, there is a clear difference in average citation impact between collaborative and non-collaborative publications. This supports the hypothesis that collaboration has a positive impact on the quality of research performed.



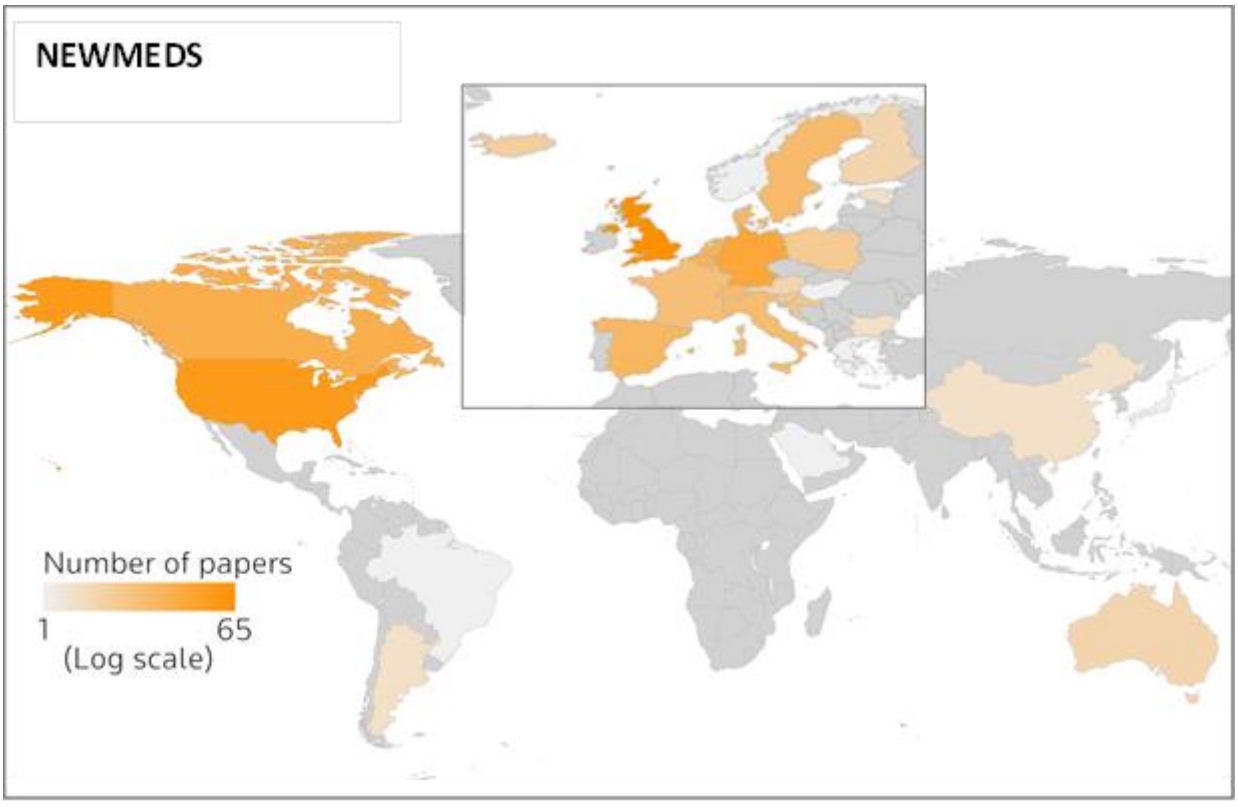
An expanded collaboration analysis was carried out at project level on publications resulting from IMI consortia on the basis of co-authorship. In terms of international collaboration BTCure has produced the most internationally collaborative publications (107.51% of total output) and PROTECT has the highest fraction of internationally collaborative publications (61.7% of total output).

[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.

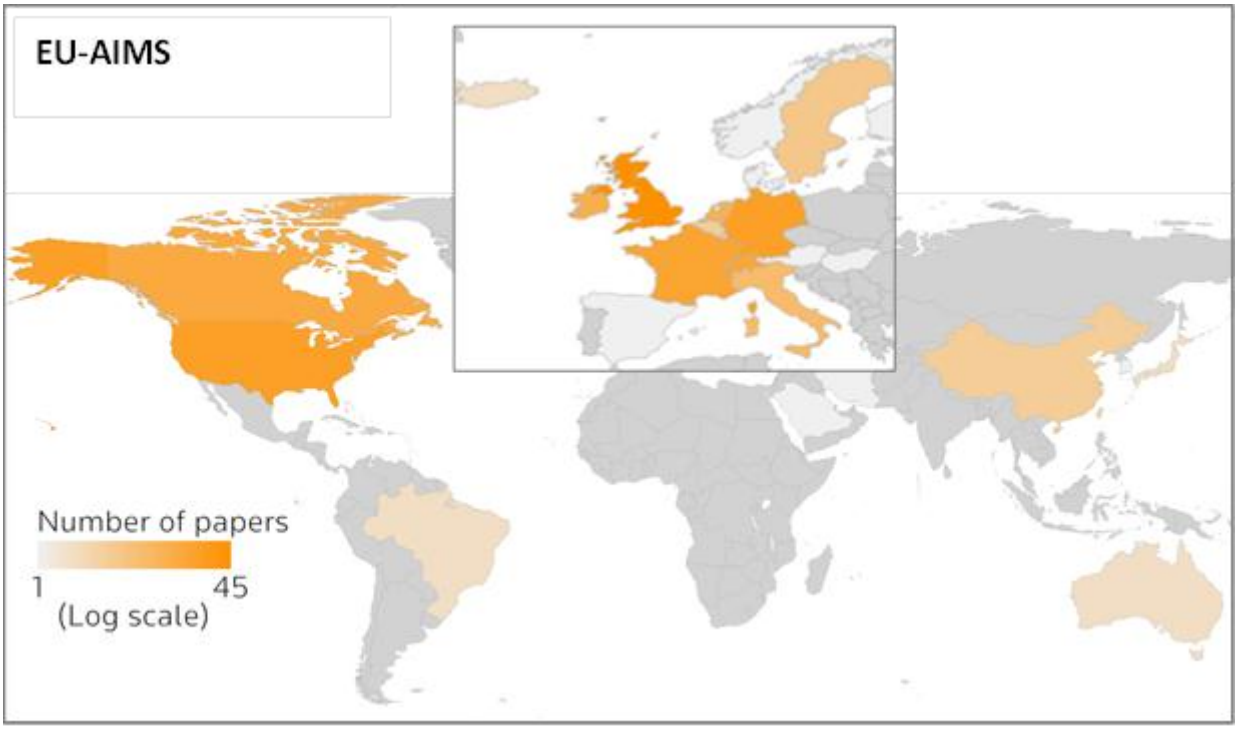
The spread of output of the three most internationally collaborative projects in terms of volume, BTCure, NEWMEDS, and EUROPAIN, is illustrated below which demonstrates the extent of co-authorship from authors around the world.



Source: Thomson Reuters analysis, 2015.



Source: Thomson Reuters analysis, 2015.



Source: Thomson Reuters analysis, 2015.

In terms of cross-institution collaboration, BTCure again produces the highest number of publications resulting from more than one institution (151.73% of total output) and PharmaCog has the highest fraction of publications resulting from more than one institution (25.92% of total output).

In terms of cross-sector collaboration, BTCure has produced the highest number of publications with authors from assigned to more than one sector (111.53% of total output) and PROTECT has the highest percentage of publications with authors from assigned to more than one sector (61.97% of total output).

1.6.2 Collaboration among consortia and with external bodies within and beyond IMI JU

Collaboration between IMI JU projects and with external bodies is strongly encouraged. Several IMI JU projects have initiated collaboration with other consortia and a number of these resulted in formal agreements. Key collaborative activity areas include: taxonomy of diseases, Alzheimer's disease, autism and antimicrobial resistance via the New Drugs for Bad Bugs (ND4BB) platform.

Collaboration with Critical Path Institute (C-Path)

IMI JU has continued to collaborate with Critical Path Institute (C-Path) and share best practices.

With respect to projects, SAFE-T and the C-Path's Predictive Safety Testing Consortium (PSTC) continue to work together. In 2014 joint work plans have been completed by the corresponding working groups of SAFE-T and PSTC and approved by the respective governance bodies of both consortia. The collaboration between both consortia proved to be highly efficient not only in terms of utilising synergies in qualification work but also with respect to regulatory interactions. In 2014 there were two scientific advice meetings with EMA and FDA for the disease areas of DIVI and DILI.

Interactions between IMI JU project Predict-TB and the Critical Path to TB Drug Regimens (CPTR) consortia have been strengthened in line with the Memorandum of Understanding between the two organisations with the co-ordination of some work on clinical trials databases and sharing of data.

IMI JU and C-Path co-hosted the second annual meeting on 3 December 2014 in Bethesda in US under the theme '*Accelerating the Developments of Drugs, Diagnostics and Devices: Partnerships to Expand the Precompetitive space'*. The meeting explored key topics around lessons learned from the public-private partnerships models set up to advance regulatory science and the importance of leveraging resources and avoiding duplication of efforts. It also reviewed the successful collaboration between IMI JU SAFE-T and C-Path PSTC consortia to deliver results on safety biomarkers and discussed the value of data shared by multiple organisations.

Collaboration with the National Institutes of Health (NIH)

EU-AIMS, working on autism spectrum disorder (ASD) has initiated data sharing agreements to enable data pooling (MRI, clinical data) and sharing of methods (iPSCs) with the NIH Autism Centres of Excellence Program (ACE) initiative. In addition EU-AIMS is working in parallel with the fNIH Biomarker Consortium on the development of outcome measures for clinical trials in ASD, including monthly teleconferences and parallel scientific advice EMA/FDA.

Implementation of data standards and collaboration with the Clinical Data Interchange Standards Consortium (CDISC)

Plans were developed to change the model for the training activities by CDISC offered to partners of IMI JU consortia. Training will now be offered through self-paced online learning and webinars for IMI JU scientists, reaching out to a wider audience. Several projects participated in the development of new data standards or the identification of existing standards that should be adopted.

IMI JU also participated in the Scientific Advisory Committee of the Coalition for Accelerating Standards and Therapies (CFAST) with a view to better expose IMI JU projects to newly developed standards. Based on this experience, IMI JU has now started to include a provision requesting applicant consortia to plan for adoption, adaptation or development of data standards in collaboration with a standards development organisation in the IMI JU Call topic texts.

Global Action against Dementia: Collaboration with The Global CEO Initiative (CEOi) on Alzheimer's Disease and the New York Academy of Science

At the G8 Dementia Summit in London on 11 December 2013, a Global Action against Dementia was launched and IMI JU was identified as one of the key vehicles to promote and foster research and development in the area. In 2014 IMI JU actively followed up work coordinated by the World Dementia Council including participation in two Global Dementia Legacy events in London on 19 June 2014 and in Ottawa on 11 and 12 September 2014.

In addition IMI JU collaborated with the Global CEO Initiative (CEOi) on Alzheimer's Disease and the New York Academy of Science throughout 2014 to make the objectives of the Global Action operational through its active AD projects EMIF and AETIONOMY and through the collaboration of the newly-started EPAD project and the Global Alzheimer's Platform (GAP) for conducting Alzheimer's clinical trials and developing novel adaptive clinical trial designs.

Organisation for Economic Co-operation and Development (OECD)

In response to the recommendations from the G8 Dementia Summit Declaration, and as part of its horizontal work on big data for health, the Organisation for Economic Co-operation and Development (OECD) has launched a project on big data for Alzheimer's disease and dementia research. IMI JU actively participated in two expert meetings aimed at providing advice and guidance to this project. The key messages of the project will be presented at a WHO meeting in March 2015.

In addition IMI JU was also involved in the OECD work to prepare discussions with the regulators for the development and update of the guidelines for development of products for Alzheimer's disease.

2 IN KIND CONTRIBUTION OF THE PHARMACEUTICAL INDUSTRY TO IMI PROJECTS

2.1 Background

The European Union (EU) supports IMI JU financially. Eligibility for funding in the context of IMI 1 JU projects is restricted to universities, research organisations, patient organisations, and SMEs, with conditions similar to those of the Framework Programme 7 (FP7). FP7 was the European Union's Research and Innovation funding programme for 2007-2013.

All entities receiving EU financial support are subject to the overall control framework of the EU. In particular, these entities are subject to *ex post* audits by IMI JU and the European Court of Auditors on the legality and regularity of their payment claims.

Large pharmaceutical companies do not receive any EU financial support. These companies contribute to IMI JU's objectives through so-called in kind contributions, which must be at least equal to the financial contribution of the European Union under the IMI JU legal framework.

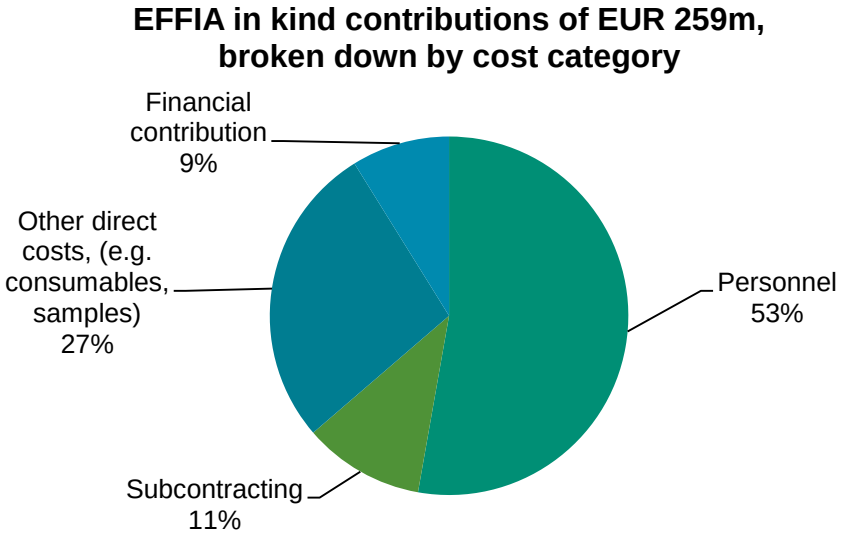
2.2 Nature of in kind contributions

In kind contributions are costs incurred by these companies in the implementation of IMI JU projects and may include, for instance, the costs of researchers, research equipment and materials (see the figure below). The total in kind contributions have to reach a value explicitly foreseen in the legislation on IMI JU.

As at the end of 2014, these companies have declared in kind contributions totalling EUR 259 million, while the total EU financial support claimed by recipients of EU funding stands at EUR 204 million. These figures evolve as each reporting period ends. To date, companies have met their commitments, and their in kind contributions currently exceed the EU's contribution to IMI JU.

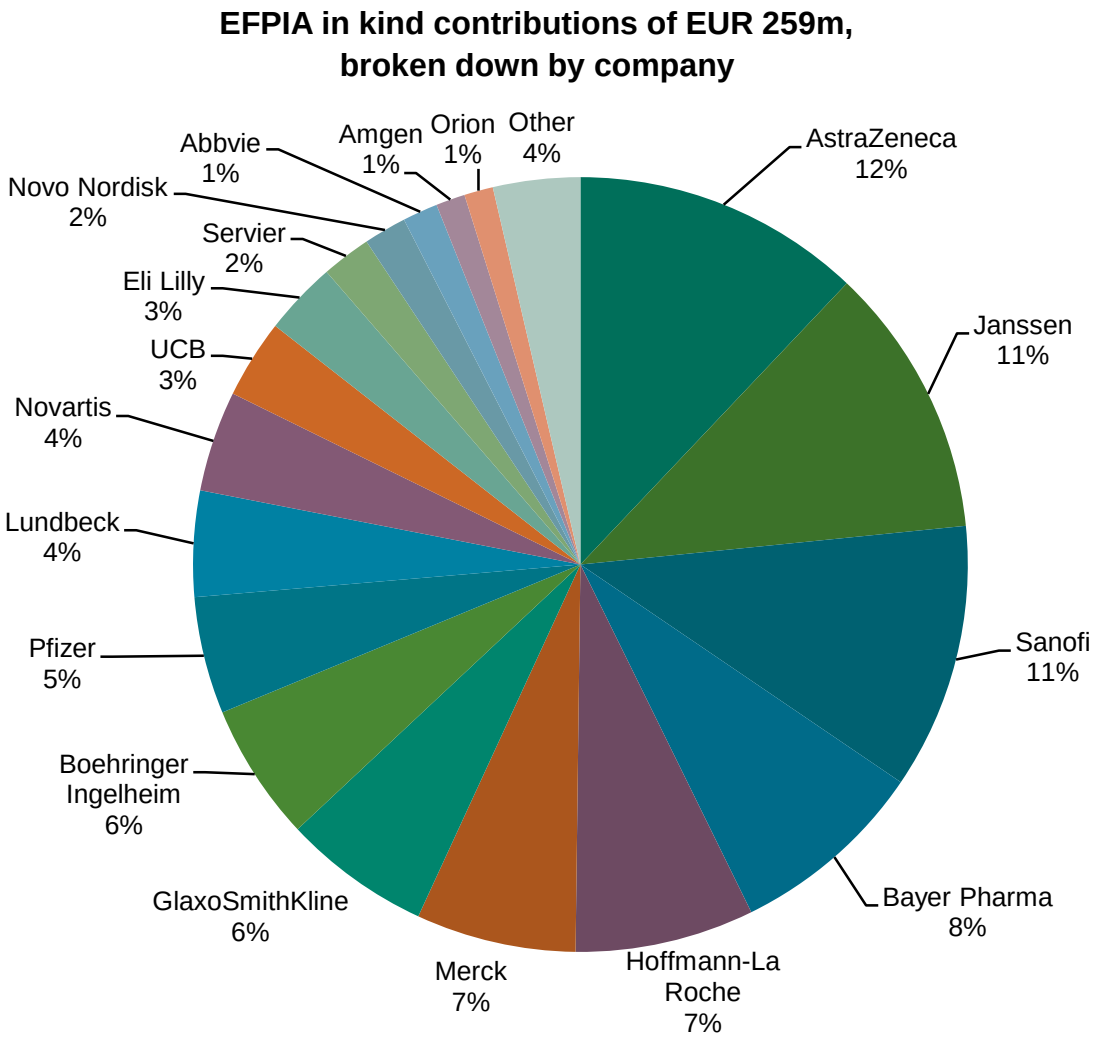
The first IMI 1 JU projects started in 2009 and IMI 1 JU's current portfolio includes 59 projects. All project consortia include a mixture of entities including SMEs, academics, research organisations, regulatory bodies, patient representatives and at least two EFPIA companies per project.

Further details about industry contributors and the type of reported contributions are set out in the graphs below:



The cost categories are:

- Personnel: staff employed by EFPIA companies directly working on IMI JU projects.
- Financial contribution: A transfer of funds from an EFPIA company to an academic institution within the same project/consortium. This financial contribution is used by the academics to hire researchers during the lifetime of the IMI JU project or to buy consumables or equipment.
- Other direct costs: consumables, equipment depreciation, samples, compounds.
- Subcontracting: clinical trials, subcontracting to clinical research organisations, subcontracting to data management companies, lab services, communication, project management support, etc.



The companies within the 'other' category (4%) are:

Merck Sharp & Dohme, Chiesi Farmaceutici, Almirall, Esteve, Grünenthal, Sanofi Chimie, Eisai, Sigma-Tau, VIFOR, Bristol Myers Squibb, Sanofi Pasteur, Astellas, Takeda, Basilea, Verband forschender Arzneimittelhersteller, Ipsen

2.3 Controls over reported in kind contributions

During the implementation of the project, in kind contributions by the EFPIA companies are reported on an annual basis, with declarations carefully scrutinised by the IMI JU programme office. All in kind contributions which are declared must be accompanied by audit certificates, during or at the end of the project. Furthermore, the IMI JU programme office audits (see section 2.4) companies providing in kind contributions using a risk-based approach[9].

So far, declared in kind contributions representing 0.5% of the total in kind contribution reported (EUR 1.3 million out of a total of EUR 259 million), have been rejected.

The IMI JU Governing Board receives regular updates throughout the year from the IMI Programme Office on the level of in kind contributions to ongoing projects. The in kind contributions are also reported in a transparent manner in the annual accounts and the annual activity reports (AAR) of IMI JU, which are made publicly available online. Before their formal approval, IMI JU's provisional annual accounts are carefully scrutinised by the European Commission. The establishment of the annual accounts, including the in kind contributions, is part of the decision-making process in which the European Commission has a controlling vote at the level of the IMI JU governing board.

The Internal Audit Service of the European Commission, which acts as the internal auditor of IMI JU has announced an audit on in kind contributions for 2015 which will provide further assurance and/or recommendations for improvement in this area.

The European Court of Auditors audits IMI JU's accounts and in doing so, the Court has full access to all documentation linked to the reporting of in kind contributions, and the validation and auditing of such reports. In this context it has also carried out audits of the external audit firms who are engaged in the audit of industry in kind contributions.

2.4 *Ex post* audits of EFPIA companies in kind contribution

In addition to the *ex post* audits covering the IMI share of the funding to beneficiaries (see section 7.2), the IMI Programme Office has also continued conducting *ex post* reviews and financial audits on the declared in kind contributions by EFPIA companies participating in IMI JU projects. These companies do not receive any IMI JU funding but contribute in kind to the projects in which they participate and benefit from.

The purpose of these audits, using a risk-based approach as per IMI JU's audit strategy, is to independently verify that the in kind contributions accepted by IMI JU have been effectively committed to the projects.

Each exercise consisted of two key elements: *ex post* review and financial audit:

- A review of the in kind methodology used by the EFPIA company to declare in kind contributions for all the IMI JU 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 were able to conclude whether:
  - the approach and basis of the actual calculations were as originally described in the accepted methodology;
  - whether any mathematical errors or other inconsistencies were noted in the actual calculations made relating to the direct personnel full time equivalent (FTE) daily cost rate;

[9] The IMI Programme Office procures the services of external audit firms PricewaterhouseCoopers, KPMG and PKF Littlejohn, under a framework contract tendered in an open procedure, to carry out *ex post* audits of beneficiaries receiving IMI JU funding and EFPIA firms contributing in kind.

- 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;
- the basis of the methodology and calculation was consistent with Article II.13.4 of the grant agreement and excludes prescribed ineligible costs.

- A financial audit of a sample of in kind contributions declared in the financial statements submitted by EFPIA companies to IMI JU in order to assess and present an opinion on whether these meet the conditions of the grant agreement

By the end of 2014, four *ex post* reviews and audits of selected EFPIA companies had been finalised and a further two reviews and audits were ongoing. These engagements cover the largest contributors of in kind contributions to IMI JU projects, thereby ensuring extensive coverage of the programme.

The table below gives an overview of the status of *ex post* audits of the in kind contribution of EFPIA.

	Selected	Launched	Ongoing	Finalised	Total accepted EFPIA contributions in the period (EUR)	Total audited EFPIA contribution (finalised audits) (EUR)	Direct coverage	Corrections (EUR)
2011					23 277 000			
2012	3	3	0	3	28 729 000	9 669 077	18.6 %	939 499.90
2013	3	3	2	1	57 969 000	3 427 266	5.9 %	- 520 940.00
2014	NA	NA	NA	NA	131 501 000	NA	NA	
Total	**6**	**6**	**2**	**4**	**241 476 000**	**13 096 343**		

This approach will be continued with other EFPIA companies in order to obtain additional risk-based coverage of declared in kind contributions on a multi-annual basis and over the lifetime of IMI JU. Seven ex-post reviews of EFPIA companies will be launched in 2015.

3 MANAGEMENT OF ONGOING PROJECTS

3.1 Interim reviews for IMI 1 JU Call 2, Call 3 and Call 4 projects

In 2014, IMI conducted 8 interim reviews of projects from IMI 1 JU Calls 2, 3 and 4, as shown in the table below.

IMI project acronym	Call #	Full project name	Interim review date
QuIC-ConCePT	IMI 1 JU Call 2	Quantitative imaging in cancer: connecting cellular process with therapy	28/02/2014
MIP-DILI	IMI 1 JU Call 3	Mechanism-based integrated systems for the prediction of drug-induced liver injury	30/05/2014
ABIRISK		Anti-biopharmaceutical immunization: prediction and analysis of clinical relevance to minimize the risk	04/06/2014
BioVacSafe		Biomarkers for enhanced vaccine immunosafety	18/06/2014
EU-AIMS		European autism interventions - a multicentre study for developing new medications	13/10/2014
EUPATI		European patients' academy on therapeutic innovation	16/10/2014
Predict-TB		Model-based preclinical development of anti-tuberculosis drug combinations	17/10/2014
EMIF	IMI 1 JU Call 4	European medical information framework	03/04/2014

The expert reviewer panel consisted of at least three experts, one from each of the IMI Scientific Committee, the full project proposal evaluation panel, and selected from suggestions by the consortium.

Overall, the reviewers were satisfied with the progress made by the projects. The consortia 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 made recommendations aimed at ensuring the delivery of 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. Further information per project is presented below.

QuIC-ConCePT

The project is clearly making progress and the program is running well and still faces some technical and kinetic challenges. The consortium had to make a major reallocation of industry resources in order to ensure that the critical biological validation clinical trial program, and imaging pathology correlation, could be delivered within the time frame. The reviewers found that the refocusing of the work proposed by the consortium at the review was appropriate, according to the difficulties encountered concerning one tracer and its availability after the project end. The reviewers suggested the involvement of imaging industry partners in the consortium.

The consortium has provided relevant answers to all comments of the reviewers, and after positive feedback, has proceeded with the planned refocusing of the project activities. Involvement of imaging industries will be explored, although the consortium signalled that the objectives of the project may be in the competitive space for these industries.

MIP-DILI

Progress against the work plan indicates that the project is meeting its early objectives overall with agreement on mechanistic endpoints, the establishment of the raw data repository, the evaluation against standard compounds of established *in vitro* models. Progress has been made in 'new technologies' in terms of sensitised (viral infection) liver spheroids and functionally competent iPSC cell lines. Signalling pathways have been established and ebiology models developed for DILI. For a complex project much of the early groundwork has been accomplished and satisfactory progress has been maintained.

ABIRISK

In the beginning, the project was significantly delayed by 1 to 1½ years for various but mostly administrative reasons. The pace of action has increased in recent months. Appropriate re-adjustments have been made by the consortium to secure its implementation. The face-to-face interim evaluation meeting in June 2014, when compared to the interim report received a couple of months earlier, has convincingly shown that milestones are progressively being reached, for instance, the validation of robust assays to measure the antibody neutralisation against TNFs (adalimumab, infliximab, etanercept), rituximab, and factor VIII.

All this represents a crucial milestone. The implementation of the database, including retrospective cohorts, has been initiated with the results of Multiple sclerosis (MS) patients; however, those of Rheumatoid arthritis (RA) and Irritable bowel disease (IBD) patients still need to be identified and characterised. The efficiency of further patient recruitment will be key to the success of the project.

BioVacSafe

The first year of the project has concentrated on the initiation of 'upstream' activities that will bear fruit when 'downstream' analyses are completed during the second half of the project. It is important that the activities in the first half are set up efficiently and effectively. This appears to be the case as demonstrated by the significant achievements obtained. The major achievements so far are the successful initiation, conduct and completion of the clinical trial (Work Packages (WPs) 1 and 3) as well as the non-clinical studies (WP 2).Overall, the project has the high potential for being able to predict and explain adverse reactions, preferentially severe and rare adverse reactions following vaccination, facilitating the identification of vaccine construction and vaccine formulation that will not cause such unfavourable effects.

EU-AIMS

EU-AIMS was recognised as a unique undertaking of unprecedented scope and with no clear benchmarks for comparison. Progress appears in general to be very satisfactory with considerable progress toward establishing an integrated and translational research programme focusing on the discovery of novel drug therapies for ASD, having already made important contributions to the literature. The project was urged to improve its data and knowledge management, its dissemination towards the general public and training of younger scientists. The consortium has provided relevant answers to all the reviewers' comments and has already updated and improved its data and knowledge management platform, significantly enhanced its communication to the general public and acted to boost training opportunities.

EUPATI

Since its inception, the project has instigated extensive collaboration between patient organisations, industry, health professionals, academics, HTA experts and the media. So far it has brought a greater understanding of pre-clinical and clinical development to a wider audience, consolidating information on research and development for ease of access and use by patients. Both the production of the materials and the development of the IT systems supporting it are being undertaken at the same time.

This program has the potential to rapidly have an impact on how patients, patient associations and the lay community view the research process, and their willingness and ability to work with academia and industry.

PREDICT TB

Many important achievements were obtained in this first phase of the project to fuel the drug development of tuberculostatic drugs. The reviewers felt there was no need for major changes in the overall direction or individual work packages. There were some issues around improving the quality of and access to existing clinical trial data, continuing to insure the good industry/academia interaction and boosting dissemination. The consortium has provided relevant answers to all comments of the reviewers including a strategy for ensuring the necessary access to clinical trial data and for boosting dissemination. Industry confirmed its full commitment to the project.

EMIF

This project actually combines three projects in one, the EMIF Platform and the two research pillars EMIF-AD and EMIF-Metabolic. A technical review was held one year into the EMIF project given the challenging objectives, in particular securing access whilst ensuring data privacy to patient level data. During the reporting period the project has made significant advances in defining mostly high-level requirements for the EMIF-Platform and key strategic important decisions have been taken. Significant work has taken place in the two vertical projects.

The reviewers urged the project to concentrate on advancing progress on a technical architecture capable of supporting its key scientific objectives and keeping the focus on delivering the objectives included in the description of work of the two research pillars. The consortium has provided relevant answers to all comments of the reviewers, clearly acknowledging the issue of creating a common data model and overarching IT infrastructure. In the second year they have intensified efforts to bring the various components of the EMIF platform in a common framework. An action plan has been developed to enhance active monitoring and management to assure all deliverables and milestones to be obtained in a timely way.

3.2 Cross-project meetings and collaborations

Taxonomy of disease

Representatives from the two taxonomy projects, AETIONOMY & PRECISESADS, met in June in Paris to evaluate possible synergies and share experiences, knowledge and strategies to establish a mechanism based taxonomy for both disease areas. It was decided that there is genuine interest to exchange ideas, concepts and experiences over the lifetime of the two projects even though neurodegenerative diseases and autoimmune, inflammatory diseases are very different from each other. A Memorandum of Understanding (MoU) has been agreed and was signed in July 2014.

Education and training

EMTRAIN, including Pharmatrain Federation, SAFESCIMET and EU2P submitted a joint ENSO application aiming at developing and implementing more personalised training including new innovative, e-learning and blended-learning course modules and evaluations of these teaching methodologies, competency profiles, competence assessments and competency portfolios, and new concepts for education and training in IMI 2 JU and Horizon 2020. These activities were formalised though a grant agreement amendment. These new activities will substantially increase the scope of the education and training projects, create new synergies and will strengthen strategies for the sustainability of the projects.

Knowledge management

A final draft of the Code of Practice on secondary use of medical data in scientific research projects was produced. This document, written by representatives of the IMI JU projects, aims to provide a set of harmonised rules applicable to secondary use of medical data. It is intended for use by research projects involving multiple legal entities established in at least two EU Member States.

Stem Cells

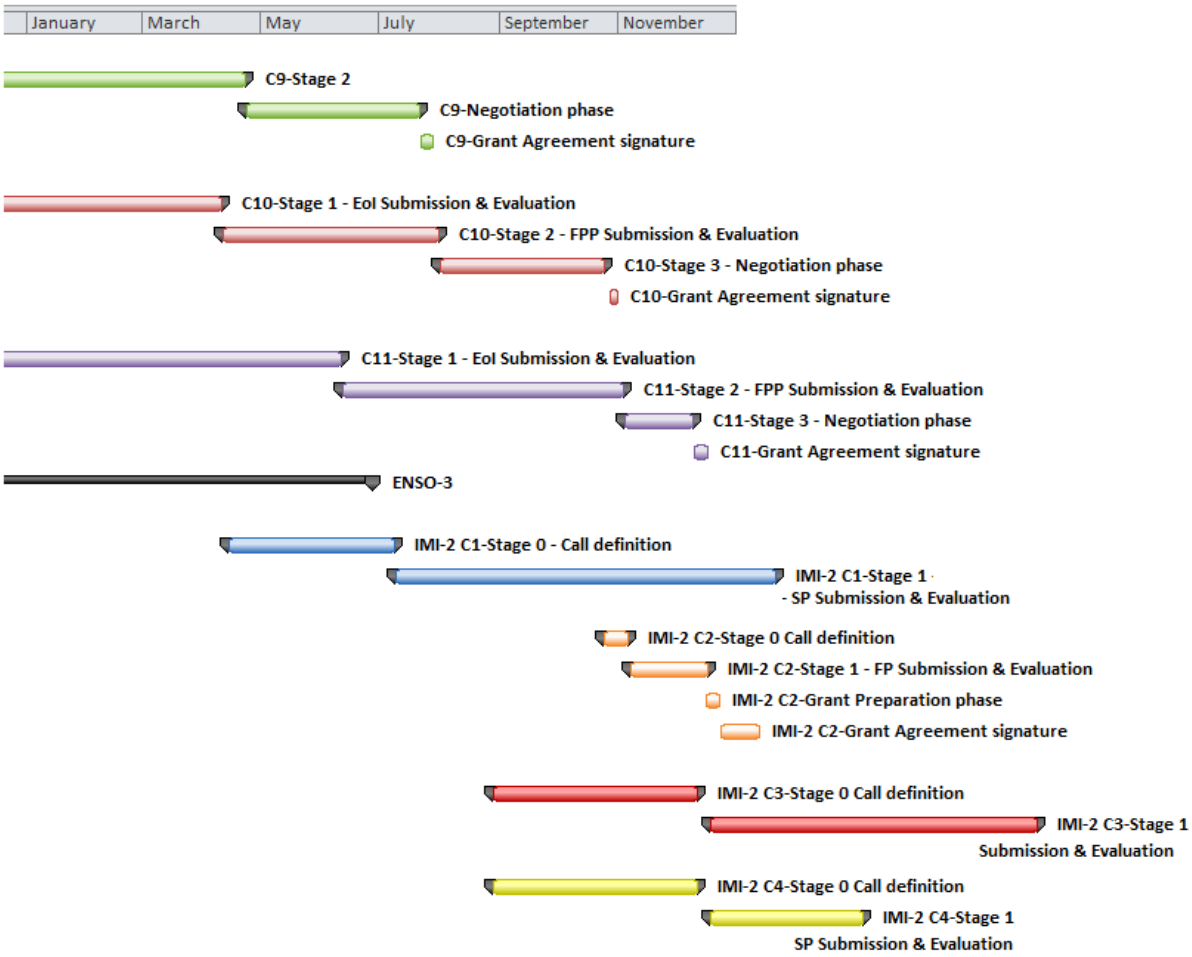
The IMI JU iPSCs cross-project meeting was organised at the IMI Programme Office on 29 April 2014 to find synergies and potential collaboration between the two IPS cells projects Stembancc and EBISC. Some areas for collaboration were identified and discussed including IPS cell distribution, expansion, quality control of cell lines, databases with all details including patient's data. A first pilot phase of collaboration is now ongoing.

Alzheimer's disease

In December 2014, as part of its annual meeting, the EMIF project organised a joint meeting with the leaders of the other two IMI JU Alzheimer's projects AETIONOMY and EPAD as well with representatives of the Dementia Platform UK (DPUK) and other FP7 projects active in the area of dementia and big data. The main output of the meeting was the agreement that the three IMI JU projects will work together in early 2015 towards a formal coordination and leveraging of activities under the umbrella of a single IMI JU Alzheimer's disease platform. In addition the first steps were taken for a leveraging of the EMIF data hierarchies for Alzheimer's disease cohorts by DPUK.

4 IMPLEMENTATION OF THE IMI JU CALLS FOR PROPOSALS

In 2014, four Calls under IMI 2 JU were launched (IMI 2 JU Calls 1, 2, 3, and 4). The final stages of the last IMI 1 JU Calls were also implemented (IMI 1 JU Calls 9, 10, 11, and ENSO-3). An overview of these activities is displayed below, as well as a mapping of how the scientific priorities identified in the Annual Work Plan 2014 (AWP2014) have been addressed through Calls launched in 2014.



CALL	Number of Topics	Priorities Implemented
IMI 2 JU Call 1	2	Metabolic disorders (diabetes) Neurodegeneration (retinal diseases)
IMI 2 JU Call 2	5	Infection control (Ebola)
IMI 2 JU Call 3	6	Enabling technologies and excellence in data management (2 topics) Metabolic disorders (diabetes) Psychiatry Infection control - vaccines (2 topics)
IMI 2 JU Call 4	1	Medicines Adaptive Pathways to Patients

Evaluation Experts

Most of the experts (89%) involved in the review of proposals submitted in response to IMI 1 JU Calls 9, 10, 11, ENSO- 3 and IMI 2 JU Call 2 came from EU- and FP7-associated countries.

For each Call in 2014, the evaluators have been as follows:

- IMI 1 JU Call 9 stage 2: 31 experts (including 2 independent observers and 3 ethics experts)
- IMI 1 JU Call 10 stage 1: 12 experts (including 1 independent observer and 2 ethics experts)
- IMI 1 JU Call 10 stage 2: 10 experts (including 1 independent observers and 2 ethics experts)
- IMI 1 JU Call 11 stage 1: 61 experts (including 2 independent observers)
- IMI 1 JU Call 11 stage 2: 54 experts (including 2 independent observers and 4 ethics experts)
- IMI 2 JU Call 2 (single stage): 21 experts (including 1 independent observer and 6 ethics experts)
- ENSO-3: 7 experts and 1 ethics expert

4.1 Implementation of IMI 1 JU Call 9

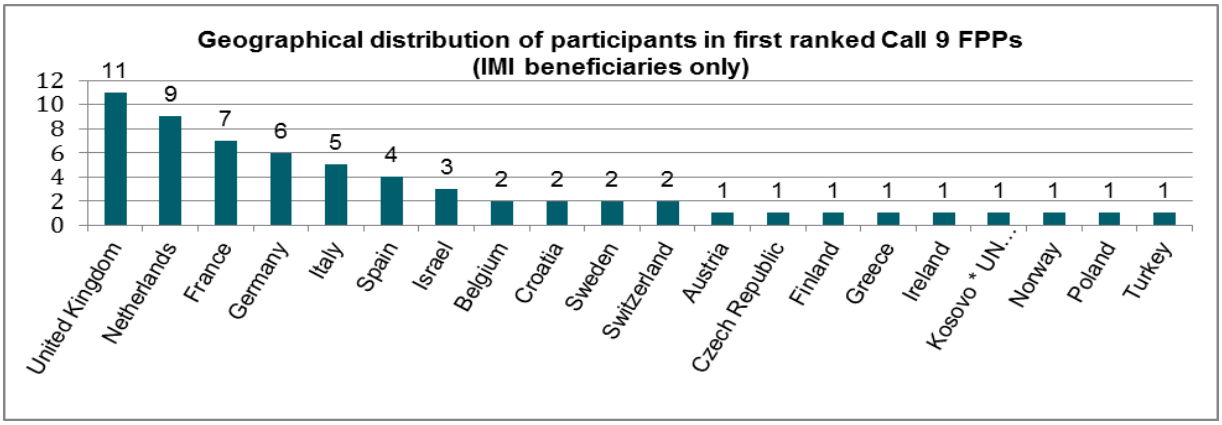
The IMI 1 JU 9th Call for proposals included the following topics:

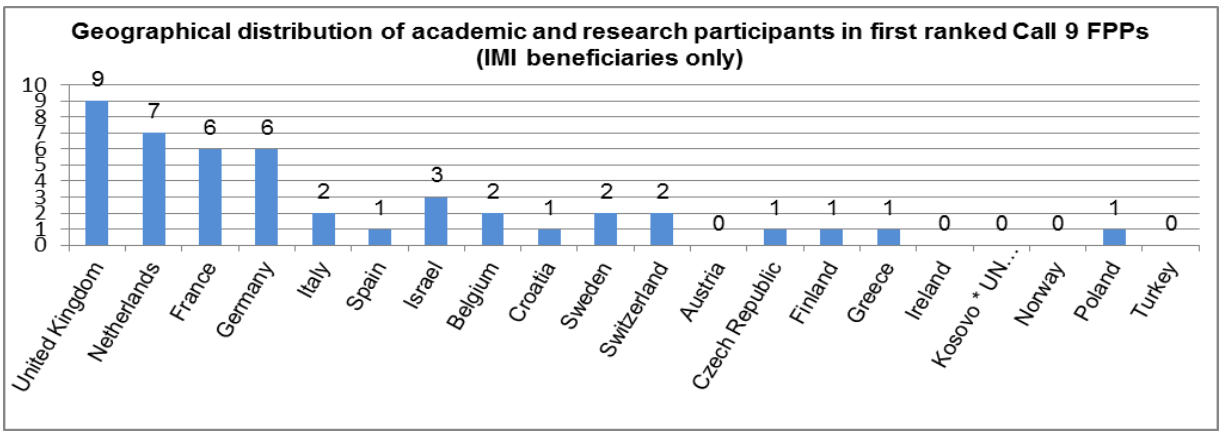
- WEBAE – leveraging emerging technologies for pharmacovigilance;
- Developing innovative therapeutic interventions against physical frailty and sarcopenia (ITI-PF&S) as a prototype geriatric indication;
- ND4BB Topic 4: Driving re-investment in R&D and responsible use of antibiotics;
- ND4BB Topic 5: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

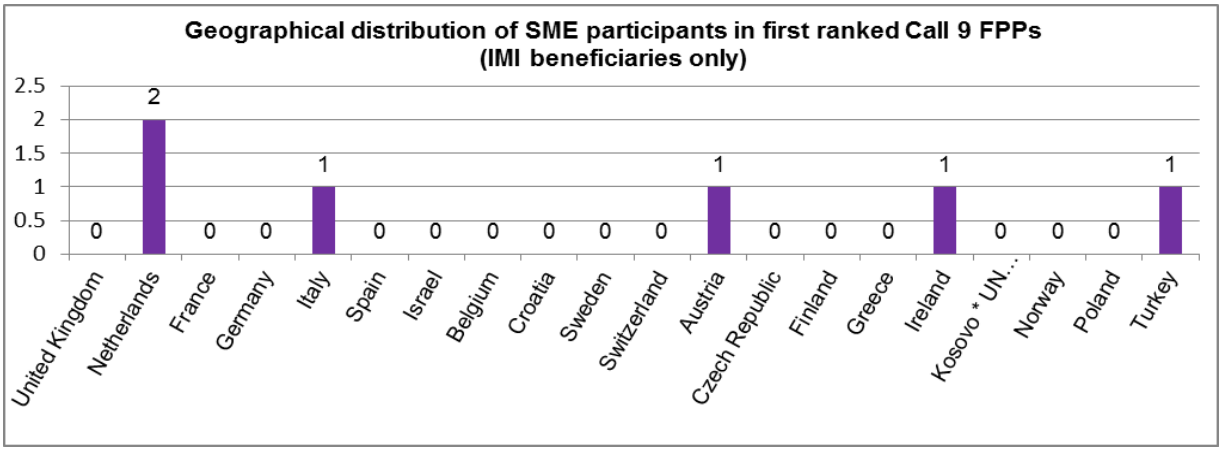
Following the approval of the recommendations of the Expression of Interest (EoI) evaluation panels by the IMI JU Governing Board in 2012, the four first-ranked EoIs were invited to prepare a Full Project Proposal (FPP) together with the pre-established EFPIA consortium. The deadline for submission of the FPP was 4 March 2014. The evaluation of the resulting FPPs was conducted by external experts working initially remotely and then at a consensus panel meeting.

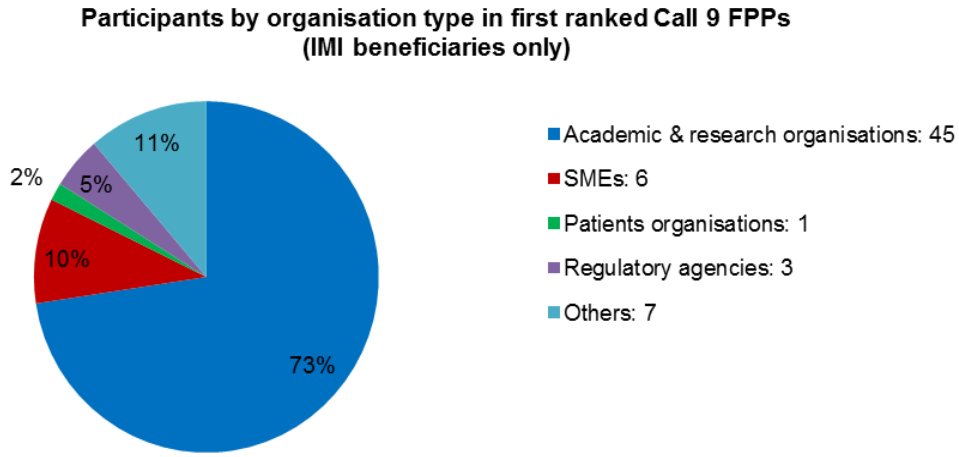
Three of the four FPPs were recommended to receive IMI JU funding and approved by the IMI JU Governing Board in May 2014. The ND4BB Topic 5 proposal was also recommended for IMI funding and approved by the IMI JU Governing Board in December 2014.

The key figures of the participants in the IMI 1 JU Call 10 full project proposal are presented below:









The grant agreements for the first three projects were signed in 2014 with the following budgets (in EUR):

IMI Project	EFPIA + IMI Funding	EFPIA in kind contribution	IMI Funding	Academic & Research	SME	Patient Org.	Others (special clause 11)[10]
DRIVE-AB	9 405 237	3 105 250	6 299 987	5 105 387	295 500	0	899 100
SPRINTT	47 890 782	23 891 343	23 999 439	17 377 905	2 804 686	0	3 816 848
WEB-RADAR	4 975 155	2 705 155	2 270 000	1 171 937	721 336	80 475	296 252
TOTAL	60 271 174	29 701 748	32 569 426	23 655 229	3 821 522	80 475	5 012 200

In SPRINTT, one of the beneficiaries is a third party (SC4).

Number of participants per project:

IMI Project	EU Beneficiaries	EFPIA Companies	Others (special clause 11)
DRIVE-AB	16	7	0
SPRINTT	17	5	1
WEB-RADAR	11	7	0
TOTAL	44	19	1

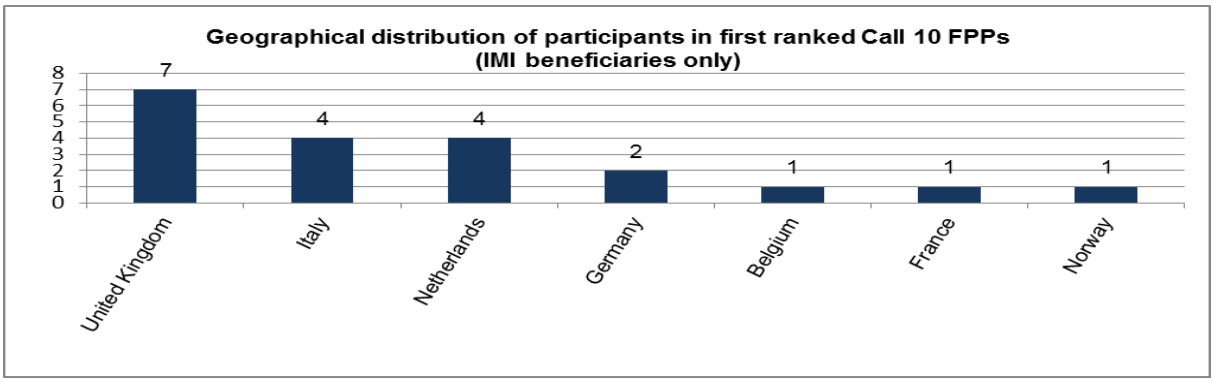
[10] *Others* are here the participants which are not eligible and not an EFPIA Member Company (Special Clause 11) from Grant preparation form A2.2.

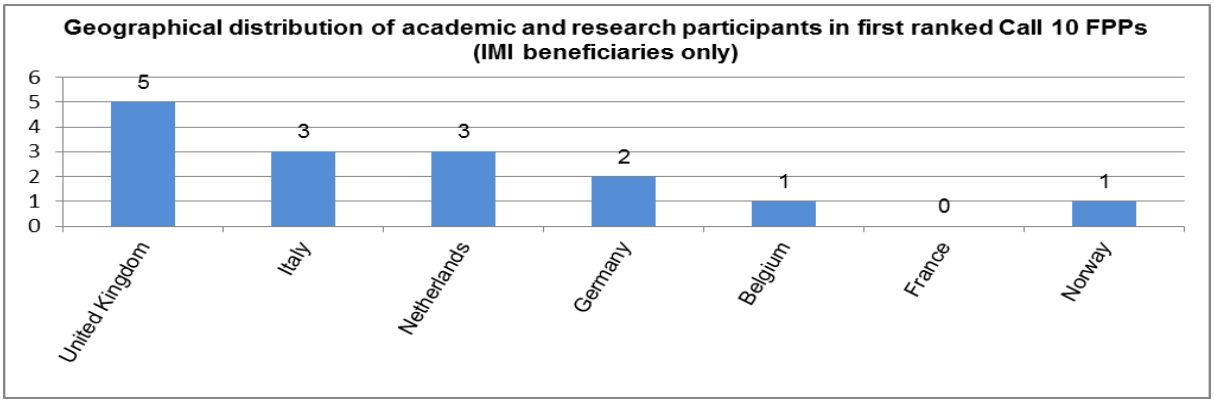
4.2 Implementation of IMI 1 JU Call 10

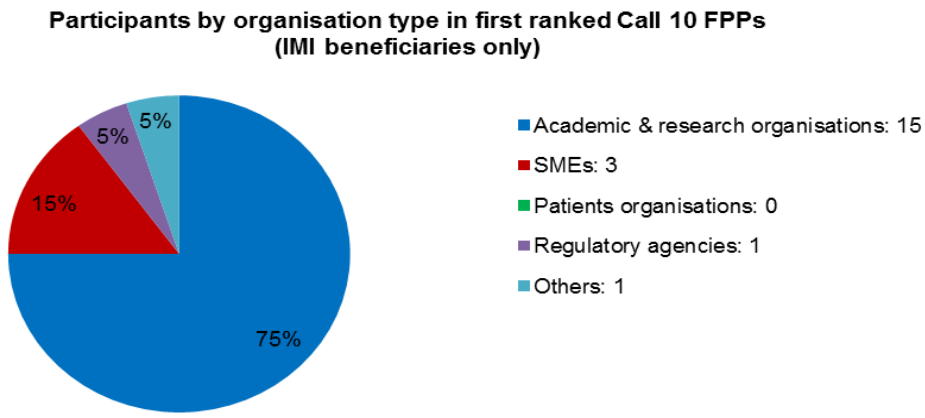
The IMI 1 JU 10th Call for proposals consisted of a single topic -immunological assay standardisation and development for use in assessments of correlates of protection for influenza vaccines. It was launched on 29 October 2013. The deadline for submission of EoIs was 28 January 2014. Two EoIs were received by the submission deadline, one of which was eligible for evaluation. Analysis of the eligible applicants revealed that 25 legal entities took part; of which 18 (72%) were academic and non-profit research organisations and 3 (12%) were SMEs.

The in-house evaluation of the EoIs was conducted by a panel of independent experts mainly from Europe. The first ranked EoI consortium merged with the EFPIA consortium and was invited to submit an FPP by 18 June 2014. The FPP evaluation was successfully completed during July 2014 with the expert panel recommending that the consortium progress to the negotiation stage. The negotiations for the IMI 1 JU Call 10 project will be concluded in early 2015. The project is scheduled to begin in the first quarter of 2015.

The key figures of the participants in the IMI 1 JU Call 10 full project proposal are presented below.







The 3 SMEs are from France, Netherlands and UK.

4.3 Implementation of IMI 1 JU Call 11

The IMI 1 JU 11th Call for proposals included the following topics:

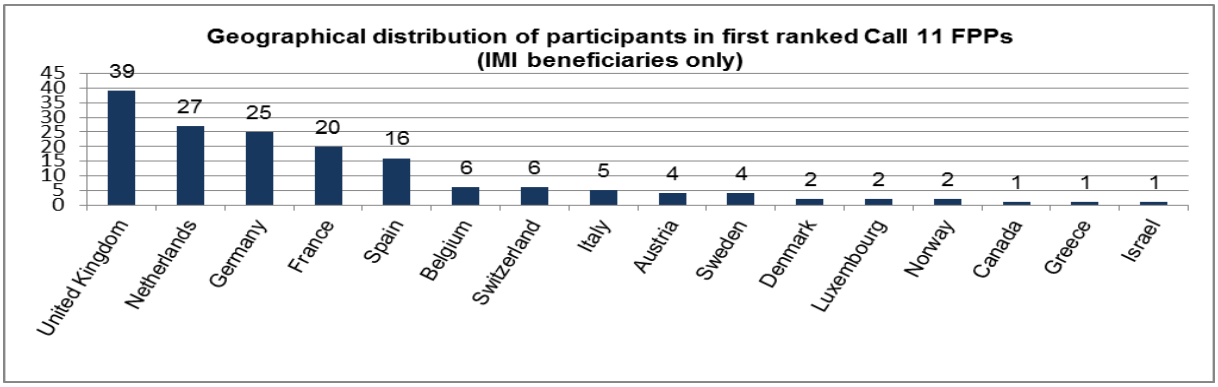
- Applied public-private research enabling osteoarthritis clinical headway (APPROACH);
- European platform to facilitate proof of concept for prevention in Alzheimer's disease (EPOC-AD);
- Blood-based biomarker assays for personalised tumour therapy: value of latest circulating biomarkers;
- Zoonoses anticipation and preparedness initiative (ZAPI);
- Generation of research tools to enable the translation of genomic discoveries into drug discovery projects;
- Epidemiology research and development of novel systemic antibacterial molecules against healthcare-associated infections due to clinically challenging gram-negative pathogens;
- ND4BB Subtopic 6A: Epidemiology research and clinical development of a novel bispecific IgG antibody, BiS4αPa, for the prevention of serious *Pseudomonas aeruginosa* disease;
- 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;
- ND4BB Topic 7: Development of novel inhaled antibiotic regimens in patients with cystic fibrosis and patients with non- cystic fibrosis bronchiectasis;
- Ecorisk prediction (ERP).

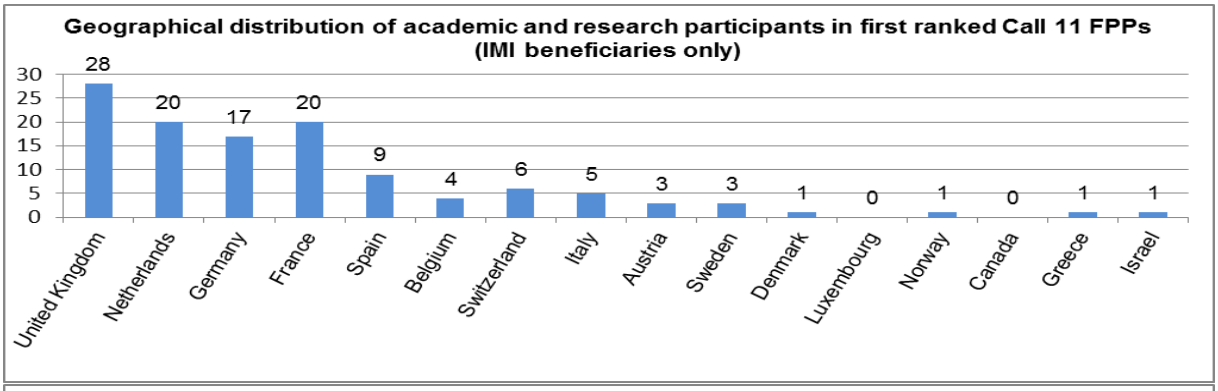
The IMI 1 JU 11th Call for proposals was launched on 11 December 2013. The deadline for submission of EoIs was 8 April 2014. 36 EoIs were received by the submission deadline, 32 of which were eligible for evaluation. Analysis of the eligible applicants revealed that 392 legal entities took part; of which 254 (65%) were academic and non-profit research organisations and 86 (22%) were SMEs. On average, there were 12.3 entities per EoI.

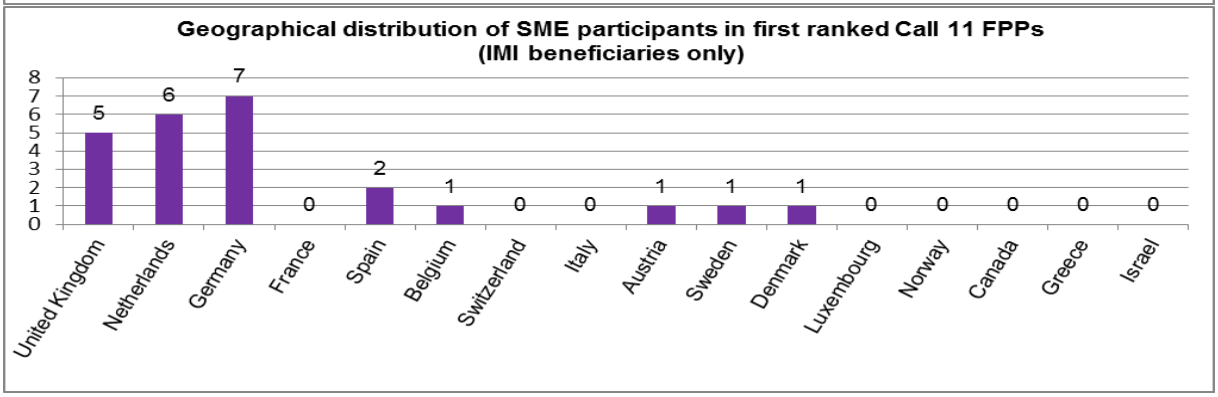
The in-house evaluation of the EoIs was conducted by a panel of independent experts mainly from Europe. The first ranked EoI consortia merged with the EFPIA consortium and were invited to submit an FPP by 9 September 2014. By that deadline, 7 of the 8 consortia had submitted FPPs. The consortium for topic 7 requested an extension of the submission period and, following an IMI Governing Board decision, the submission deadline for Topic 7 was extended to 3 November 2014. The FPP evaluation for the 7 remaining topics was successfully completed during October 2014 with the expert panels recommending to the IMI JU Governing Board that the consortia progress to the negotiation stage.

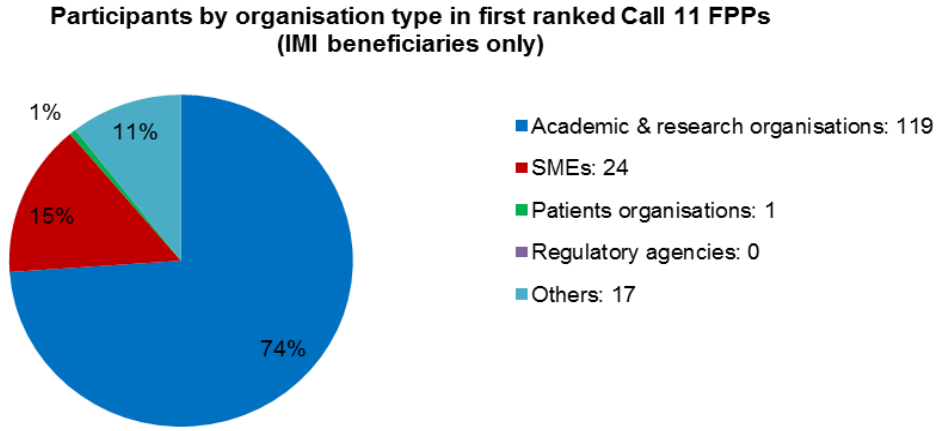
The negotiations for six of the seven remaining projects were concluded in December 2014. The FPP evaluation for Topic 7 was successfully completed during December 2014 with the expert panel recommending to the IMI JU Governing Board that the consortium progress to the negotiation stage. The Grant Agreement signatures for six of the eight projects took place in December 2014. The Grant Agreement signatures for the remaining two topics (Topic 1, Topic 7) will be signed in early 2015.

The key figures of the applicants in all of the IMI 1 JU Call 11 FPPs are presented below:









Call 11 projects for which Grant Agreements were signed in 2014 and their budget (EUR)

IMI Project	EFPIA + IMI Funding	EFPIA in kind contribution	IMI Funding	Academic & Research	SME	Patient Org.	Other (special clause 11)[11]
iPiE	8 698 230	5 698 230	3 000 000	1 997 523	815 800	0	186 677
EPAD	56 084 986	30 204 986	25 880 000	22 974 901	2 664 099	241 000	0
COMBACTE -MAGNET	167 002 413	91 662 413	75 340 000	71 624 969	280 000	0	3 435 031
ZAPI	19 413 688	9 875 000	9 538 688	7 843 988	1 694 700	0	0
ULTRA-DD	42 864 981	21 664 981	21 200 000	21 200 000	0	0	0
TOTAL	294 064 298	159 105 610	134 958 688	125 641 381	5 454 599	241 000	3 621 708

[11] *Others* are the participants which are not eligible and not an EFPIA Member Company (Special Clause 11) from Grant Preparation Form A2.2.

Number of participants per project:

IMI Project	EU Beneficiaries	EFPIA Companies	Others (special clause 11)
iPiE	12	12	1
EPAD	20	13	2
COMBACTE-MAGNET	33	5	0
ZAPI	17	3	0
ULTRA-DD	4	4	2
TOTAL	86	37	5

4.4 Implementation of ENSO-3 Call

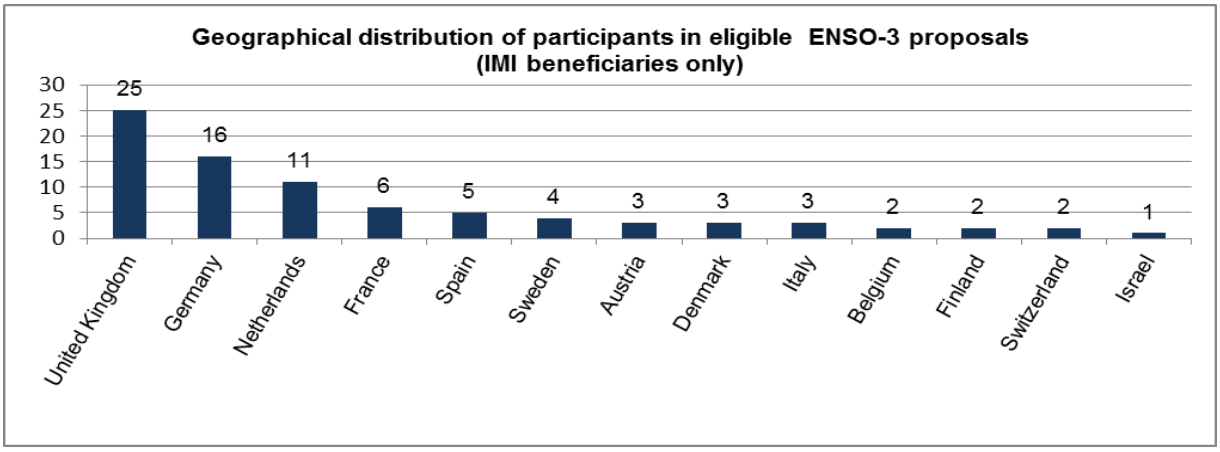
The ENSO-3 Call was initially launched on 20 August 2012 as a continuous submission call with several deadlines. The 3rd ENSO Call deadline was 15 December 2013. By the submission deadline, 8 applications had been submitted, all 8 were found eligible.

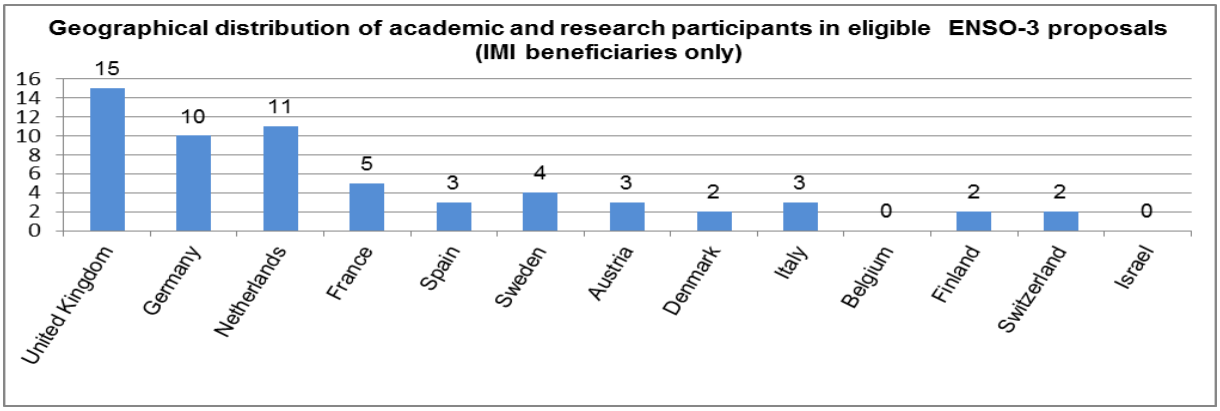
Projects submitting an application were:

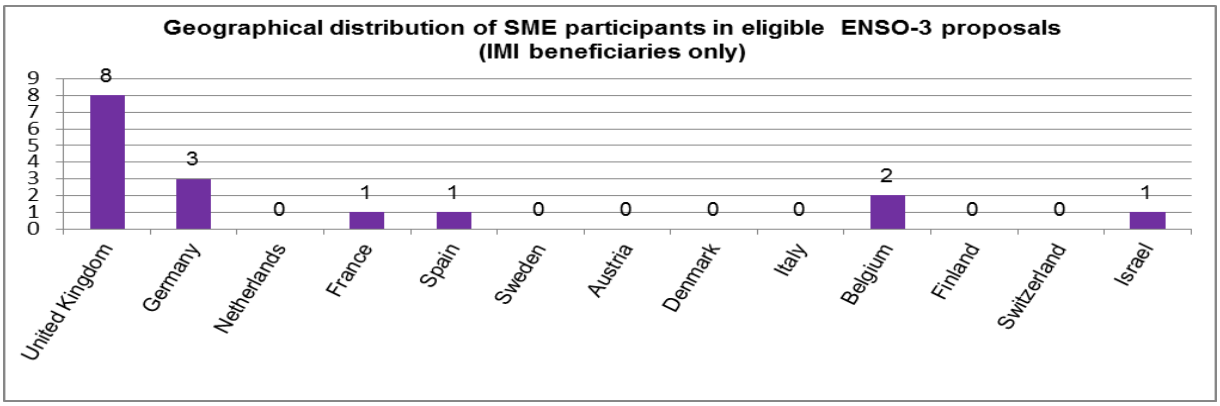
- SUMMIT
- EUROPAIN
- U-BIOPRED
- DDMoRe
- Open PHACTS
- ONCOTRACK
- EU-AIMS
- EMTRAIN/SafeSciMET/EU2P combined application.

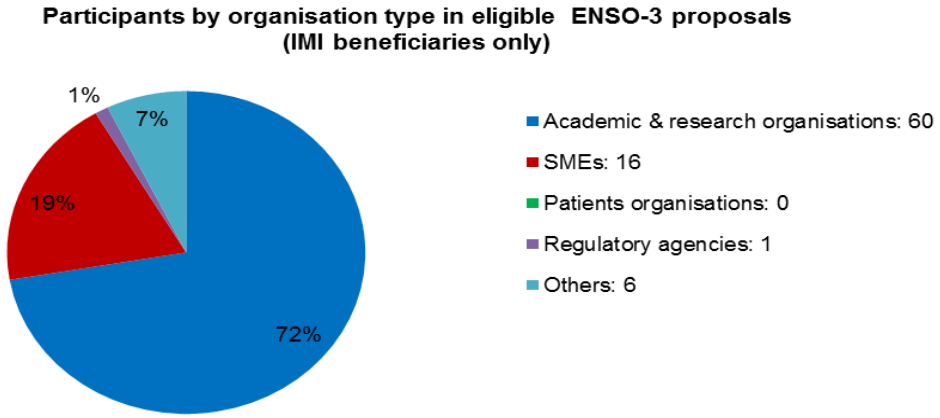
The evaluation of the proposals was successfully completed by a panel of independent experts in January and February 2014 with the expert panel recommending to the IMI JU Governing Board that all proposals progress to the negotiation stage. The Grant Agreement amendments for all projects were signed in 2014.

The key figures of the participants in the eligible ENSO-3 proposals are presented below.









The ENSO-3 participants and information on the funding (in EUR) are included below:

IMI Project	Organisation Legal Name	IMI Funding	EFPIA in kind	Type	Country
EUROPAIN	H. Lundbeck A/S *	0	30 000	EFPIA	Denmark
EUROPAIN	Neuroscience Technologies Ltd	12 000	0	SME	UK
U-BIOPRED	Arachos Pharma Limited	36 900	0	SME	UK
EMTRAIN	PharmaTrain Federation	10 1000	0	Non-profit	Switzerland
DDMoRe	Takeda Development Centre Europe	0	50 0000	EFPIA	UK
Open PHACTS	ALMIRALL S.A.	0	14 8654	EFPIA	Spain
Open PHACTS	SciBite Limited	89 414	0	SME	UK
EU-AIMS	Islensk Erfdagreining ehf	0	50 3564	EFPIA	Iceland

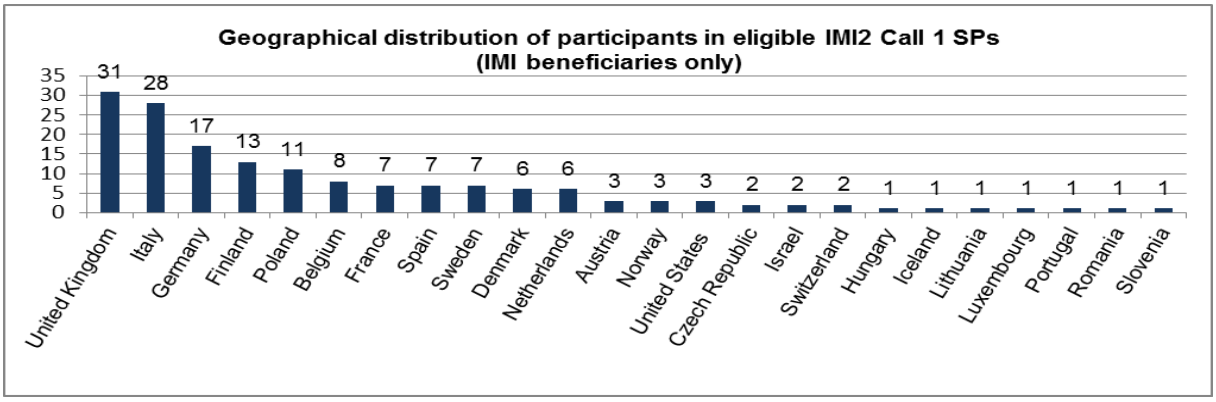
4.5 Launch of IMI 2 JU Call 1

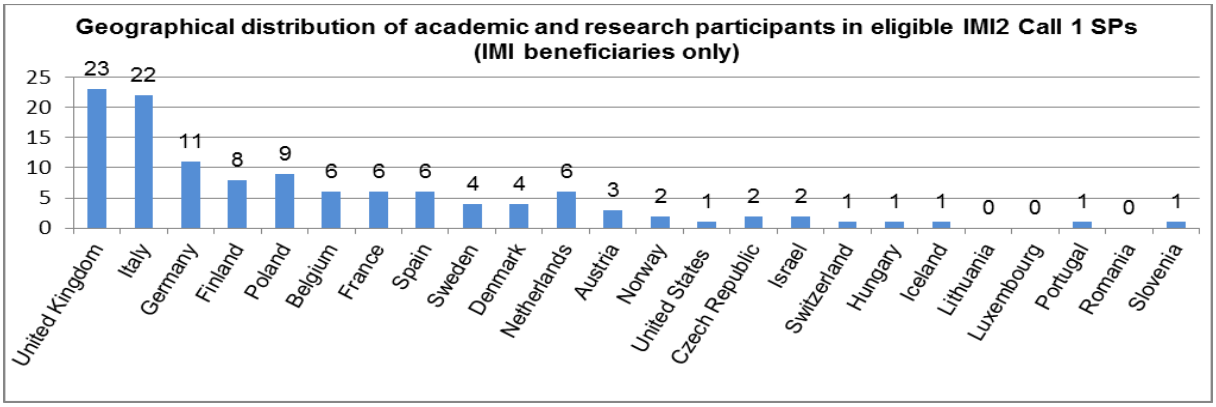
The IMI 2 JU Call 1 included following topics:

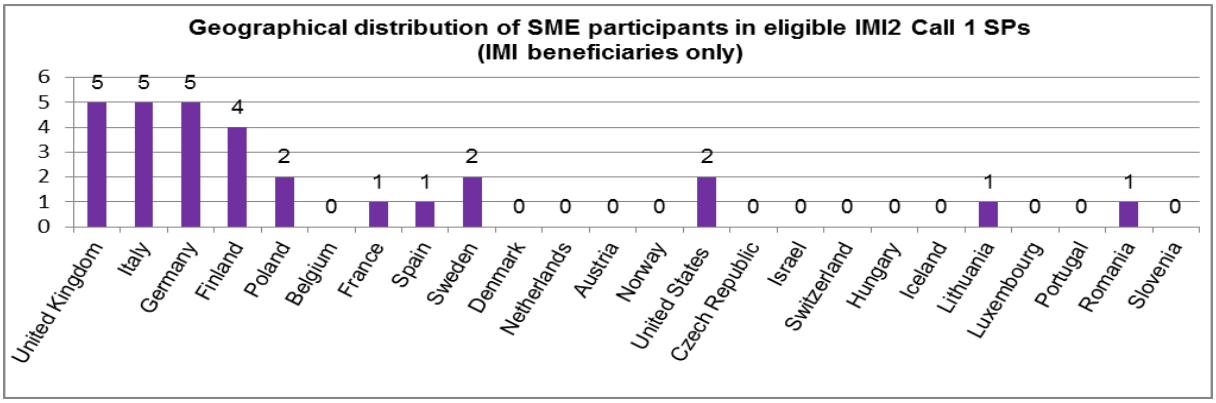
- Translational approaches to disease modifying therapy of type 1 diabetes mellitus (T1DM);
- Discovery and validation of novel endpoints in dry age-related macular degeneration and diabetic retinopathy.

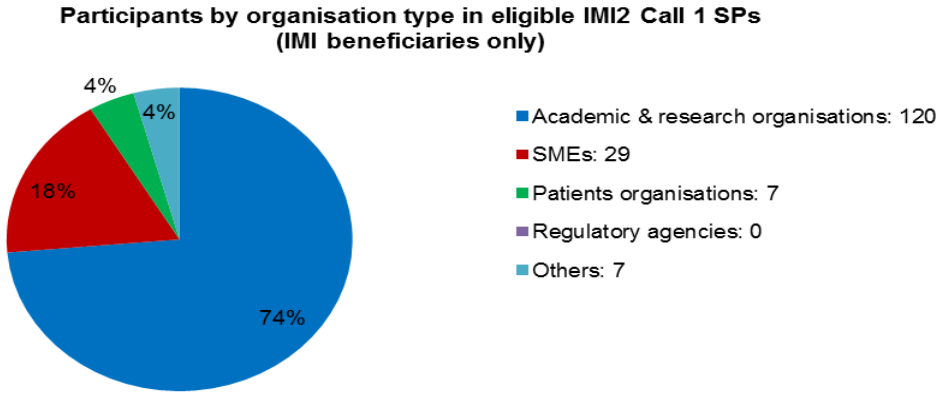
The EFPIA & IMI 2 JU Associated Partners in kind contribution committed to the IMI 2 JU Call 1 projects is EUR 24.6 million and the IMI 2 JU contribution is also EUR 24.6 million. The final text of the IMI 2 JU Call 1 topics was sent for consultation on 23 May 2014, and following IMI 2 JU Governing Board approval, the IMI 2 JU Call 1 for proposals was launched on 9 July 2015. The deadline for submission of Short Proposals (SPs) was 12 November 2014. The launch of IMI 2 JU Call 1 was announced to the media with a press release entitled '*EUR 3.3 billion IMI 2 JU programme to pave the way for next generation treatments, starting with diabetes & eye diseases*'.

Webinars were held in July and September 2014 to present the topics to potential applicants. 14 SPs were received by the submission deadline, 11 of which were eligible for evaluation. Analysis of the eligible applicants revealed that 163 legal entities took part; of which 120 (74%) were academic and non-profit research organisations and 29 (18%) were SMEs. On average, there were 14.8 entities per SP. The in-house evaluation of the SPs was conducted by a panel of independent experts mainly from Europe. The first ranked SP consortia will be invited to merge with the industry consortia and submit a Full Proposal (FP) by 14 April 2015.









4.6 Launch of IMI 2 JU Call 2

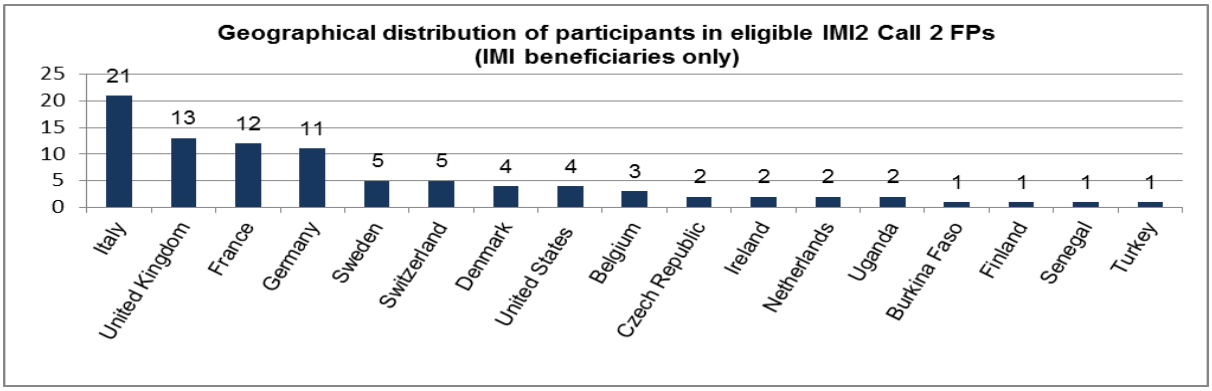
The IMI 2 JU Call 2 for proposals included following topics:

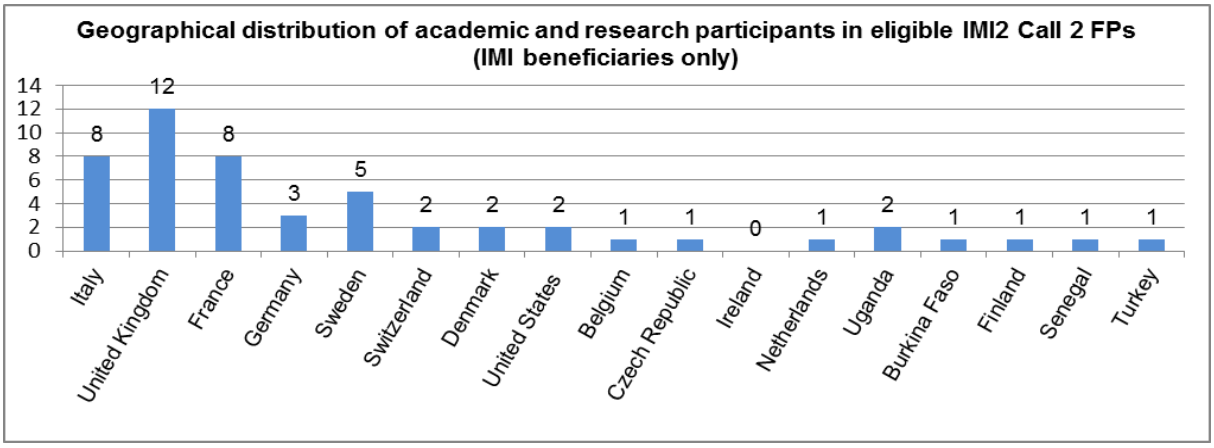
- Vaccine development Phase I, II, and III;
- Manufacturing capability;
- Stability of vaccines during transport and storage;
- Deployment and compliance of vaccination regimens;
- Rapid diagnostic tests.

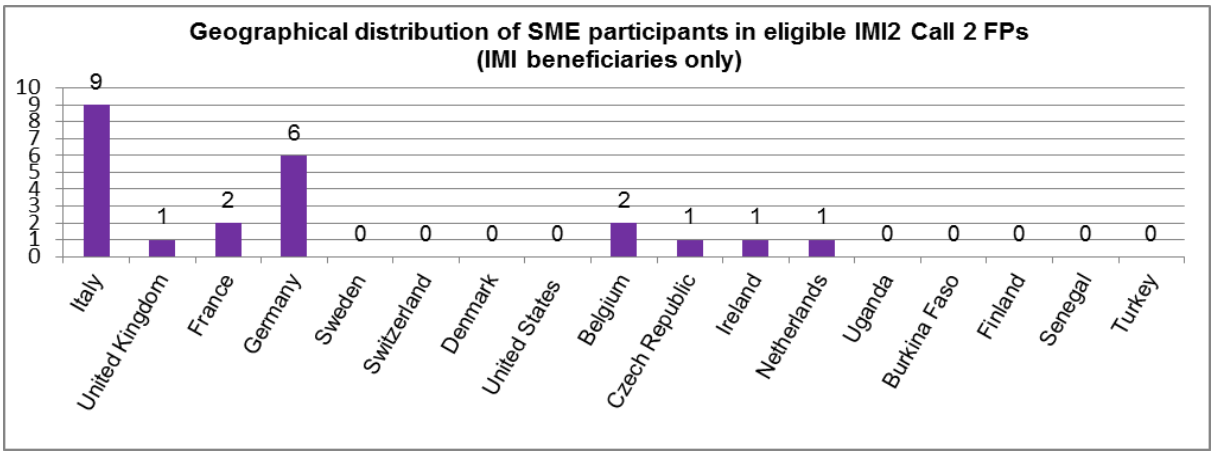
The EFPIA in kind contribution committed to the IMI 2 JU Call 2 projects was EUR 101.9 million and the IMI 2 JU contribution was up to EUR 116.6 million. The final text of the IMI 2 JU Call 2 topics was sent for consultation on 31 October 2014, and following IMI 2 JU Governing Board approval, the IMI 2 JU Call 2 for proposals was launched on 6 November 2013. The deadline for submission of FPs was 1 December 2014. The launch of the IMI 2 JU Call 2 was announced to the media with a press release entitled '*Innovative Medicines Initiative launches Ebola+ programme*.' Webinars were held in November 2014 to present the topics to potential applicants. 19 FPs were received by the submission deadline, 14 of which were eligible for evaluation. Analysis of the eligible applicants revealed that 81 legal entities took part; of which 50 (62%) were academic and non-profit research organisations and 23 (28%) were SMEs. On average, there were 5.8 entities per FP.

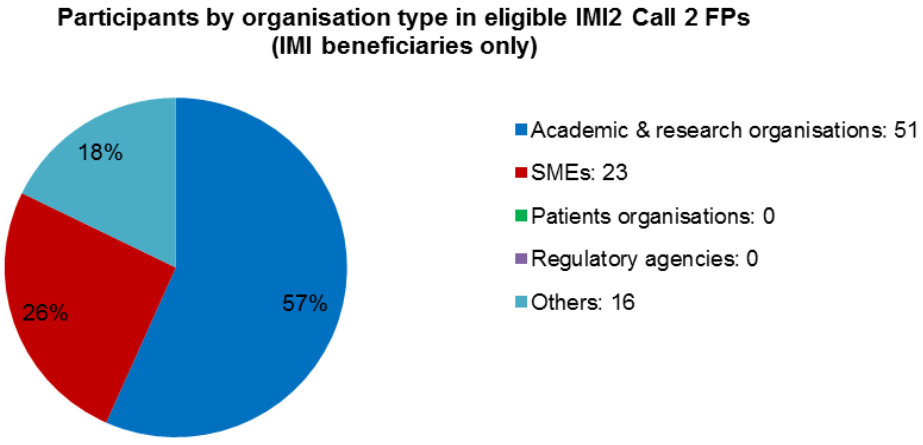
The FP evaluation was successfully completed during December 2014 with the expert panel recommending to the IMI 2 JU Governing Board that 8 consortia progress to the grant preparation stage. The grant preparation for the 8 selected projects will be concluded in early 2015.

The key figures of the participants in the IMI 2 JU Call 2 FPs are presented below:


Geographical distribution of participants in eligible IMI2 Call 2 FPs
(IMI beneficiaries only)
25
20
15
10
5
0
21
13
12
11
5
5
4
4
3
2
2
2
2
1
1
1
1
Italy
United Kingdom
France
Germany
Sweden
Switzerland
Denmark
United States
Belgium
Czech Republic
Ireland
Netherlands
Uganda
Burkina Faso
Finland
Senegal
Turkey


Geographical distribution of academic and research participants in eligible IMI2 Call 2 FPs
(IMI beneficiaries only)
14
12
10
8
6
4
2
0
8
12
8
3
5
2
2
2
1
1
0
1
2
1
1
1
1
Italy
United Kingdom
France
Germany
Sweden
Switzerland
Denmark
United States
Belgium
Czech Republic
Ireland
Netherlands
Uganda
Burkina Faso
Finland
Senegal
Turkey


Geographical distribution of SME participants in eligible IMI2 Call 2 FPs
(IMI beneficiaries only)
10
9
8
7
6
5
4
3
2
1
0
9
1
2
6
0
0
0
0
2
1
1
1
0
0
0
0
0
Italy
United Kingdom
France
Germany
Sweden
Switzerland
Denmark
United States
Belgium
Czech Republic
Ireland
Netherlands
Uganda
Burkina Faso
Finland
Senegal
Turkey


Participants by organisation type in eligible IMI2 Call 2 FPs
(IMI beneficiaries only)
18%
26%
57%
Academic & research organisations: 51
SMEs: 23
Patients organisations: 0
Regulatory agencies: 0
Others: 16

4.7 Launch of IMI 2 JU Call 3

The IMI 2 JU Call 3 for proposals included following topics:

- Remote assessment of disease and relapse-CNS
- Assessing risk and progression of prediabetes and type 2 diabetes to enable disease modification
- Linking clinical neuropsychiatry and quantitative neurobiology
- The consistency approach to quality control in vaccine manufacture
- Pertussis vaccination research
- Patient Advocacy Knowledge Repository to enable Patient Focused Medicine Development.

The EFPIA & IMI 2 JU Associated Partners in kind contribution committed to the IMI 2 JU Call 3 projects is EUR 56.4 million and the IMI 2 JU contribution is also EUR 56.4 million. The final text of the IMI 2 JU Call 3 topics were sent for consultation on 7 October 2014, and following the IMI 2 JU Governing Board approval, the IMI 2 JU Call 3 for proposals was launched on 17 December 2014. The deadline for submission of SPs is 24 March 2015. The launch of the IMI 2 JU Call 3 was announced to the media with a press release entitled '*IMI launches EUR 115 million Calls for proposals to develop vaccines & medicines of the future'.*

4.8 Launch of IMI 2 JU Call 4

The IMI 2 JU Call 4 for proposals included a single topic for a coordination and support action (CSA):

- Enabling platform on medicines adaptive pathways to patients.

The EFPIA in kind contribution committed to the IMI 2 JU Call 4 projects is EUR 1.13 million and the IMI contribution is also EUR 1.13 million. The final text of the IMI 2 JU Call 4 topic was sent for consultation on 7 October 2014, and following the IMI 2 JU Governing Board approval, the IMI 2 JU Call 4 for proposals was launched on 17 December 2014. The deadline for submission of SPs is 11 February 2015. The launch of the IMI 2 JU Call 4 was announced to the media under the same press release as the IMI 2 JU Call 3 entitled *'IMI launches EUR 115 million Calls for proposals to develop vaccines & medicines of the future'.* A webinar was held on 17 December 2014 to present the topic to potential applicants.

5 COMMUNICATION AND NETWORKING

5.1 Strategy and key messages

In 2014, the priorities for IMI JU's communication efforts were:

- updating the IMI communication strategy, corporate identity, messages and materials to reflect the launch of the IMI 2 JU programme;
- promoting the first IMI 2 JU Calls for proposals.

Updates to the communication strategy and messages take into account new features in IMI 2 JU such as the concept of Associated Partners, the inclusion of other sectors, and the expansion of funding eligibility to new groups. It also addresses the greater emphasis of the IMI 2 JU programme on speeding up patient access to new treatments, and on personalised healthcare. In collaboration with founding members of IMI, the communication team also developed a corporate mission, vision and values for IMI.

2014 also marked the launch of a new, fresher version of the IMI logo and the rollout of a new corporate and visual identity. The lettering of the new logo is bigger, to make it more visible, and the loop around the 'IMI' is now complete (something that many people feel reflects IMI JU's greater openness towards other healthcare sectors). The new visual identity also includes a broad colour palette, images and templates, all of which should ensure that all IMI materials have a common 'look and feel'.

IMI JU's communication activities are a team effort, and IMI JU's communication successes in 2014 were considerably boosted by the efforts of many IMI staff, the European Commission and EFPIA, the SRG, Scientific Committee, the projects themselves as well as external contractors.

5.2 Improving IMI JU outreach

Events

Event	Date & location	Outcome
IMI 1 JU Call 11 webinars Webinars held on all Call topics plus IMI JU's rules and procedures	8 January-5 February 2014, online	Over 900 registrations Opportunity for potential applicants to learn more about topics plus rules and procedures Networking among participants
Investing in Excellence SME networking event Organised jointly by IMI and International Venture Club Presentations on SME funding opportunities Extensive networking	18 February 2014 Brussels	Over 120 participants (including venture capitalists, corporate investors, health entrepreneurs, SMEs) Promotion of IMI SMEs as leading innovators Participant feedback positive (majority of survey respondents found event useful and said it met their expectations)

Event	Date & location	Outcome
DIA EuroMeeting IMI stand at exhibition IMI networking dinner with key stakeholders IMI projects EUPATI, SAFE-T and GetReal presented in conference sessions EMTRAIN project stand at exhibition	25-27 March 2014 Vienna	Promotion of IMI towards approx. 3 000 high-level representatives from industry and other sectors Networking
IMI-JDRF Diabetes Patient Focus meeting Event organised jointly by IMI and JDRF Goal of meeting was to identify research & development (R&D) gaps and challenges in the diabetes area from the patient perspective	20 May 2014 Brussels, online	Over 100 attendees in person plus 50 via the live webstream, including patients, carers, policy-makers, industry decision-makers, SMEs, academia and researchers Extensive opportunities for dialogue between patients and researchers in industry and academia
IMI Stakeholder Forum Morning: focus on IMI stem cell projects Afternoon: discussion on IMI 2 JU	21 May 2014 Brussels, online	Around 280 attendees in person plus 200 via the live webstream Highly positive feedback (overall event rated 'good' or 'excellent' by 88% of survey respondents) Press coverage
JTI **IMI 2 JU** Launch Event Organised by European Commission with input from all JTIs plus industry associations Half-day conference plus exhibition	9 July 2014 Brussels	High-level speakers included several commissioners, ministers and MEPs plus industry CEOs High visibility towards senior policymakers and opinion leaders Press coverage
IMI 2 JU-**C**all 1 webinars Webinars held on both Call topics plus the new IMI 2 JU rules and procedures	11 July – 3 September 2014 Online	Over 500 registrations Opportunity for potential applicants to learn more about topics plus rules and procedures Networking among participants
IMI 2 JU Open Info Day Introduction to rules and procedures of IMI 2 JU Overview of current and planned topics Networking opportunities	30 September 2014 Brussels, online	Over 290 attendees in person and online Pre-event networking possible via registration tool Use of 'elevator pitches' to promote networking on the day 81% of survey respondents found the Info Day 'very good' or 'good'

Event	Date & location	Outcome
IMI 2 JU Launch Event Event designed to mark start of IMI 2 JU programme and position IMI as a successful PPP among key stakeholders	29 September 2014 Brussels	Strong attendance, including many high-level people from European Commission, industry, and others
Ebola webinars Webinars covered Call topics and special Call procedure	12-17 November online	Around 200 registrations Opportunity for potential applicants to learn more about topics plus rules and procedures Networking among participants
Bringing health-related life science and technology sectors into IMI 2 JU Meeting to promote discussion between IMI and companies and organisations from other healthcare sectors interested in working with IMI	26 November 2014 Brussels	Around 40 attendees from a range of organisations and sectors Networking among participants
C-Path and IMI 2 JU 2nd Annual Meeting Follow up of successful joint meeting held in March 2013. Theme: 'Accelerating the development of drugs, diagnostics, and devices: partnerships to expand the precompetitive space'	3 December 2014 Bethesda, Maryland (US), online	Around 100 attendees from a range of organisations and sectors Lively discussions appreciated by audience
Webinars on IMI 2 JU Calls 3 and 4 Webinars cover Call topics and special Call procedure	17 December 2014 - 26 January 2015, online	Opportunity for potential applicants to learn more about topics plus rules and procedures Networking among participants

In addition to the events listed above, many States Representatives Group members and other national organisations organised info days on IMI 2 JU throughout the Member States. IMI JU supported these efforts by sending speakers and materials and promoting the events via the website, newsletter, and other channels.

- The Netherlands – 3 July – Session on IMI JU during the info day 'Research & Innovation for a Healthy Europe' in The Hague;
- Germany – 10 July – IMI 2 JU Info Day in Frankfurt;
- Spain – 10 July – Session on IMI JU during JTI launch day in Madrid;
- Austria - 16 July - Info session on IMI 2 JU in Vienna;
- Finland – 26 August – IMI 2 JU Info Day in Helsinki ;
- Denmark (in collaboration with Sweden) – 28 August – IMI 2 JU launch event in Copenhagen;
- France - 9 September - IMI JU info event in Paris;
- Lithuania - 11 September - Workshop on IMI and Horizon 2020 during Life Sciences Baltics conference;
- Poland - 16 September – IMI JU info event in Warsaw;
- Hungary - 25 September – IMI JU info event in Budapest;
- Czech Republic - 6 October - IMI 2 JU Info Day in Prague;
- Spain - 26 November - IMI 2 JU Info Day in Barcelona;
- Romania - 2 December - IMI 2 JU Info Day in Bucharest;
- Norway (in collaboration with Sweden) - 16 December - IMI 2 JU info day and networking event in Oslo.

Promoting IMI JU's Calls for proposals

IMI started 2014 by continuing with the promotion of IMI 1 JU Call 11, which was launched at the end of 2013. IMI subsequently launched IMI 2 JU Calls 1, 2, 3 and 4 during 2014. Calls were promoted via the following channels:

- IMI website
- Press
- Webinars
- IMI Newsletter
- Social media (Twitter, LinkedIn)
- Flyers
- Events organised by others (e.g. SRG members)
- Direct e-mails to stakeholder organisations (e.g. academic societies, patient groups) and relevant individuals
- IMI events
- Presentations by IMI staff at external events.

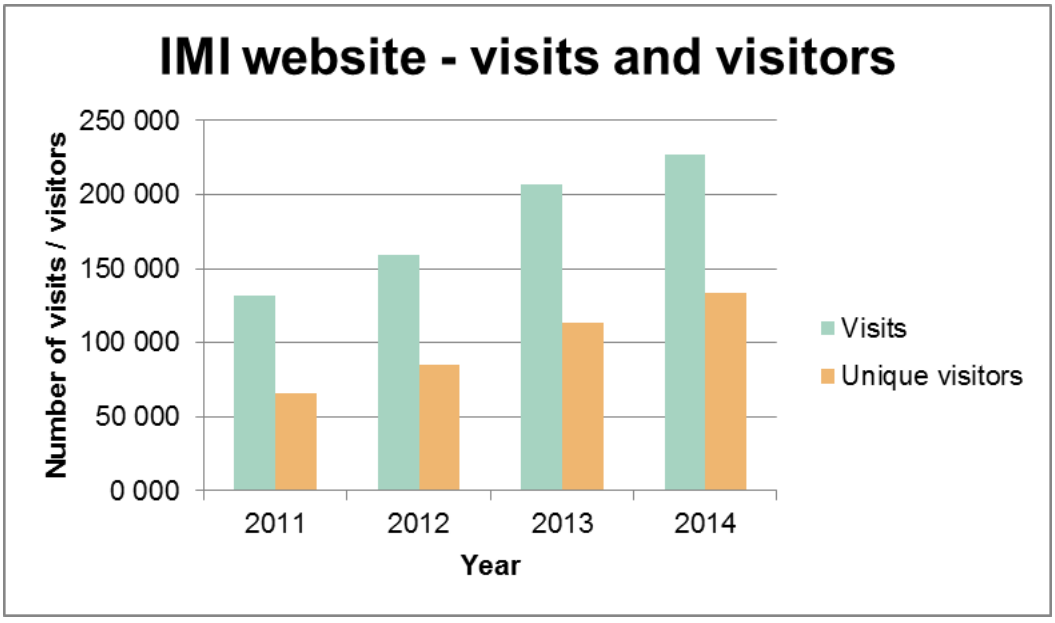
Promoting IMI JU's project successes

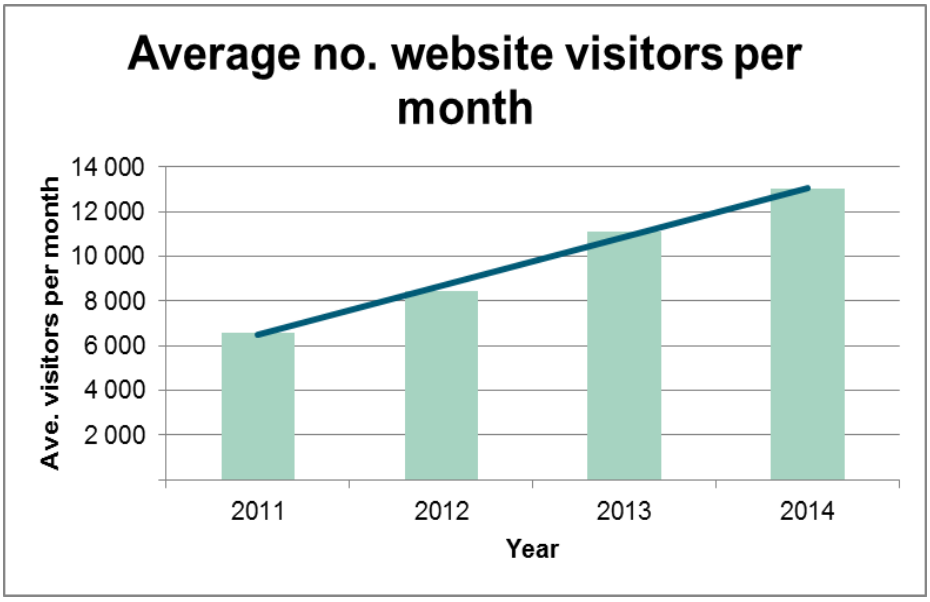
The Communications team promotes the successes of IMI projects through a variety of channels:

- 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, and the average number of visitors per month for 2014 was 13 035.





Infodesk

In 2014, the IMI Infodesk email address, which is managed by the Communications team, received 690 queries. The Infodesk facilitates interaction with stakeholders on key issues and helps to raise awareness of IMI activities and procedures.

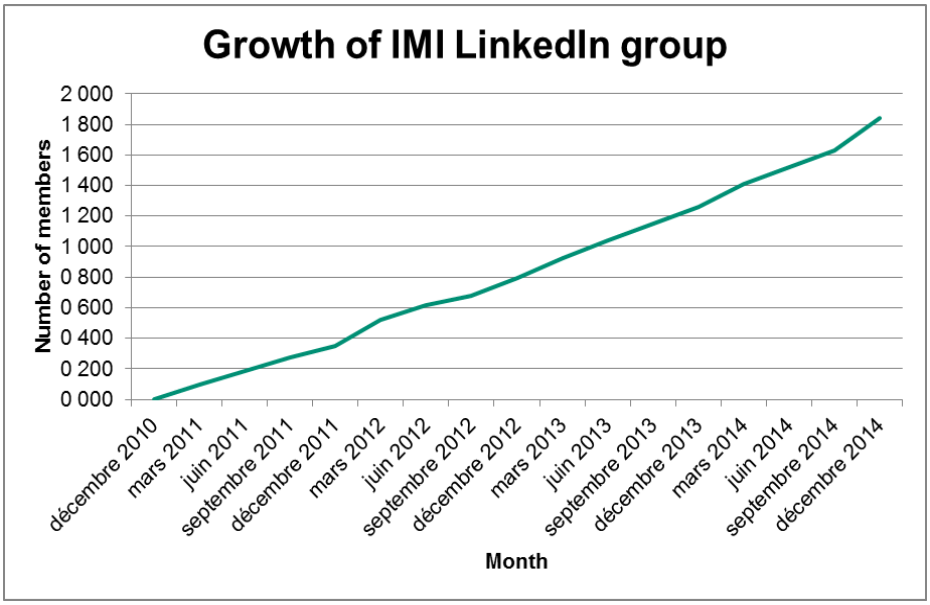
IMI Newsletter

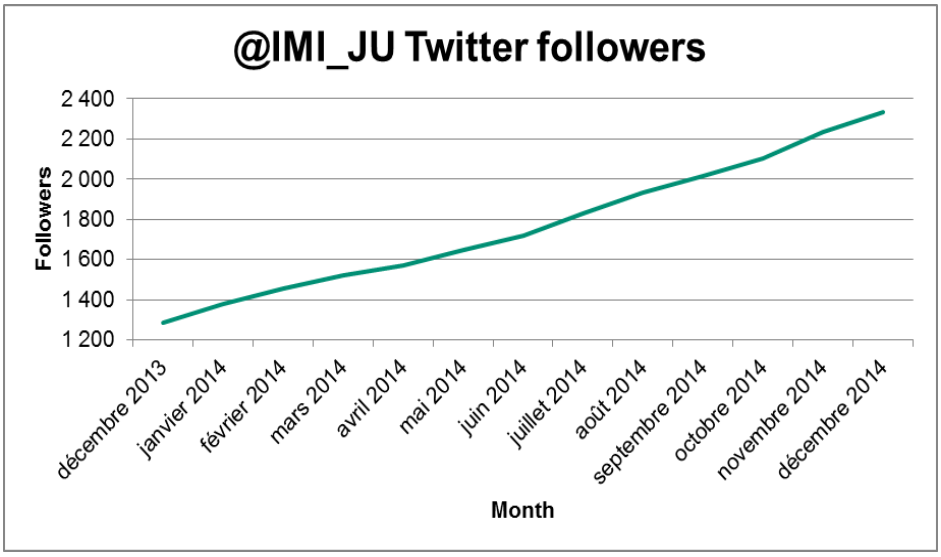
IMI sent out 11 newsletters and one newsflash in 2014, covering Call launches, new projects, IMI event announcements, news on IMI reports and publications, and news from the projects. At the end of 2014, there were over 4 300 newsletter subscribers.

Social Media

IMI JU's social media reach continues to expand. By the end of 2014, IMI JU had 2 332 followers on Twitter and 1 840 members in its LinkedIn Group. IMI JU uses social media to promote its activities and those of its projects, and to provide live quotes from events.

Months in graphs below:





Media relations

In collaboration with its public relations (PR) agency, Media Consulta, IMI JU updated its press list to include more journalists from across Europe. In addition to sending out 15 press release (on Calls for proposals, new projects, events, and changes in IMI governance), IMI JU invited journalists to key events and had a number of interviews with a diverse range of outlets. Media monitoring by Media Consulta reveals that IMI JU achieved coverage in almost all EU Member States and has appeared in a number of influential news outlets. Analysis of the articles reveals that the tone of coverage is generally neutral or positive, with little negative coverage.

The following list sets out some of the most significant press articles mentioning IMI JU in 2014.

- *Nature Medicine* (UK), 7 January 2014
  Infectious disease leads in first phase of Europe's IMI effort
- TV Ciência (Portugal), 15 January 2014
  Cientista portuguesa nomeada para presidir Comité Científico da Iniciativa Medicamentos Inovadores da UE (Portuguese scientist appointed as president of the EU Innovative Medicines Initiative)
- TV2 (Denmark), 18 February 2014
  Ny antibiotika skal bekæmpe resistente bakterier (New antibiotics to combat resistant bacteria)
- *El Pais* (Spain), 18 March 2014
  Curar las enfermedades de 'House' (Curing 'House' diseases)
- *Washington Post* (US), 7 April 2014
  What we need to do about antibiotic-resistant infections
- *The Economist* (UK), 7 April 2014
  Decentralising drug research
- Radio Rai (Italy), 25 May 2014
  IMI Stakeholder Forum 2014
- RTBF – Matière Grise (Belgium), 3 June 2014
  Le combat des scientifiques contre les bactéries mortelles (The fight of scientists against deadly bacteria)
- *Financial Times* (UK), 2 July 2014
  Keep medicine out of the dark ages (editorial)
- *The Independent* (UK), 6 July 2014
  The microbe is mightier than the market (comment)
- *Nature Reviews Drug Discovery* (UK), 1 October 2014
  Momentum builds around new antibiotic business models
- *Corriere della Sera* (Italy), 7 October 2014
  Contrastare l'invecchiamento: l'obiettivo di un progetto italiano (Fighting ageing: the objective of an Italian project)
- *De Morgen* (Belgium), 27 October 2014
  UAntwerpen mee in de bres tegen resistente antibiotica (UAntwerpen joins the fights against antibiotic resistance)

- Reuters (international), 6 November 2014
  EU scheme commits $350 million for research on Ebola vaccines, tests
- ORF.at (Austria), 6 November 2014
  Ebola-Serum: 280 Mio. Euro von EU und Pharmafirmen (Ebola serum: 280 million euros from EU and pharmaceutical companies)
- *Le Monde* (France), 17 November 2014
  Antibiotiques: trop de consommation, pas assez de nouvelles molécules (Antibiotics: Too much consumption and not enough new drugs)

Publications

IMI JU produced a new brochure which was published in time for inclusion in participant packs at the Stakeholder Forum in May 2014. IMI JU subsequently updated the content of the brochure as well as the layout to reflect the launch of the IMI 2 JU programme and the new IMI JU visual identity. This updated brochure was published in November 2014. Both versions of the brochure were distributed widely at IMI JU and at external events. IMI JU also produced a general two-page flyer outlining the organisation's goals and activities, as well as flyers on individual Calls for proposals.

Another important output in 2014 was the publication of a video on IMI JU's autism project, EU-AIMS, which has already been viewed over 1 000 times.

In addition, IMI JU and its stakeholders wrote a number of papers published in academic journals:

- *Nature Reviews Drug Discovery*, published online 12 December 2014
  Goldman, M., Seigneuret, N. & Eichler, H.-G. (2014) The Innovative Medicines Initiative: an engine for regulatory science
- *Journal of Health Policy and Outcomes Research*, Vol. 2, pp. 12-17
  Wittelsberger, A. & Goldman, M. (2014) Public-private collaboration to advance the development and benefit-risk assessment of vaccines: The Innovative Medicines Initiative
- *New England Journal of Medicine*, Vol. 370, pp. 2163-2165
  Kush, R. & Goldman, M. (2014) Fostering responsible data sharing through standards
- *Nature Reviews Drug Discovery* , Vol.13, pp. 239–240
  Marti-Solano, M., Birney, E., Bril, A. , Della Pasqua, O., Kitano, H., Mons, B., Xenarios, I. & Sanz, F. (2014) Integrative knowledge management to enhance pharmaceutical R&D
- *Marquette Intellectual Property Law Review*, Vol. 18 (1), pp. 31-32
  Laverty, H. & Poinot, P. (2014) IP policy forum: Intellectual property rights (IPR) in collaborative drug development in the EU: Helping a European public-private partnership deliver - the need for a flexible approach to IPR

5.3 Support to IMI JU's Governance and Consultative bodies

5.3.1 Governing Board

Under IMI 1 JU, the Governing Board held two meetings (on 10 March 2014 and on 10 June 2014) with the following main items on the agenda: the Annual Activity Report 2013 and the first IMI 2 JU Annual Work Plan for 2014 (updating the IMI JU Annual Implementation Plan for 2014). On 7 July 2014, during its first meeting of IMI 2 JU the Governing Board adopted its own Rules of procedure, the IMI 2 JU Financial rules, and endorsed the Strategic Research Agenda for IMI 2 JU.

The members also approved the mandate of the Strategic Governing Groups (SGGs) and the setting up of the first 5 SGGs, the specific criteria and the selection process for the composition of the IMI 2 JU Scientific Committee, the IMI 2 JU Annual Work Plan 2014 (revising the Annual Implementation Plan 2014), the launch of the first IMI 2 JU Call for proposal together with the IMI 2 JU Call documents. For the first time, Associated Partners were accepted to join the IMI 2 JU programme (see section 5.4).

The second meeting was held on 3 November 2014.

5.3.2 Scientific Committee

In 2014 the IMI JU Scientific Committee held three meetings, two under IMI 1 JU and one under IMI 2 JU. The meetings were held at the IMI Programme Office and were attended also by representatives from EFPIA, the European Commission and the EMA as permanent Observer. The IMI JU Governing Board agreed to keep the same membership as in the last elected IMI JU Scientific Committee and the first meeting was held on 9 October 2014. In the meeting the Rules of procedures were adopted, and the participation of Scientific Committee members in Strategic Governance Groups was confirmed.

5.3.3 States Representatives Group

The IMI 1 JU States Representatives Group (SRG) held its last meeting in March 2014 and the IMI 2 JU Group met for the first time in September 2014. Detailed updates on IMI JU activities with a specific focus on call and projects' achievements were provided.

During 2014, the SRG was also consulted on the Call topics and documents and on the Annual Work Plans. In addition, the IMI Programme Office organised a webinar in June 2014 to facilitate the consultation with the SRG concerning the IMI 2 JU first Call for proposals. Moreover, the process for the adoption of new rules of procedures and the election of a new Chair and Vice-Chair was launched.

A wide range of Information Days were organised by several Member States and associated countries at the initiative of the SRG representatives and/or the national industry associations with the support of the IMI Programme Office in order to promote the Calls for proposals and explain the IMI 2 JU new rules and procedures as much as possible to all stakeholders.

5.3.4 Stakeholder Forum

IMI organised its annual Stakeholder Forum on 21 May 2014 in Brussels. This year's event featured two sessions: in the morning on breakthrough scientific trends in stem cells research; the afternoon focused on the next phase of IMI, in order to open a debate with all IMI JU's stakeholders on how to drive health innovation under Horizon 2020. Around 250 people attended and 200 more watched the live webstream. Participants included policy-makers, industry decision-makers, SMEs, patient groups, academia and researchers, representatives of other PPPs and research funding organisations.

5.3.5 Strategic Governing Groups

The Strategic Governing Groups (SGGs) ensure the coordination of IMI JU's work in certain strategic areas and work to make the development of new topics more transparent and effective. As such, the SGGs are made up of representatives of companies active or interested in the area covered by the scope of the SGG as well as representatives from the European Commission, the IMI Programme Office and the IMI Scientific Committee. The SGGs were created on the basis of Article 7.3.p of the legislation establishing the IMI 2 JU programme. This allows the IMI JU Governing Board to set up advisory groups where appropriate.

In 2014 six SGGs were established focusing on the following areas:

- Immunology
- Diabetes / metabolic disorders
- Neurodegeneration
- Translational safety
- Data and knowledge management
- Infections control.

The Diabetes and metabolic disorders Strategic Governance Group (SGG) was the first one to form and kicked off already in 2013. So far six face to face meetings were held.

The SGG has developed a comprehensive strategy for future projects in IMI JU to address diabetes and metabolic related diseases. In 2014 two topics resulting from this SGG have already been launched: Type 1 diabetes related topic in IMI 2 JU Call 1 and Type 2 diabetes related topic in IMI 2 JU Call 3.

The Neurodegeneration SGG had its kick-off meeting on 29 September 2014.This SGG aims to develop a comprehensive strategy for future projects in IMI 2 JU to tackle neurodegenerative diseases, and in particular Alzheimer's disease.

The Data and Knowledge Management SGG had their kick off meeting in September 2014. The goal of this SGG is to develop guidance for new projects, identify sustainability policies regarding the maintenance of the data and knowledge generated by new projects as well as IMI 1 JU projects. Furthermore the SGG focuses on the review of Call topic ideas as well as the planning of topics for the data and knowledge management platforms of the future.

In the context of the Data and Knowledge Management SGG, provisions were made in the Annual Work Plan and Call topic texts regarding data governance as documented in a data management plan, to adopt standards or adapt/develop novel standards in collaboration with a data standards organisation. Furthermore initial steps were taken towards the establishment of a catalogue of resources generated or being generated by IMI JU projects.

The Infection Control SGG had its first kick-off meeting on 19 November 2014. It is chaired by AstraZeneca and. it aims to develop a comprehensive agenda for future projects under IMI 2 JU covering infectious diseases including vaccines.

The Immunology SGG has interests in tackling diseases such as Rheumatoid Arthritis, Lupus, type 1 diabetes, Multiple Sclerosis and rare-immune-mediated diseases. In 2014 no topics were issued by this group.

The Translational Safety Strategic Governance Group (SGG) had its kick-off meeting on 7 July 2014.This SGG aims to develop a comprehensive strategy for future projects in IMI 2 JU by consolidating each company's strategy into a common SGG strategy for translational safety.

In addition, the Translational Safety SGG aims to understand and react to strategy gaps, identify new project ideas and approaches, as well as, adapt to scientific progresses in the area of translational safety. The SGG will monitor projects throughout their lifecycles to improve planning and execution, and optimise outcome and drive their extension towards applications. Importantly, the SGG will aim to ensure timely and appropriate communication of tangible outcomes and identify potential synergies across projects, with other SGGs, and across initiatives.

5.4 Associated partners

In 2014 IMI has stepped up cooperation with stakeholders by allowing other partners' expertise to contribute to the research agenda and activities, as foreseen under IMI 2 JU legal framework. These partners may include organisations from the knowledge management, IT, diagnostics, imaging, medical devices and animal health sectors.

Firstly, the IMI JU Governing Board has received three applications for association in 2014. The Juvenile Diabetes Research Foundation (JDRF) and the Helmsley Trust became Associated Partners of the IMI 2 JU Call 1 topic on type 1 diabetes, while the Bill and Melinda Gates Foundation joined IMI 2 JU as an Associated Partner for the IMI 2 JU Call 3 topic on pertussis vaccines.

The Governing Board assessed the applications taking into account the relevance and the potential added value of the applicant for the achievements of IMI 2 JU objectives.

Secondly, non-pharmaceutical companies will be invited to join EFPIA companies in generating cross-sector, multidisciplinary projects and to invest in IMI 2 JU. The Zeiss company already took advantage of this opportunity by becoming EFPIA Partner on Research in the IMI 2 JU Call 1 topic addressing retinal degeneration.

On 26 November IMI organised the first of a series of workshops which gathered 50 participants from health-related life science and technology companies and organisations to understand what technologies, expertise and approaches from non-pharmaceutical companies and sectors can bring to support the objectives of Strategic Research Agenda, as well as explaining the different routes for new partners to take part in IMI activities.

According to Article 4 (3) of the Council Regulation establishing the IMI 2 JU Associated Partners shall report each year to the Governing Board on the value of the in kind contributions in the previous year.

Associated Partners

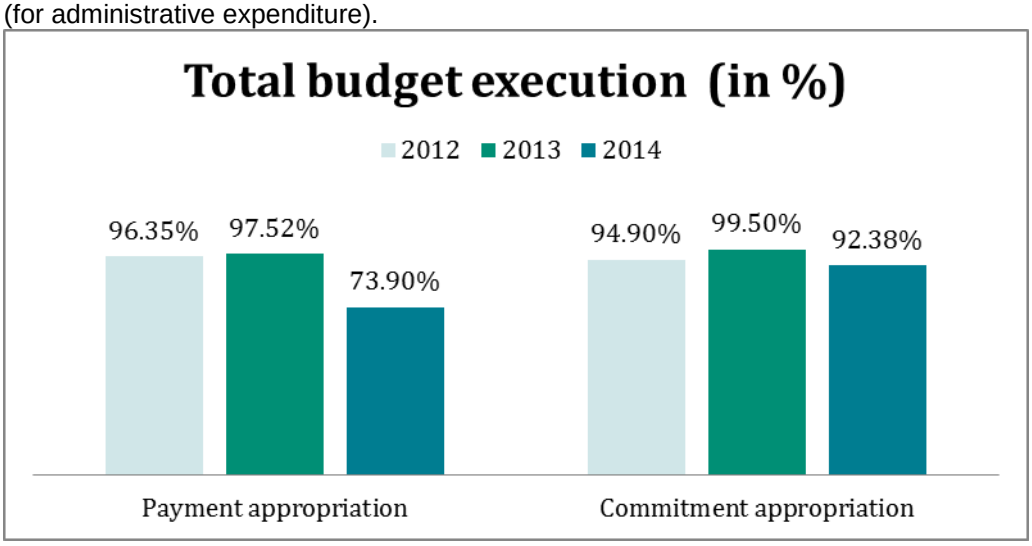
Entity	Date of Request	Status	COMMENTS
JDRF	24 June	accepted	Area of Research: Diabetes IMI 2 JU Call 1 for Topic 1 on translational approaches In kind commitment: EUR 2.8 million
Helmsley Trust	2 July	accepted	Area of Research: Diabetes IMI 2 JU Call 1 for Topic 1 on translational approaches In kind commitment: EUR 2.2 million
Bill & Melinda Gates Foundation	30 September	accepted	Area of Research: Vaccines IMI 2 JU Call 3 for Topic 1 on pertussis vaccination research In kind commitment: EUR 7 million

6 PROGRAMME OFFICE MANAGEMENT

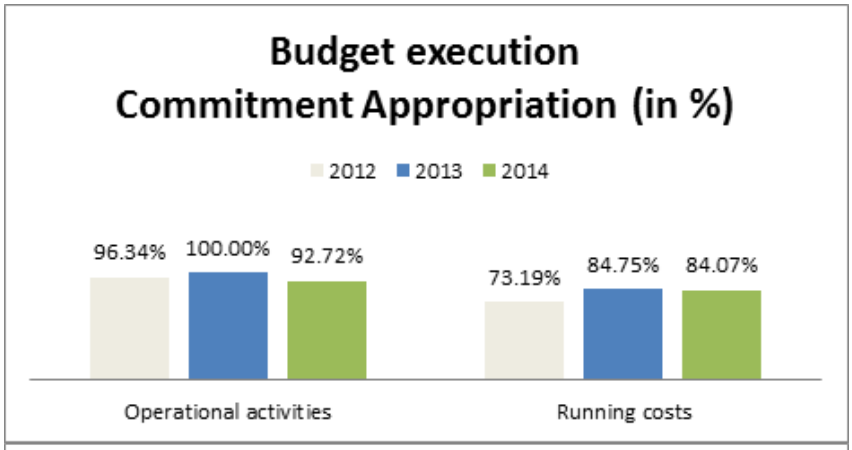
6.1 Budget and finance

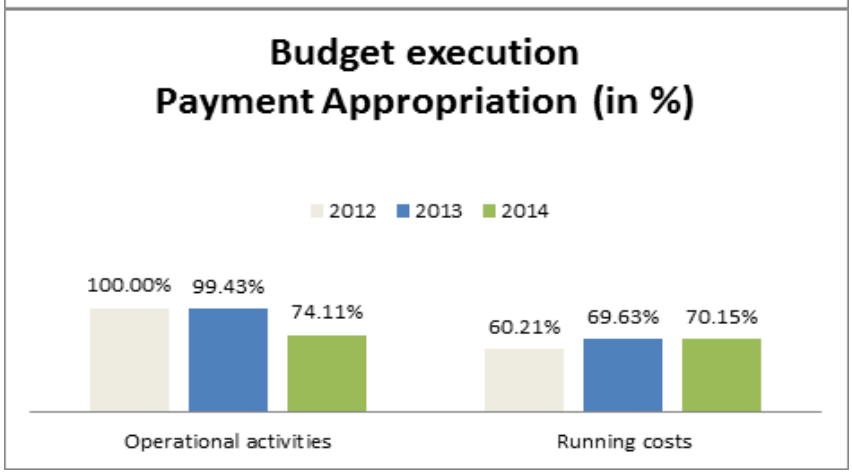
6.1.1 Budget execution

In 2014, the budget execution of both commitment and payment appropriations reached 92.38% and 73.90% respectively. This was due to delays in negotiations of a few projects (for operational expenditure) and to postponement of the recruitment of staff on the request of the Governing Board (for administrative expenditure).



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





6.1.2 Financial operations

IMI JU handled a total of 1 494 financial files (payments, commitments, forecasts of revenue, recovery orders and budget transfers) in 2014. More detailed information is presented in the section 7.2.

6.1.3 Time to pay

Since January 2013, IMI JU has been applying different payment time limits than those used in 2012. Therefore, average time to pay for operational payments in 2012 is not mentioned in the table below to avoid confusion.

Maximum payment time limit	Average time to pay (days)		
Year	2012	2013	2014
Administrative payments			
30 days	17	15	14
45 days*	23	19	14
60 days	25	14	18
Operational payments			
30 days		18	7
90 days		66	71

*From 2013 onwards 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 JU contribution to projects). In 2014, IMI JU continued to emphasise preventive actions (financial workshops, advice to consortia by the financial officers, etc.) in order to raise the quality of, and reduce errors in, periodic reports provided by IMI JU projects.

6.1.4 Time to grant

Call	Acronym	EoI open	EoI deadline	FP open	FP deadline	GA signature	TTG
IMI1 C9	WEB-RADR	09/07/2013	09/10/2013	11/12/2013	04/03/2014	18/08/2014	167
IMI1 C9	SPRINTT	09/07/2013	09/10/2013	11/12/2013	04/03/2014	31/07/2014	149
IMI1 C9	DRIVE AB	09/07/2013	09/10/2013	11/12/2013	04/03/2014	12/08/2014	161
IMI1 C11	EPAD	11/12/2013	08/04/2014	16/06/2014	09/09/2014	19/12/2014	101
IMI1 C11	ZAPI	11/12/2013	08/04/2014	16/06/2014	09/09/2014	19/12/2014	101
IMI1 C11	ULTRA-DD	11/12/2013	08/04/2014	16/06/2014	09/09/2014	19/12/2014	101
IMI1 C11	Combacte-MAGNET	11/12/2013	08/04/2014	16/06/2014	09/09/2014	19/12/2014	101
IMI1 C11	IPIE	11/12/2013	08/04/2014	16/06/2014	09/09/2014	19/12/2014	101
						Average	**122.75**

State of play of founding members' contribution

The following table provides an overview of budgeted (committed) and reported EU and EFPIA contributions at the end of 2014. The committed amounts do not include commitments for one project in IMI 1 JU Calls 9 and 10 and for three projects of IMI 1 JU Call 11, for which the grant agreements will be signed in 2015.

	Nbr of projects	EU (EUR)			EFPIA (EUR)		
		Committed	Reported	%	Committed	Reported	%
Call 1	15	116 082 075	87 621 397	75.48	149 125 031	111 772 367	75.00
Call 2	8	85 765 138	45 549 110	53.10	74 210 882	33 060 345	44.50
Call 3	7	112 839 908	29 756 106	26.40	70 834 231	15 396 932	21.70
Call 4	7	97 943 541	23 639 634	24.10	109 692 826	27 257 647	24.80
Call 5	1	79 999 157	10 416 283	13.00	91 337 070	68 899 176	75.40
Call 6	2	125 417 213	4 378 133	3.50	142 058 215	2 456 587	1.70
Call 7	2	12 999 811	974 790	7.50	11 927 750	608 353	5.10
Call 8	4	98 732 937			49 163 653		
Call 9	3	32 569 426			29 701 748		
Call 10	0	0			0		
Call 11	5	134 958 688			159 105 610		
Total	**54**	**897 307 894**	**202 335 453**	**22.55**	**887 157 016**	**259 451 407**	**29.20**

IMI 1 JU Call 9 project Combacte-CARE-under negotiation at 31/12/2014
IMI 1 JU Call 10 project FLUCOP-under negotiation at 31/12/2014
IMI 1 JU Call 11 projects Approach, CANCER-ID and iABC-under negotiation at 31/12/2014

After signing these grant agreements the EU commitment will reach EUR 965 731 003 and the EFPIA commitment EUR 974 876 624.

Reported amounts show that the EFPIA contribution is EUR 57 million higher than the EU contribution. This is due to the fact that the IMI1 JU Call 5 project requires two-thirds of the EFPIA contribution at the beginning of the project while the EU contribution follows a more linear pattern.

Commitment to IMI JU projects by founding members (in EUR per IMI JU Call)[12]

IMI1			
Call	**No of projects**	**EU**	**EFPIA**
Call 1	15	116 082 075	149 608 531
Call 2	8	85 765 138	74 210 882
Call 3	7	112 839 908	70 834 231
Call 4	7	97 943 541	109 692 826
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	3	32 569 426	29 701 748
Call 10	0	0	0
Call 11	5	134 958 688	159 105 610
Total IMI1	**54**	**897 307 894**	**887 640 516**

IMI2				
Call	**No of projects**	**EU**	**EFPIA**	**IMI2 Associated Partners**
Call 1	2	24 630 000	19 745 192	5 038 841
Call 2	8	116 615 966	99 481 044	0
Call 3	6	56 430 000	49 430 000	7 000 000
Call 4	1	1 130 000	1 130 000	0
Total IMI2	**17**	**198 805 966**	**169 786 236**	**12 038 841**
TOTAL IMI1 + IMI2	**71**	**1 096 113 860**	**1 057 426 752**	**12 038 841**

6.2 Human resources

Staffing level

IMI JU staff numbered 34 at 31/12/2014. The objective set by the AWP 2014 was to increase the staff up to 41 members to cope with the new objectives and obligations assigned to IMI 2 JU by the new Regulation (EU) 557/2014 and inducted by H2020 *modus operandi*. As a result, a vacancy notice for a reserve list of scientific project officers was published. At the same time one IT contract assistant joined IMI 2 JU during the year.

2014 also featured the end of the contract of the Executive Director, who has been temporarily replaced by the Acting Executive Director as from 16 December, and by four resignations in key positions. For two of those a vacancy notice was published and the corresponding recruitments will be finalised in Q1-2015.

The three graphs below show the rate of achievement of objectives set up with a focus on staff gender and geographical balance within IMI 2 JU:

[12] Extract from the IMI 2 JU accounts for 2014.

Objective: recruit, train, assess, motivate and retain highly qualified staff with a view to ensure effective and efficient operation of the IMI JU as well as providing equal opportunities.		
Indicator	**Target 2014**	**Status 31/12/2014**
% of filled positions	100% of positions authorised	85.3%
Average time to fill a vacant position	Up to 3 months from authorisation of selection procedure to sending the offer	4.5 month
Nr of staff who attended at least a training course during the year	80%	82.3%
Gender balance	50%	Female: 64.7% Male: 35.3%
% of women in Grade above AD 9	50%	75%

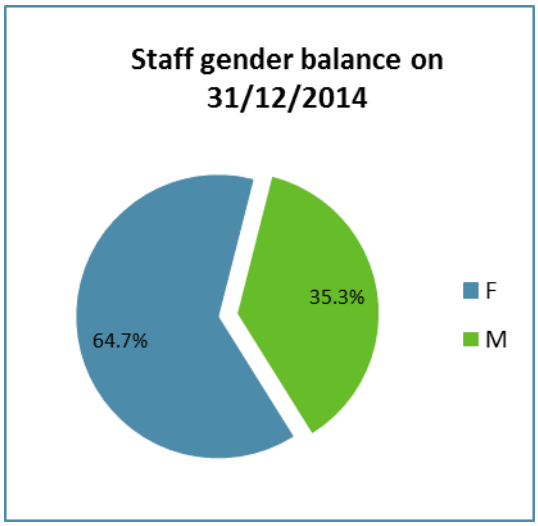
Staff regulation and organisation

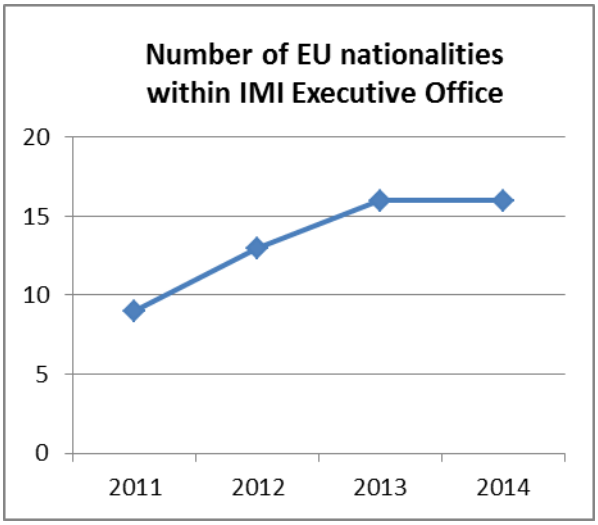
According to the objective given in the AWP 2014 the new European Commission Staff Regulations of have been implemented introducing an increase in working time to 40 hours weekly and a reduction of some leave entitlements. The IMI JU Governing Board accordingly adopted the first batch of implementing rules adapted to IMI 2 JU's legal nature and size. The IMI Programme Office is working on a second set of rules to be adopted in line with the new Staff Regulations and Human Resources and Security Directorate General.(DG HR) guidelines.

Learning and professional development

The organisational efficiency takes in particular account the learning and professional training in order to keep staff members up-to-date. The main areas covered were:

- Scientific knowledge (drug development cycle, medicines regulations or more specific topics linked to research area);
- Operational and legal context: H2020 new environment, IP recent case law, financial regulations, audit rules, staff regulations;
- Communication: communication strategy, social media, public speaking, languages;
- IT skills (Word, Excel, MS Project or ABAC and any IT tool developed by IMI);
- A team-building seminar was organised in June 2014 called 'Better working together' and followed up by Human Resources in the second half of the year).





6.3 Information and communication technology

IMI JU's strategic ICT objective is to enable established and new business initiatives, thus supporting and shaping the present and future of IMI JU. The ICT applications and infrastructure support the implementation of IMI JU's strategy and business objectives, thus streamlining IMI JU processes and making them more efficient.

The IT development in the year 2014 was filled with increased coverage of IMI JU in-house processes, enhancements of applications and in particular numerous adaptations necessary in the light of Horizon 2020. The following table gives an overview of the most important achievements in 2014.

IMI Core Business	
SOFIA (Submission of Information Application)	▪ Interim Review Workflow ▪ EFPIA monitoring of in kind cap per project ▪ Improved summary reporting ▪ One-stop shop Document Inventory ▪ Added read-only features for safer audit ▪ Training and support to project participants ▪ Refactoring for more efficient use of space and time ▪ Ethics experts use H2020 compatible forms ▪ New single-stage evaluation workflow for Ebola Call ▪ Numerous adaptations for the change to IMI 2 JU
Other IMI Business Applications	
Events Registration Application	▪ Addition of a new event type
IMI website and newsletter	▪ Prevent spam: removed messaging to third parties

ICT Internal Support	
DORA (Document Repository Application)	▪ No development required
ISA (Information System for Absences)	▪ Enhanced and extended to manage additional types of absences: teleworking and part-time ▪ Prepared to share with other JUs and EU Agencies
eCDR (electronic Career Development Report)	▪ No development required
BIT (Booking of IT material)	▪ Simplification to reflect insourced IT Assistant
eMA **(electronic Missions Application)**	▪ Requirements analysis and workflow implementation
ICT Internal Support to other Jus	
Vacancies and ISA	▪ Prepared to share with EU Agencies

6.3.1 Support to IMI JU core business

The SOFIA (Submission OF Information Application) implements the core business workflow of IMI as web application. It supports streamlines and documents the management of the Call process and project life cycle. SOFIA is a key tool to make the IMI JU core processes efficient. In 2014, SOFIA was subject to significant development as described below.

- Interim Review Workflow

Since IMI JU projects have been proceeding through their life cycle, SOFIA has been extended to cover collection of documents, evaluation, and communication about outcomes with the consortium.

- Document Inventory

To find all legally relevant documents related to a project quickly, whether in the document repository DORA or in SOFIA, a one-stop-shop page has been created in SOFIA to give a comprehensive overview with links to easily navigate to documents or tables. In a concerted effort within IMI JU, documentation about projects has become much more accessible to IMI JU officers and for audit purposes.

- New fast-track workflow to defeat Ebola

The kick-off of the IMI 2 JU Ebola+ programme, under a one-stage evaluation required some quick adaptations to SOFIA.

- Horizon 2020

Following the new institutional framework of IMI 2 JU, numerous adaptations of the Call and project data and some of the workflow have entered the development pipeline, with the most important structural changes already in place by the year-end.

- SOFIA performance improvements

The SOFIA software is evolving fast in response to new needs and to become more efficient. However, this growth has meant a decrease in speed of some pages at some times. First steps have been taken to counter the problem for some pages of SOFIA, but higher operational priorities have prevented the complete resolution of this issue.

6.3.2 ICT internal support

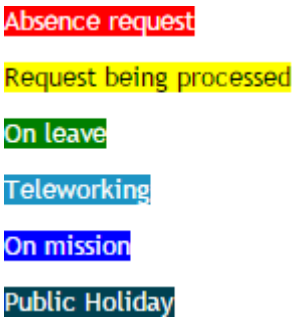
- DORA (Document Repository Application)

While no major development was needed, training was given internally and presentations to potentially interested users in Strategic Governance Groups (SGGs) and other European Agencies.

- ISA (Information System for Absences) / eMA (electronic Missions Application)

ISA has been the key tool at the IMI Programme Office to help manage HR processes.

Certain IMI Programme Office staff members have to undertake missions to meet interested communities, partners and project representatives. The electronic handling of missions is an extension to ISA, which aims to map the in-house workflow from mission invitation to expense claims.



6.3.3 ICT internal support to other JUs

The IMI Programme Office has been providing the services of ISA and Vacancies to Fuel Cells and Hydrogen and Clean Sky JUs since 2013. In 2014, ECSEL JU joined as another partner using that platform for internal operations, further increasing the economies of scale.

6.3.4 ICT sharing of software with other European Partners

ISA and the Vacancies management tools have been licensed under the European Union Public License (EUPL) and given 'as-is' to the Internal Market and Services Directorate General and European Monitoring Centre for Drugs and Drug Addiction for them to evaluate. Ongoing IT support by the IMI Programme Office is not included in this open-source arrangement. The software is flexible, so that organisations can apply their branding with minimal effort.

European Monitoring Centre for Drugs and Drug Addiction

6.4 Procurement and contracts

The large majority of IMI JU's procurement in 2014 was done under existing multi-annual framework contracts. Those framework contracts which are the most significant in volume, namely in IT services, audits and interim staff provision, have been concluded jointly with other JUs to avoid duplication and minimise administrative effort.

Where possible, IMI JU has made use of the European Commission's framework contracts that it is party to. In 2014, the most significant of these in usage volume terms were in software licenses and in communications consultancy services.

Apart from the contracts mentioned above, a significant number of specific contracts were concluded for the rental of meeting premises for organising project evaluations under a framework contract IMI JU tendered for on its own in 2012.

Two open procedures were carried out in 2014. The first was a joint procurement with other JUs for a framework contract in IT and telephony services, with IMI JU acting as the lead contractor. The contract replaces earlier framework contracts that expired in November 2014. The second open procedure was for a framework contract for the analysis of bibliometric data and other program output indicators that IMI JU concluded on its own. The maximum duration for both framework contracts is four years.

In addition, IMI JU published two contract notices for negotiated procedures with a maximum procedural budget threshold of 134.000 EUR, one for a service contract for producing promotional videos and another for a framework contract for providing audio-visual equipment and support at meetings.

The table below gives the details on these including the procedure used in each case, the publication date, the award date and the name of the contractor(s). Only tenders with a value exceeding EUR 15 000 are listed here:

Tender procedures in 2014				
Reference and subject	**Procedure**	**Publication date**	**Award date**	**Contractor(s)**
IMI/2014/SC/036: Production of promotional videos	Negotiated procedure (<134.000 EUR) – Service contract	28/02/2014	0/04/2014	Radio Télévision Belge de la Communauté Française (RTBF), Belgium
IMI/2014/FWC/043: Managed IT Services (OJEU 14.05.2014 - Ref. 2014/S 092-160729)	Open procedure – Framework contract	14/05/2014	04/11/2014	Realdolmen NV/SA, Belgium
IMI.2014.FWC.129: Audio-visual equipment and support services	Negotiated procedure (<134.000 EUR) – Framework contract	29/08/2014	27/10/2014	OnScreen sprl, Belgium
IMI/2014/FWC/146 – Analysis of bibliometric data and other IMI project output indicators (OJEU 08.10.2014 - 2014/S 193-339891)	Open procedure – Framework contract	08/10/2014	09/01/2015	Thomson Reuters Scientific LLC, United States

6.5 Data protection and access to documents

6.5.1 Data protection

In 2014, IMI JU pursued the implementation of data protection principles within its activities involving the processing of personal data.

Regular communication with IMI JU staff, with the network and the JUs' data protection officers, and with the European Data Protection Supervisor (EDPS) services, enabled the continuing 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 2014 IMI JU followed up the notifications to the EDPS, submitted in 2013 and related to existing processing operations. There is no specificity on the IMI JU processing of personal data to report.
Recommendations from the EDPS as an outcome of IMI JU notifications are being implemented.

- Notifications to the DPO

By December 2014, the DPO had received 17 notifications from staff members responsible for the processing of personal data within IMI JU. This covers IMI activities including communication with IMI JU 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 2014.
The DPO has collaborated on the work developed by the projects to adopt a guidance code on the secondary use of health data. The Code's aim is to provide guidance for researchers and ease the exchange of patients' health data. It explains and interprets provisions of the European Data Protection Regulation and Directive. It was prepared on the initiative of the IMI JU projects. The document is at its final stage and exchanges with the EDPS were held, in view of a formal consultation in 2015.

- Inspections

There were no site visits by the EDPS in 2014.

- Complaints

There were no complaints to the EDPS in relation to IMI JU's processing of personal data to report in 2014.

- Network activities

In 2014, the DPO participated in two meetings of the network hosted by the EDPS and the European Centre for the Development of Vocational Training (CEDEFOP). 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. In 2014, the DPO participated in Directorate-General for Research and Innovation (DG RTD) common support service meetings to discuss privacy statements on experts and grants, in view of publication on the European Commission participants' portal.

- Training/Communication activities

The DPO participated in a course organised by the European Institute of Public Administration on data protection compliance. This training is part of a certification programme.
Information on developments in data protection activities was provided to the IMI Programme Office staff.

Other:

- DPO mandate

The DPO's mandate was renewed until 2016.

- EDPS Surveys

IMI JU participated in the survey for the implementation of Regulation 45/2001. The findings of the surveys were used as a basis to prepare the EDPS guidance.

- Data Protection Day

IMI JU participated in the activities related to Data Protection Day 2013 and information was provided to all IMI Programme Office staff.

6.5.2 Thematic guidelines

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	concluded	Pending adoption by EDPS of specific guidelines
Anti-harassment procedures	NO	preparatory work	Procedures being developed in IMI JU

EDPS Guidelines	Notification to EDPS	Status of procedure	Comments
Administrative inquiries and disciplinary proceedings	NO	preparatory work	Procedures being developed in IMI JU
Video surveillance	NO	not applicable	IMI JU is not the controller of the data

- Access to documents

During 2014 IMI JU continued to promote transparency and access to information and documents through the IMI Infodesk (see section 5.2). IMI also implemented the guidance regarding access to data related to IMI JU projects.

6.6 Conflict of Interests

IMI JU has comprehensive and well-defined policies and procedures in place for an adequate prevention, identification and management of conflict of interest situations in its various activities. These measures thoroughly address all legal provisions governing the JU and also reflect best practices for organisations managing grants and public funds.

The policy governing conflicts of interest for the Executive Director and staff of IMI JU is publicly available on the IMI JU website. In Q4 2014 IMI JU launched its second annual exercise. Declarations of interests from IMI staff in sensitive positions were collected and are undergoing assessment.

The Acting Executive Director's declaration of interests statement was published on the IMI JU website. The names of the members of the IMI JU's Governing Board, Scientific Committee and States Representatives Group are all publicly available via the website. In the case of the Scientific Committee, the members' *Curricula Vitaes* are also available.

6.7 Internal control strategy and environment

In 2014, there was an impact on the internal control system caused by the establishment and launch of IMI 2 JU which entered into force in the second half of the year. This change brought with it a new set of strategic goals and objectives as well as a different *modus operandi* and processes that will be implemented under the H2020 framework.

This strategic, legal and operational transition in 2014 has also included changes to the governing bodies of the JU, a revised annual work plan for the second half of the year, the adoption of new financial rules as well as the adoption of new agreements with the European Commission (through a Delegated agreement) and with EFPIA. During this change process the organisational structure of the JU was retained with no changes to the existing positions, in view also of the additional change at the end of 2014 of the Executive Director whose contract came to an end.
Furthermore, the programme and funding management of the new IMI 2 JU research actions is now subjected to the regulations and principles governing Horizon 2020 and these will also require a number of changes to the whole administrative and operational environment of the IMI Programme Office (formerly referred to as IMI Executive Office).

These circumstances have clearly had an impact on the governance, internal control and risk management of the IMI 2 JU. Nevertheless 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 JU's administrative, support and grant management systems and workflows.

IMI 2 JU has confirmed the existing defined framework of 16 Internal Control Standards (ICS) designed to maintain an efficient and effective internal control system also in accordance with the new 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.

During 2014, internal control issues and actions have been systematically discussed and reviewed on a regular basis through weekly management meetings. In parallel, the internal control coordinator monitored the progress made towards achieving compliance with and effectiveness of the internal controls system on a quarterly basis (including a mid-year formal self-assessment). In addition, at the end of 2014 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 JU's mission and objectives were also systematically identified, assessed and managed through the annual risk assessment exercise (RAE) together with a list of mitigating actions to reduce the impact of risks to an acceptable level.

In view of these actions, the strategic risks triggered by the transition to IMI 2 JU have been controlled since the first semester and all along the year through an explanatory and informative set of tools, including:

- a transitional plan associated with a monitoring scorecard periodically updated;
- an ad hoc risk and control self-assessment (RCSA) of events and risks that may impact the implementation of the plan and on the management of projects;
- management guidance and targeted internal training intended to help IMI JU staff members during the transitional phase and providing directions on how to deal with specific activities linked with the transition and implementation of IMI 2 JU.

Ex post control of operational expenditure has continued to play an important role in the overall internal control framework. By the end of 2014, 14 audits of beneficiaries and 1 audit of an EFPIA company were finalised bringing the cumulative total since beginning of IMI JU up to end of 2014 to 84 audits of beneficiaries and 4 audits of EFPIA companies.

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 JU'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 2015 as part of a process of continuous improvement, as highlighted in the Annual Work Plan 2015.

7 ELEMENTS LEADING TO THE DECLARATION OF ASSURANCE

7.1 Background

As a European Union body, IMI JU is required to include a structured assessment of the effectiveness of internal controls and on other elements in its Annual Activity Report supporting the Declaration of Assurance by the Executive Director in the capacity of 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;
- stakeholder feedback.

7.2 Assessment by management

Implementation of operational and administrative budgets

The budgets for 2014 were adopted by the IMI JU Governing Board together with the corresponding Annual Implementation Plan on 20 December 2013. These were amended and approved by the Governing Board on 7 July 2014 to take into account the launch of the IMI 2 JU programme.

Operational budget

At the end of 2014, 52 operational payments were made for a total of EUR120 million. Budget execution was therefore 74.1% (99.4% in 2013). As noted in section 5.1 above this was lower in 2014 compared to 2013 due to delays in negotiations finalisation of some projects.

In 2014, on average it took 7 days to process pre-financing payments (18 days in 2013) thereby achieving an excellent result, especially when comparing the year's performance against the maximum payment limit and KPI target of 30 days.

The average time to pay for cost claims slightly increased from 66 days in 2013 to 71 days in 2014. This is still considerably below the maximum payment limit and KPI target for interim and final payments of not more than 90 days. During 2014, there were 12 late payments from which one payment generated interest due to beneficiary. The late payments were mainly caused by the increased workload related to the analysis of reports and processing of payments and the limited resources in the financial team.

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
2012	26	16	65	60	125	96	4
2013	33	14	44	66	110	91	9
2014	32	15	53	71	126	63	37

*Interim payments in 2014 after the 60 contractual days for submission

IMI JU processed 53 interim reports. The analysis of the reports 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 larger number of reports were being handled in 2014 when compared to the previous year (from 35 in 2013 to 53 in 2014 – an increase of 51.5%), with the receipt of the first claims from an additional 5 projects from IMI 1 JU Calls 4, 5 and 6. 32 interim reports resulted into an interim payment.

In 2014, the average processing time (from the date of report submission to the IMI JU bank execution date for the payment of the cost claims) was 126 days (as compared to 110 days in 2013). This was primarily due to an increase in the required suspension period (on average from 44 days to 53 days).

During the year, IMI JU continued to facilitate and streamline the process for project participants and IMI Programme Office staff, including:

- the publication of guidance on its website and the organisation of a workshop for participants on the applicable financial rules and the correct completion of the financial statements;
- the use of simplified internal workflows and key documents;
- the use of IMI JU's core business application SOFIA that automates and further supports project-related processes.

Administrative budget (running costs)

As of 31 December 2014, payments were made for a total of EUR 6.2 million, resulting in a budget execution of 70.2% (as compared to 69.6% in 2013). As noted in section 6.1 above, the main reason for not achieving a higher level of budget execution for administrative expenditure was the decision by the Governing Board to postpone the recruitment of staff. The execution of the commitment appropriation is higher than the execution of the payment appropriation due to the fact that payments for some of the contracted services in 2014 will only be due in 2015.

In 2014, the Programme Office maintained the satisfactory performance achieved for administrative payments in 2013 despite the increased workload in 2014 and the limited resources in the financial team.

Maximum payment time limit	% paid on time			% paid beyond time limit			Average time to pay (days)		
Year	2012	2013	2014	2012	2013	2014	2012	2013	2014
30 days	85	92	93	15	8	7	17	15	14
45 days	90	92	98	10	8	2	23	19	14
60 days	84	100	99	16	0	1	25	14	18
All	N/A	92.5	95.6	N/A	7.5	4.4	N/A	18	14

Control systems

IMI JU's *ex ante* controls form an integral part of the respective procedures, workflows and financial circuits for both the administrative and operational budgets. These controls are documented and enforced through internal policies, management decisions, documented procedures and templates as well as by a series of established internal checks and balances aimed 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, as from 2014, also for 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 JU 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 JU rules, procedures and checks carried out during the negotiation; and grant preparation and signature processes.

In 2014, independent observers compiled five reports on the publication of IMI JU Calls, the selection of independent experts and the evaluations of the IMI 1 JU Call 9 (Stage 2), Call 10 (Stages 1 and 2) and the Call 11 (Stages 1 and 2). 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, well-qualified 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 skilfully 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 and conformed to international standards of peer review and;
- the consensus evaluation reports generated by all panels incorporated the opinions of all experts and truly represented the consensus opinions of the panels;
- The independent observers' reports and IMI JU replies are also published on the JU's website.

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 2014 and this provides a further indication of the robustness of the grant award process and the effectiveness of the internal controls.

IMI JU was also visited in 2014 by staff from the Office of the European Ombudsman to follow up on a complaint made by a member of a consortium that was unsuccessful in a Stage 1 evaluation of a Call of Proposals that was held in 2012. The complainant is acting individually, and not on behalf of the unsuccessful consortium, on a case that was already addressed and closed in February 2013. A final report from the European Ombudsman on the outcome of this visit is expected in 2015.

During the implementation of the projects, IMI JU also actively monitors the progress of the funded projects through the systematic review of technical reports and through interim reviews of each. In 2014, 8 interim reviews were held and overall these had positive conclusions on the progress made and the early achievements of IMI 1 JU Calls 2, 3 and 4 projects as well as on the additional measure that can be taken to ensure successful completion of the projects by the end of the respective funding periods (see section 3.1 for more information).

Ex post controls: audit and corrective actions

Ex post audits are used extensively by IMI JU to independently measure and assess the legality and regularity of interim (and eventually) final payments made to beneficiaries on a multi-annual basis. Findings from the *ex post* audits are carefully analysed by the IMI Programme Office and used for recovery and corrective actions, as well as to reinforce and fine-tune the preventive measures put in place by the JU 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 JU does not allow for the setting up of an internal team of auditors for these purposes. Nevertheless, the IMI Programme Office remains 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.

In 2014, the IMI Programme Office continued with the implementation of the critical changes and improvements made to the *ex post* audit process in 2014, namely:

- a dedicated full time position for ex post audit and control activities;
- the additional quality review stages to further improve the quality of the reporting in the audit reports;
- the use of the standard operating procedure for the operational planning and management of outsourced financial audits of beneficiaries as well as for the main processes and procedures relating to the follow-up of audits.

The following table gives an overview on the resources devoted to ex post audits.

	2011	2012	2013	2014
Internal resources[13] *Ex post* audits	0.50 FTE	1 FTE	1.5 FTE	2 FTE
Costs of externalised audits (Commitments)	EUR 370 790	EUR 367 143	EUR 568 060	EUR 199 163

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*** **(RepER)** 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 JU. 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*** (**ResER**) is the level of error remaining in the population after deducting corrections and recoveries made by IMI JU. 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.

[13] Due to the lean structure of IMI2 JU and cost-efficiency reasons the *ex post* audits manager is supported by various staff at different level of responsibility. The reported figure in FTE (Full Time Equivalent) is therefore an estimation of the time devoted by various members of JU staff to *ex post* audits in order to manage the three processes under the JU's responsibility (i.e. (1) planning, (2) monitoring/quality checks and (3) evaluation/implementation of audit results).

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 JU's *ex post* audit strategy can only be fully measured and assessed during the final stages of IMI JU, 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 JU 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 (covering the periodic report of year 2010 and 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 four representative samples covered payments to beneficiaries made between December 2010 (when the first and only interim payment to an IMI JU project was made in 2010) and the end of August 2014 (cut-off period for the last extracted sample).

160 different beneficiaries participating from projects in IMI 1 JU Calls 1 to 6 have so far been selected for *ex post* audit. This significant broad coverage of beneficiaries is in line with the current strategy approved by the IMI JU Governing Board.

From this total, 144 audits (90%) were launched by the end of 2014. The remaining 16 audits were on hold either due to ongoing or booked audits by the EC with the same beneficiaries or because 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 instead be outsourced to other audit firms using alternative EC framework contracts for audit services to which IMI JU has access for such cases.

By 31 December 2014, IMI JU had finalised[14] a total of 85 audits, of which 81 are "Representative"[15] and 4 are "Risk-based"[16].

Indicators of coverage: Number of audits and audit coverage (cumulative)

	Total population	Audited	Audit coverage
Beneficiaries	626	85	13.6%
Projects	57	24	42.1%
Costs accepted by IMI JU (cumulative)	EUR 90,757,444	EUR 15,109,596	16.65%

[14] An audit is considered finalised when the audit adjustment and the related "error rate" is final as of the cut-off date for the preparation of the AAR. This comprises either audits with "Final Audit Reports" received and accepted by IMI or if not received and accepted, with a "Pre-final Audit Report" (after contradictory procedure with the beneficiary) approved by the JU and therefore with a definitive audit adjustment and error rate.

[15] According to IMI JU Ex post Audit Strategy "Representative audits contribute towards an error rate representative for the whole population and thus to confirm the effectiveness of the systems and provide input to the assurance declaration of the Authorising Officer."

[16] According to IMI JU Ex post Audit Strategy "Risk-based audits aim at ensuring that specific populations not sufficiently covered by representative audits (including the audit of all 'Individually significant cost claims'), which might present specific risks, are properly addressed through Ex post audits."

The following table gives an overview of the status at the cut-off date of 31 December 2014:

Population sampled	Number of *ex post* audits					
	Audits launched	Audits ongoing	Audits finalised			
			Representative	Risk-based	Total	%
1st Sample (2011)[17]	60	2	56	2	58	96.7%
2nd Sample (2012)	37	16	20	1	21	56.8%
3rd Sample (2013)	29	23	5	1	6	20.7%
4th Sample (2014)	18	18	0	0	0	0%
Total	**144**	**59**	**81**	**4**	**85**	**59.0%**

The First Sample includes 60 audits, of which 58 have been finalised as of 31/12/2014.

- The 2 ongoing audits from this first sample were identified as risk-based and are addressed through further appropriate actions.

The Second Sample includes 40 audits, of which 21 have been finalised as of 31/12/2014.

- As for the remaining 19 audits from this sample:
  - 16 are ongoing and are at different stages of implementation;
  - 3 audits are on hold as:

    For 2 of them all the external audit firms available through the IMI JU framework contract for external audit services had reported a conflict of interest with the beneficiaries in question. These audits will be outsourced to other contractors using alternative European Commission framework contracts for audit services;

    The remaining audit is on hold due to the ongoing or booked audits by the European Commission with the same beneficiary.

The Third Sample includes 35 audits, of which 6 have been finalised as of 31/12/2014.

- As for the remaining 29 audits from this sample:
  - 23 are ongoing and are at different stages of implementation. 7 of these audits were launched later in the year (one in June and six in July) after the closure of audits with the same beneficiaries by the EC and/or the European Court of Auditors (ECA);
  - 6 are on hold as:

    For 2 of them all external audit firms available through the IMI framework contract for external audit services reported a conflict of interest with the beneficiaries in question. These audits will be outsourced to other contractors using alternative European Commission framework contracts for audit services;

    The remaining 4 audits are on hold due to ongoing or booked audits by the European Commission with the same beneficiaries.

The Fourth Sample covering more recent claims and comprising of 25 audits was selected in 2014. The first set of 18 audits from this sample was launched in October 2014 and all engagements were ongoing by the end of the year.

As for the remaining 7 audits, these are on hold due to ongoing or booked audits by the European Commission with the same beneficiaries.

Representative and Residual Error Rates as of 31 December 2014

First Representative Sample

The Representative Error Rate (RepER) resulting from the 58 concluded audits of the first representative sample was estimated at 4.37% as of 31 December 2014.

[17] The audit sample 2011 includes the accepted cost claims received in 2010 and 2011.

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 are undertaken), was estimated at 2.74% as of 31 December 2014.

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

- the 58 audits cover a substantial 36.96% % 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 7.4 below).

Second Representative Sample

The RepER resulting from the 20 concluded representative audits of the second sample was estimated at 2.50% as of 31 December 2014.

The 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 are undertaken), was estimated at 2.04% as of 31 December 2014.

These estimates, based on the initial completion of just over half of the sample, indicate a gradual reduction over time in the error rate level when compared to the first representative sample. They will continue to evolve with the completion of the remaining 19 audits in the sample. Moreover, it is relevant to note that these percentages reflect similar levels as those identified by the European Commission among similar beneficiaries of the FP7 programme.

Third Representative Sample

The RepER resulting from the first 6 concluded representative audits of the second sample was estimated at 1.81% as of 31 December 2014.

The 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 are undertaken), was estimated at 1.77% as of 31 December 2014.

Fourth Representative Sample

None of the audits in this most recent representative sample have been finalised.

Cumulative Error Rates

In conclusion, as of the cut-off reporting date (31/12/2014):

- 160 audits were sampled and 144 launched.
- 85 have been finalised, of which 81 are considered "Representative" and 4 "Risk-based".
- The remaining 59 audits are ongoing.

The **cumulative Representative Error Rate** (RepER) resulting from the above 81 finalised audits is 2.37% and the cumulative Residual Error Rate (ResER) is 1.98% as detailed in the table below:

Sample ref. (a)	Audits finalised in 2014 (b)	Total audits finalised (c)	Total Population (accepted IMI contribution in EUR) (d)	Finalised EPA Value to Date (accepted IMI contribution in EUR) (e)	Coverage (e/d) (f)	Annual Error Rate (g)	Annual Residual Error Rate (h)	Cumulative Error Rate (i)	Cumulative Residual Error Rate (j)
2011	0	56	11 610 139	4 290 571	36.96%	**-4.37%**	**-2.74%**	-1.19%	-0.83%
2012	7	20	29 610 139	5 444 825	18.39%	**-2.50%**	**-2.04%**	-0.68%	-0.62%
2013	5	5	48 981 789	1 053 941	2.15%	**-1.81%**	**-1.77%**	-0.50%	-0.53%
2014	0	0	0	0	0%	0%	0%	0%	0%
Total	**12**	**81**	**90 202 067**	**10 582 832**	**11.96%**	**/**	**/**	**-2.37%**	**-1.98%**

Implementation of audit results for audits finalised in 2014

Following the finalisation of each audit by an external audit firm, IMI JU launches the necessary corrective actions to recover and offset against subsequent claims of the same beneficiaries any amounts that have been found to be unduly paid.

The table below provides an estimate of the negative adjustments to be made in 2015 as a result of the 14 audits (of which 12 representative and 2 risk-based) finalised by the end of 2014.

Status of adjustments implementation as of 31/12/2014	Total	Implemented	To be implemented
Adjustments in favour of IMI offset or recovered from the 2012 sample (in EUR)	51 293	2 022	49 271
Adjustments in favour of IMI offset or recovered from the 2013 sample (in EUR)	59 724	21 880	37 844
TOTAL (in EUR)	**111 017**	**23 902**	**87 115**

In addition, the ongoing process initiated in 2014 for extending the systematic errors identified through the audits 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 will also be continued. These will lead to further adjustments and corrections.

A balanced and risk-based approach to ex post control

IMI JU 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 JU 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 IMI 1 JU Call 7 onwards, the full impact of IMI JU's actions can only be seen in the longer term, when more projects submit cost claims and *ex post* audits cover a greater part of the total population of beneficiaries.

Ex post review of EFPIA companies in kind contribution

Details about Ex post audits of industry's in kind contributions are presented under section 2 of this Report.

Fraud prevention and detection

Since its inception, IMI JU has ensured that procedures to fight against fraud at all stages of the management process are applied across the organisation. In October 2008, the IMI JU 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 IMI Programme Office has also collaborated closely with the European Commission on this matter over the years, and its staff has participated actively in coordination meetings and on training on fraud awareness.

Moreover, the IMI JU Anti-Fraud approach is based on the Research family anti-fraud strategy of the European Commission for the FP7 and H2020 research programmes. IMI JU has started the process of developing a new strategy, building on the work developed by the European Commission services, to prepare the Common anti-fraud strategy in the research family. The strategy takes into account the specificities of the new framework programme for research, and translates the JU's anti-fraud priorities, addressing risks that are relevant for the operations managed by IMI JU.

7.3 Results from audits of IMI JU during the reporting year

Internal audit

In January 2014, the Internal Audit Service of the European Commission (IAS) finalised an internal audit on project monitoring and the reporting of operational performance at IMI JU. The main objective of the audit was to assess whether the JU had 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 JU to put in place key performance indicator (KPIs) and the challenges faced within the pioneering context in which IMI JU operates.

The IAS recommended that objective setting and performance measurement and reporting be further developed by IMI JU 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 JU for project monitoring and reporting. Several of the agreed actions have already been implemented by the IMI Programme Office during 2014 with the remainder being carried over to 2015 in order to also reflect the ongoing transition and integration to H2020 business processes, IT applications and new work practices.

Between September and November 2014, the IAS also carried out two on-the-spot visits to IMI JU. The first was to audit the JU *ex ante* controls for operational expenditure. The second visit was for the conduct of a comprehensive risk assessment of the JU's core and support processes and activities in preparation for the next Internal Audit Strategy that will be submitted to the Governing Board and the Executive Director in 2015.

With regard to audit of *ex ante* controls, a final report on this exercise was received from the IAS in February 2015. The main objective of the audit was to assess the economy, efficiency, effectiveness and reliability of *ex ante* control procedures at IMI. 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'. In the report, the IAS acknowledges the efforts undertaken by IMI JU to maximise the efficient use of its available resources, to reduce the administrative burden for beneficiaries in line with FP7 provisions as well as to apply preventive measures to mitigate the risk of errors in beneficiaries' cost claims.

The IAS also recommends that IMI JU continues to further improve the effectiveness of its *ex ante* controls with the aim of using a more risk based and balanced approach. Moreover, the IAS recommends improvement in the control procedures connected with the Certificates on Financial Statements (CFS) as well as enhancements to the current practice of management reporting on the results of *ex ante* controls. The IAS also noted IMI JU's strengths in *ex ante* control, including the consistent use of control checklists, as well as the structured, organised, accurate and well-documented processes of checks and controls. In 2015, IMI will use the results of the audit to draw up a plan to implement the accepted recommendations for improvement.

Furthermore, during 2014, the IMI JU's Internal Audit Manager, 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 European Court of Auditors (ECA) and the IAS, providing additional support to the auditors in the conduct of their work. This included conducting in November 2014 the joint internal audit risk assessment exercise with the IAS.

External audit

In its report on the 2013 accounts issued in October 2014, the 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 legal and regular in all material respects except for a qualification on the basis of the error rate detected *ex post* by IMI JU's own audits being higher than the 2.0% materiality threshold. At the time of the ECA audit, IMI JU was already taking corrective and recovery actions and had also launched additional audits to cover more recent claims (refer to section 7.2 above).

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 been taken by IMI JU to mitigate the risk of errors in financial statements submitted by beneficiaries and these will be continued in the foreseeable future. More information on these measures can be found in the sections on financial operations (section 6.1), on *ex-post* controls and recoveries (section 7.2) as well and the analysis and action plan (section 7.5).

Without calling into question its opinions as outlined above, the ECA also provided in its report on the financial year 2013 general comments on the following:

- the overall positive budget implementation rate of 99.5% for commitment appropriations and 97.5% for payment appropriations;
- the successful commitment of the entire budget for research under the FP7 programme (EUR 970 million of IMI funding and the matching in kind contributions from EFPIA companies of EUR 982 million);
- the revision of the financial rules of IMI JU on 7 July 2014 to reflect the changes of the new Financial Regulation;
- the conclusions as well as the follow up on recommendations and action plans resulting from internal audits and risk assessments;
- the progress made by IMI to integrate in the Commission's system for monitoring and reporting on research results as well as on the need for further development in this area;
- the various measures in place within IMI for the prevention and management of conflict of interest situations;
- the positive conclusions and recommendations of the Commission's Second Interim Evaluation of IMI JU;
- the outstanding need for the Accounting Officer's validation of the accounting system to also cover the implementation of ex post audit results;
- the satisfactory completion of the certification of methodologies for the evaluation of in kind contributions declared by EFPIA companies and the ongoing audits of these companies' contributions.

7.4 Audits from previous years

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

All comments from the ECA from the report on the 2012 Accounts issued in November 2013 were addressed by IMI JU in 2013 and 2014 with one action to be duly finalised in 2015.

These concerned:

- the continued implementation of preventive and corrective measures to mitigate the risk of errors in financial statements submitted by beneficiaries. More information on these activities can be found in the sections on financial operations (section 6.1), on *ex post* controls and recoveries (section 7.2) as well and the analysis and action plan (section 7.5);
- the implementation of the budget in terms of both commitment and payment appropriations (see the financial tables and graphs in section 6.1 on the achievements in 2014 and previous years);
- the implementation in 2014 of the final stages of the IMI 1 JU Calls for Proposals financed through FP7 (refer to section 4);
- the completion of the recommended documentation of internal controls for *ex post* and accounting closure activities in 2013 (reported in the AAR of 2013);
- the implementation of the recommendations of the IAS in 2012 and the closure of the last remaining action (reported in the AAR 2013 and below);
- the information made available in 2013 for the monitoring report that is regularly produced for FP7 (reported in the AAR of 2013);
- the coverage of *ex post* audit activities in the validation of the accounting system (to be completed in the next update of the validation exercise in 2015).

Follow-up on outstanding internal audit recommendations from previous years

The only internal audit recommendation outstanding from previous years was the one related to the implementation of the updated and consolidated policy for the management of conflict of interest for the Executive Director and staff in 2013. This was successfully closed in March 2014, after the IAS conducted an on-the-spot verification of the supporting evidence and concluded that the action had been implemented.

7.5 Reservations

The error rate on ex post audits of beneficiaries is on a downward trend.

IMI2 JU has increased its internal resources to better implement its audit plan and continues to implement preventive and corrective measures aimed at reducing the error rate. Therefore, the representative and residual error rates will continue to develop as more audits are closed and more corrections and recoveries are undertaken.

However, for reasons of prudence, a reservation is made concerning the rate of residual errors with regard to the accuracy of cost claims submitted by beneficiaries receiving IMI2 JU funding.

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 participants together with the resulting corrective and recovery actions, including the updating to the JU's *ex post* audit strategy and a review of the current high audit coverage of beneficiaries cost claims (40%);
- 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 JU's financial rules.

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 beneficiaries of IMI JU funding
Domain	IMI JU projects.
Activity and amount	Payment appropriations related to intermediate payments made to beneficiaries in 2014: EUR 84 654 145.
Reason for the reservation	At the end of 2014 it is not possible to state with certainty that the residual error rates in the cost claims of beneficiaries of IMI funding will remain below the materiality threshold of 2% at the end of the multi-annual period.

Materiality criterion/criteria	The materiality criterion for beneficiaries' cost claims is the estimated 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 estimated 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 cumulative residual error rate of 2.0% in favour of IMI JU as at 31 December 2014 by the amount of intermediate and final payments made to beneficiaries during the financial year 2014. The estimated impact on interim and final payments made to beneficiaries in 2014 is therefore EUR 1.7 million.
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.
Responsibility for the weakness and its correction	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 remaining scope is to reduce the risk of errors through the following actions: ▪ the continued systematic launch of *ex post* audits of participants 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; ▪ 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.

7.6 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.

8 STATEMENT OF REASONABLE ASSURANCE

I, the undersigned, Irene Norstedt, acting 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 internal assessments, *ex post* controls, the handover file of my predecessor, 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 error rate on ex-post audits of beneficiaries is on a downward trend. IMI2 JU has increased its internal resources to better implement its audit plan and continues to implement preventive and corrective measures aimed at reducing the error rate. IMI2 JU expects the residual error rate at the end of the programme to be below 2%. For reasons of prudence, a reservation is made concerning the rate of residual errors with regard to the accuracy of cost claims submitted by beneficiaries receiving IMI2 JU funding.

Signed in Brussels, on 30 June 2015

Irene Norstedt

Acting Executive Director

ANNEX A – FINANCIAL INFORMATION

In accordance with the IMI2 JU Financial Rules Article 20 paragraph 1 information on the accounts and the report on budgetary and financial management should be included in the annual activity report.

Budget

Budget of IMI JU is divided in three titles:

- Title 1 covers staff expenditure such as salaries, training, costs associated with recruitment procedures and staff well-being;
- Title 2 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 3 covers operational activities of IMI JU.

The 2014 budget was approved by the Governing Board on 20 December 2013 and adjustments were made based on the Decision of the Governing Board on carry over amounts of 27 January 2014.

Following entry into force of the Council Regulation 557/2014 establishing IMI2 JU, an amending budget 2014 was approved by the Governing Board on 7 July 2014. This amendment represented an increase of the budget by the amounts available for IMI2 JU activities in the given year.

Budget 2014 in EUR						
	Voted budget		**Amending budget**		**Final budget**	
	CA	**PA**	**CA**	**PA**	**CA**	**PA**
Revenue						
EU	3,950,000	165,137,993	214,023,700	490,000	217,973,700	165,627,993
EFPIA	3,950,000	3,950,000	490,000	490,000	4,440,000	4,440,000
C2	880,903	733,257			880,903	733,257
Total revenue	**8,780,903**	**169,821,250**	**214,513,700**	**980,000**	**223,294,603**	**170,801,250**
	Voted budget		**Amending budget**		**Final budget**	
	CA	**PA**	**CA**	**PA**	**CA**	**PA**
Expenditure						
Title 1	4,541,000	4,541,000	314,000	314,000	4,855,000	4,855,000
Title 2	3,359,000	3,359,000	666,000	666,000	4,025,000	4,025,000
Title 3 – C1	0	161,187,993	213,533,700		213,533,700	161,187,993
Title 3 – C2	880,903	733,257			880,903	733,257
Total expenditure	**8,780,903**	**169,821,250**	**214,513,700**	**980,000**	**223,294,603**	**170,801,250**

Budget transfers

No budget transfer between Titles was done during 2014.

Twelve budget transfers between chapters were authorised in 2014 which led to the following changes:

Chapter	Amending Budget No 1/2014	Budget transfer	Budget after transfers
Chapter 11	4,370,000	(-) 26,346	4,343,654
Chapter 14	250,000	(+) 26,346	276,346
Chapter 20	590,000	(+) 26,735	616,735
Chapter 21	583,000	(+) 42,213	625,213
Chapter 22	145,000	(-) 110,246	34,754
Chapter 25	160,000	(-) 36,887	123,113
Chapter 26	500,000	(-) 100,702	399,298
Chapter 29	620,000	(+) 178,887	798,887

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

Budget execution

Details on the budget execution are reported in the section 6.1 of this Annual Activity Report.

Revenue

IMI JU's revenue for the year:

Source of revenue	Amount (in EUR)			
	2014		2013	
	Budget	Cashed	Budget	Cashed
EU Contribution from European Commission	165,627,993.00	165,627,993.00	125,829,159.00	125,829,159.00
Contribution from EFPIA	4,440,000.00	*3,354,419.95	4,200,000.00	2,742,987.80
Bank interest		100,843.08	104,808.00	95,796.81
Miscellaneous income		11,270.12		100,112.92
Interest on pre-financing		31,161.05		54,072.68
TOTAL		**169,125,687.20**		**128,822,129.21**

*EUR 1,356,351 of EFPIA contribution was cashed in 2015

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 31/12/2014
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	
2014	3,354,419.95	3,114,577.04	399,910.42	
Total	**14,662,775.80**	**13,069,948.29**	**1,729,826.07**	***(136,998.56)**

*The amount due to IMI will be paid by EFPIA together with the first instalment 2015.

Expenditure

Administrative expenditure (Title 1 and Title 2)

Title 1

In 2014 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 2

Other administrative expenditure is reported under Title II including:

- rent and related charges;
- development and maintenance of IT tools (SOFIA, DORA, etc.);
- ABAC fees;
- purchase, rent and maintenance of equipment;
- 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 2014, IMI mainly relied on these existing contracts for its procurement needs. Two open procedures were carried out in 2014, both for new framework contracts. The first was a joint procurement with other Joint Undertakings for a framework contract in IT and telephony services with IMI acting as the lead contractor. The contract replaces earlier framework contracts that expired in November 2014. The second open procedure was for a framework contract for the analysis of bibliometric data and other program output indicators that IMI concluded on its own. The maximum duration for both framework contracts is four years.

Administrative expenditure – budget execution

In July 2014, the administrative budget was increased by EUR 980,000 intended to cover costs of increased number of staff and other related expenditure following the start of the new IMI programme – IMI2. On the request of the IMI Governing Board the recruitments of staff was postponed to 2015 and therefore the additional budget was not used. Works related to extension of working space to accommodate additional staff are also postponed to 2015 resulting into underspending of office equipment budget.

IMI continued to execute its budget applying principles of sound financial management which resulted into savings for example in organisation of meetings and workshops. Savings were also made in costs of ex post audits. With the maturity of IMI projects the necessary coverage can be achieved with less audit assignments as in previous years.

Unused appropriations will be re-entered into budget in the following years (see table "Overview of amounts available to be entered into budget in the following years"). Note that the difference between available commitment and payment appropriation is due to the ex post audit commitments which will be paid in 2015 (commitments on C8 in 2014) as well as a small difference of EUR 8,145 for which commitment was carried forward but they will be de-committed in 2015 and therefore payment appropriation entered into 2015 on C2 was lowered by this amount.

Title 1	Budget	After Amending Budget No 1	Committed/ Paid	%	Carried forward to 2015	Available for following years
C1						
Commitments	4,541,000	4,855,000	4,045,147	83.32	154,177	809,853
Payments	4,541,000	4,855,000	3,890,969	80.14		964,031
C4*						
Commitment	3,185		0			3,185
Payments	3,185		0			3,185
C8						
Commitment	58,844		26,582			32,262
Payments	58,844		26,582			32,262
Title 2	**Budget**	**After Amending Budget No 1**	**Committed/ Paid**	**%**	**Carried forward to 2015**	**Available for following years**
C1						
Commitments	3,359,000	4,025,000	3,420,465	84.98	1,444,741	604,535
Payments	3,359,000	4,025,000	2,338,185	58.09		1,686,815
C4*						
Commitment	3,071		0			3,071
Payments	3,071		0			3,071
C8						
Commitment	1,220,915		1,135,699	93.02	**362,461	85,216
Payments	1,220,915		773,238	63.33		447,677

*Under C4 the "budget" shows amounts recovered during the year from suppliers

**Commitments for ex post audits not finalised in 2015 are carried forward to 2015

Administrative expenditure – budget execution per chapter – C1

Chapter	Administrative expenditure 2014				
	Final Budget	Execution Commitment appropriation		Execution Payment appropriation	
Execution C1 and C2		**EUR**	**%**	**EUR**	**%**
11 - Staff in active employment	4,343,654	3,553,694	81.81	3,553,694	81.81
12 - Misc. expenditure on staff recruitment	25,000	21,779	87.11	20,879	83.51
13 - Missions and duty travel	190,000	185,012	97.37	158,437	83.39
14 - Sociomedical structure	276,346	270,486	97.88	151,798	54.93
17 - Entertainment and representation	20,000	14,176	70.88	6,160	30.80
Total Title 1	**4,855,000**	**4,045,147**	**83.32**	**3,890,969**	**80.14**
20 - Office building and associated costs	616,735	616,735	100.00	615,015	99.72
21 - Information technology purchases	625,213	625,213	100.00	394,501	63.10
22 - Office equipment (movable property)	34,754	19,224	55.31	14,387	41.40
23 - Current administrative expenditure	130,000	103,009	79.24	64,430	49.56
24 - Telecommunications & postal expenses	67,000	56,038	83.64	20,952	31.27
25 - Expenditure on formal meetings	123,113	97,830	79.46	66,646	54.13
26 - Exp. in connection with oper. activities	399,298	269,158	67.41	153,670	38.48
27 - External communication	650,000	614,895	94.60	295,295	45.43
28 - Service contracts (studies, audits)	580,000	245,802	42.38	10,939	1.89
29 - Expert contracts and evaluations	798,887	772,562	96.70	702,350	87.92
Total Title 2	**4,025,000**	**3,420,465**	**84.98**	**2,338,185**	**58.09**
Total Administrative Costs	**8,880,000**	**7,465,612**	**84.07**	**6,229,154**	**70.15**

Operational expenditure (Title 3)

Operational expenditure on Title III covers all the expenses linked to the Research Agenda of IMI JU. In 2014, intermediate payments for Calls 1 - 6 projects had been made as well as pre-financing for projects of Call 9 and Call 11. These payments consumed 74.11% of the payment appropriation available for 2014. The budgeted payment appropriation was not fully used in 2014 due to delays in negotiations of several projects (one project of Call 9, one project of Call 10 and 3 projects of Call 11) for which the payment of pre-financing is postponed to 2015.

According to the IMI Financial Rules in place until July 2014, the appropriations authorised for the current financial year should be used first. This rule changed following the adoption of the new IMI Financial Rules in July 2014. However, due to the human error, the fund source C2 was not executed fully in 2014. The non-used amount will be entered into budget 2015.

Budget execution of the commitment appropriation reached 92.72 %. The commitment appropriation available under the fund source C1 was available for IMI2 operational activities and under the fund source C2 for IMI1 activities. The appropriation on C1 fund source was consumed by launching IMI2 Calls 1 – 4. All the commitments made for IMI2 activities are global commitments as no grant agreements were signed by the end of 2014.

The fund source C2 was not used during 2014 as all IMI1 activities were sufficiently covered by the commitments made in the previous year. Part of the commitments on fund source C8 (IMI1 activities) were de-committed due to delays in negotiations mentioned above. The cancelled appropriation will be entered into budget 2015.

Title 3	Budget	After Amending Budget No 1	Committed	%	Not used/ Cancelled	Paid	%	To be carried over
C1								
Commitment	0	213,533,700	198,805,966	93.10	14,727,734	n/a		14,727,734
Payments	161,187,993	161,187,993	n/a		**41,247,367	119,940,625	74.41	41,247,367
C2								
Commitment	880,903	0	0	0	880,903	n/a		880,903
Payments	733,257	0	n/a		673,257	60,000	8.18	673,257
C4*								
Commitments	55,312	n/a	0		55,312	n/a		55,312
Payments	55,312	n/a	n/a		**5,012	50,299		5,012
C8								
Commitments					73,117,015			73,117,015

*Under C4 the "budget" shows amounts recovered from beneficiaries during 2014

** 1 Euro difference due to rounding

Overview of the contractual obligations (on-going projects/calls)

Call	Commitment	Paid pre-financing	Cost claims paid in 2010	2011	2012	2013	2014	Recovered 2013	Recovered 2014	RAL
IMI1										
Call 1	116,082,075	36,333,838	534,382	15,213,166	24,990,569	23,788,876	12,604,928	16,823	59,804	2,692,943
Call 2	85,765,138	30,151,325			8,469,655	19,125,340	17,954,115			10,064,703
Call 3	112,839,908	36,108,768				10,144,282	19,611,824			46,975,034
Call 4	97,943,541	34,076,849				6,367,511	15,487,317			42,011,864
Call 5	79,999,157	21,200,715					10,416,283			48,382,159
Call 6	125,417,213	31,133,919					4,378,133			89,905,161
Call 7	12,999,811	6,599,939								6,399,872
Call 8	98,732,937	33,112,485								65,620,452
Call 9	32,569,426	12,250,479								20,318,947
Call 10	0									-
Call 11	134,958,688	36,538,551								98,420,137
Total IMI1	**897,307,894**	**277,506,868**	**534,382**	**15,213,166**	**33,460,224**	**59,426,009**	**80,452,600**	**16,823**	**59,804**	**430,791,272**
IMI2										
Call 1	24,630,000									24,630,000
Call 2	116,615,966									116,615,966
Call 3	56,430,000									56,430,000
Call 4	1,130,000									1,130,000
Total IMI2	**198,805,966**									**198,805,966**
TOTAL	**1,096,113,860**									**629,597,238**

For IMI1 Calls, the amounts showed in the last column represent remaining obligation under signed grant agreements per Call. Figures for IMI2 Calls show the global commitment made for each Call.

Overview of appropriations carried over to 2015

Title 3	Commitment appropriation	Comment
IMI2 – C1	14,727,734	Non-used appropriation in 2014
IMI1 – C2	880,903	Non-used appropriation in 2014 carried over from 2013
IMI1 – C4	55,312	Non-used appropriation (recoveries in 2014)
IMI1 – C8	73,117,015	Cancelled commitment appropriation in 2014
TOTAL	**88,780,964**	

Title 1, 2, 3	Payment appropriation	Comment
Title 1, 2 – C1	1,590,774	Appropriation corresponding to the administrative commitments carried forward to 2015
Title 3 - C1	41,247,367	Non-consumed appropriation 2014
Title 3 – C2	673,257	Non-consumed appropriation 2014 carried over from 2013
Title 3 – C4	5,012	Non-consumed appropriation (recoveries in 2014)
TOTAL	**43,516,410**	

Overview of amounts available to be entered into budget in the following years (excluding appropriations entered into budget 2015)

Title	Commitment appropriation	Comment
Title 1 – C4	2,234	Non-used C4 app. 2013 to be entered until 2016
Title 2 – C4	14,385	Non-used C4 app. 2013 to be entered until 2016
Title 3 – C4	16,823	Non-used C4 app. 2013 to be entered until 2016
Title 1 – C1	809,853	Non-used C1 app. 2014 to be entered until 2017
Title 2 – C1	604,535	Non-used C1 app. 2014 to be entered until 2017
Title 1 – C4	3,185	Non-used C1 app. 2014 to be entered until 2017
Title 2 – C4	3,071	Non-used C1 app. 2014 to be entered until 2017
Title 1 – C8	32,262	Non-used C1 app. 2014 to be entered until 2017
Title 2 – C8	85,216	Non-used C1 app. 2014 to be entered until 2017
Title 1, 2 or 3	100,843	Bank interest –2014
Total	**1,672,407**	
Title	**Payment appropriation**	**Comment**
Title 1 – C4	2,234	Non-used C4 app. 2013 to be entered until 2016
Title 2 – C4	14,385	Non-used C4 app. 2013 to be entered until 2016
Title 3 – C4	16,823	Non-used C4 app. 2013 to be entered until 2016
Title 1 – C1	810,856	Non-used C1 app. 2014 to be entered until 2017
Title 2 – C1	249,216	Non-used C1 app. 2014 to be entered until 2017
Title 1 – C4	3,185	Non-used C1 app. 2014 to be entered until 2017
Title 2 – C4	3,071	Non-used C1 app. 2014 to be entered until 2017
Title 1 – C8	32,262	Non-used C1 app. 2014 to be entered until 2017
Title 2 – C8	447,677	Non-used C1 app. 2014 to be entered until 2017
Title 1, 2 or 3	100,843	Bank interest – 2014
Total	**1,680,552**	

The above appropriations have not been re-entered into budget. The year of origin and the year until which they can be entered into budget based on the JU's needs (and according to the IMI Financial Rules) are indicated in the comment. The difference between available commitment and payment appropriations is explained in the section Administrative expenditure – budget execution.

Budget outturn account

	2014	2013
Revenue	EUR	EUR
EU contribution – European Commission DG RTD	165,627,993.00	125,829,159.00
EFPIA contribution for running costs	3,354,419.95	2,742,987.80
Bank interest	100,843.08	95,796.81
Interest on pre-financing	31,161.05	54,072.68
Miscellaneous income	11,270.12	100,112.92
Total revenue (a)	**169,125,687.20**	**128,822,129.21**
Expenditure	EUR	EUR
Personnel expenses – Title I	**3,917,551.62**	**3,794,286.01**
Payments on current year appropriations (C1)	3,890,968.86	3,722,901.56
Payments on previous year appropriations (C8)	26,582.76	71,384.45
Administrative expenses – Title II	**3,111,423.01**	**2,879,576.07**
Payments on current year appropriations (C1)	2,338,185.22	2,127,552.13
Payments on previous year appropriations (C8)	773,238.09	752,023.94
Operational expenses – Title III	**120,050,924.63**	**121,467,419.45**
Payments on current year appropriations (C1) + (C4)	119,990,924.63	121,467,419.45
Payments on previous year appropriations (C2)	60,000.00	0
Total expenditure (b)	**127,079,899.56**	**128,141,281.53**
Outturn for the financial year (a-b)	**42,045,787.64**	**680,847.68**
Cancellation of unused appropriations	(+) 1,546,267.00	(+) 396,881.33
Appropriations carried forward (Title I and II)	(-) 1,590,774.00	(-) 2,135,227.22
Appropriations carried over (Title III)	(-) 41,925,636.00	(-) 691,202.00
Balance of the outturn account for the financial year	**75,644.64**	**-1,748,700.21**

ANNEX B – HUMAN RESSOURCES

In accordance with the Delegation Agreement between the European Union and the IMI2 JU, Art 16 paragraph 2, as an annex to the annual activity report, the IMI2 JU shall also report on the use of and changes to staff resources and changes to the staff establishment plan, detailing the recruitment by function group, grade and category, the reclassification exercise and any changes to the number of staff members during the financial year of the annual activity report.

Changes to the Establishment Plan: None

Staff recruited:

Type of the contract	Position	As of
FG III	IT Assistant	16 June 2014
AD 14	Acting Executive Director (Seconded from the European Commission	16 December 2014

Resignations/end of contract:

Type of the contract	Position	As of
FG IV	HR Manager	15 June 2014
AD 8	IT Manager	30 June 2014
AD 8	Internal Audit Manager	Resignation received on 25/11/2014[18]
AD 14	Executive Director	15 December 2014
AD 5	Ex post Audit & Finance Officer	31 December 2014

Reclassification exercise: None

[18] The Internal Audit Manager announced his resignation during 2014 with his last working day being on 28/02/2015.

Category and grade	Establishment plan in EU Budget 2013		Modifications in 2013 in application of flexibility rule[19]		Establishment plan in amended EU Budget 2014		Modifications envisaged in establishment plan 2014 in application of flexibility rule[20]		Establishment plan 2015		Establishment plan 2016		Establishment plan 2017	
	officials	TA	officials	TA	officials	TA	officials	TA	officials	TA	officials	TA	officials	TA
AD 15 to AD 16	-	0	-	0	-	0	-	0	-	0	-	0	-	0
AD 14	-	1	-	1	-	1	-	1	-	1	-	1	-	1
AD 13	-	0	-	0	-	0	-	0	-	0	-	0	-	0
AD 12	-	1	-	1	-	1	-	1	-	1	-	1	-	1
AD 11	-	4	-	4	-	4	-	4	-	4	-	4	-	4
AD 10	-	0	-	0	-	0	-	0	-	0	-	0	-	0
AD 9	-	5	-	2	-	2	-	2	-	2	-	2	-	2
AD 8	-	11	-	9	-	9	-	9	-	9	-	9	-	9
AD 7	-	1	-	5	-	5	-	7	-	5	-	5	-	5
AD 6	-	0	-	0	-	0	-	0	-	0	-	0	-	0
AD 5	-	0	-	1	-	11	-	3	-	13	-	16	-	17
Total AD	-	23	-	23	-	33	-	27	-	35	-	38	-	39
AST 9 to AST 11	-	0	-	0	-	0	-	0	-	0	-	0	-	0
AST 8	-	1	-	1	-	0	-	1	-	0	-	0	-	0
AST 4 to AST 7	-	0	-	0	-	0	-	0	-	0	-	0	-	0
AST 3	-	5	-	5	-	0	-	5	-	0	-	0	-	0
AST 1 to AST 2	-	0	-	0	-	0	-	0	-	0	-	0	-	0
Total AST	-	6	-	6	-	0	-	6	-	0	-	0	-	0
AST/SC 1 to AST/SC 6	-	0	-	0	-	0	-		-	0	-	0	-	0
Total AST/SC	-	0	-	0	-	0	-	0	-	0	-	0	-	0
TOTAL	**-**	**29**	**-**	**29**	**-**	**33**	**-**	**33**	**-**	**35**	**-**	**38**	**-**	**39**

[19] *In line with Article 15 (4) of the draft Commission delegated regulation on the model financial regulation for public-private partnership bodies, stating that "The establishment plan shall show next to the number of posts authorised for the financial year, the number authorised for the preceding year and the number of posts actually filled […]" which provides flexibility to allocate staff according to the needs, as long as IMI does not overstep the allocated budget.*

[20] *Ibid.*

Staff population		Staff population actually filled in 31.12.2012[21]	Staff population in EU Budget 2013[22]	Staff population actually filled at 31.12.2013[23]	Staff population in amended EU Budget 2014[24]	Staff population in Draft EU Budget 2015	Staff population envisaged in 2016[25]	Staff population envisaged in 2017[26]
Officials	AD	-	-	-	-	-	-	-
	AST	-	-	-	-	-	-	-
TA	AD	22	23	23	33	35	38	39
	AST	6	6	6	0	0	0	0
Total[27]		28	29	29	33	35	38	39
CA GFIV		2	2	2	2	2	2	2
CA GF III		4	4	4	5	6	6	7
CA GF II		1	1	1	1	1	1	1
CA GFI		-	-	-	-	-	-	-
Total CA[28]		7	7	7	8	9	9	10
SNE[29]		-	-	-	-	-	-	-
TOTAL		35	36	36	41	44	47	49
Structural service providers[30]		1,3	1,3	1,3	1	1	1	1
External staff[31] *for occasional replacement*[32]		2		2				

[21] Offer letters sent should be counted as posts filled in with a clear reference in a footnote **with a number how many posts/positions it concerns.**

[22] As authorised for officials and temporary agents (TA) and as estimated for contract agents (CA) and seconded national experts (SNE).

[23] Offer letters sent should be counted as posts filled in with a clear reference in a footnote **with a number how many posts/positions it concerns.**

[24] As authorised for officials and temporary agents (TA) and as estimated for contract agents (CA) and seconded national experts (SNE).

[25] Figures should not exceed those indicated in the Legislative Financial Statement attached to the founding act (or the revised founding act).

[26] *Ibid.*

[27] Headcounts – Total matching the Legislative Financial Statement annexed to the EC's proposal for IMI2.

[28] FTE – Total matching the Legislative Financial Statement annexed to the EC's proposal for IMI2.

[29] FTE

[30] **Service providers** are contracted by a private company and carry out specialised outsourced tasks of horizontal/support nature, for instance in the area of information technology. At the Commission the following general criteria should be fulfilled: 1) no individual contract with the Commission; 2) on the Commission premises, usually with a PC and desk; 3) administratively followed by the Commission (badge, etc.) and 4) contributing to the value added of the Commission. FTE

[31] FTE

[32] For instance replacement due to maternity leave or long sick leave.

ANNEX C – 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 JU's control strategy can only be fully measured and assessed at the final stages in the life of the IMI JU 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 D – INTERNAL CONTROL FOR BUDGET IMPLEMENTATION

Key figures

Details on budget execution and time to pay for administrative and operational expenditures are provided in sections 6.1 and 7.2.

Management and control systems: stages and main actors

IMI JU 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 and as defined in the routing sheet. This financial circuit, together with the management and accounting systems, segregation of duties and procedures, internal controls, reporting structures, and control functions were established in line with the requirements of the IMI JU financial rules.

The Executive Director acts as Authorising Officer, with authority being delegated to the Head of Administration and Finance and, when necessary as backup, to another member of staff. In accordance with its financial rules, IMI JU 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 IMI Programme Office also has an Internal Control Coordinator (ICC), an Audit Manager 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 JU projects is based on a single or a two-stage evaluation process which includes a public Call for proposals, official rules of participation, eligibility screening of the proposals; ethical reviews by independent external experts; controls to ensure conformity with IMI JU rules as well as procedures and checks carried out during the evaluation, grant preparation and signature processes. Each key stage is endorsed by a decision of the IMI JU 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 JU 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 JU 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 IMI JU Governing Board, management team meetings, management of scientific activities meetings, finance and administration meetings, staff 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 texts, guidelines for applicants and participants and information on the website); the organisation of meetings with Governance and Consultative bodies and other stakeholders (such as the ILG), special information sessions linked to the different Calls for proposals; 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 and final reports which include financial statements and an explanation on the use of resources for all participants including EFPIA companies.

For the first IMI JU research programme within the EC's 7th Framework Programme, the cumulative threshold for the presentation of a certificate on the financial statements issued by an independent external auditor is EUR 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 JU. These processes and controls are currently being reviewed and aligned to reflect the changes that have come into force with the establishment of IMI 2 JU and the launch of Calls for Proposals within the H2020 Programme.

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 2011in addition, interim reviews have also been systematically used to complement the detective and corrective controls. In 2014, 8 interim reviews were organised.

Corrective controls and audit

Ex post audits are a key element of corrective controls (refer to the section on *ex post* audits in 7.2 above). IMI JU follows the comprehensive *ex post* audit strategy which was approved by the IMI JU Governing Board following harmonisation with the corresponding FP7 strategy. In 2015 the process will also start to update the strategy to reflect the lessons learned from the first years of implementation for FP7 projects as well as to integrate the new context and specificities of H2020.

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.

By the end of 2014, IMI JU had launched four major representative samples of audits of beneficiaries. 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. 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. Preventive measures, such as workshops and guidance to participants and auditors, and further strengthening of *ex ante* controls are also being implemented. The results of these representative samples are also used to calculate the estimated error rates in the total population of claims submitted by beneficiaries.

In addition, by the end of 2014, IMI JU had also launched six 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 will be continued with other EFPIA companies, particularly among the largest contributors of in kind contributions to IMI JU projects.

Anti-fraud measures

Anti-fraud measures are embedded in various *ex ante* and *ex post* controls for prevention and detection purposes. In 2015 in addition, IMI JU will build on the Anti-fraud strategy and action plan 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 2014, 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 JU.

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 2014, 7 exceptions were registered by management. These related to processes and workflows concerning procurement and contract management (3 registered exceptions), Call management (2 registered exceptions), communication of plans (1 registered exception) and grant management (1 registered exception).

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 internal control checks.

As from 2012, independent verifications and follow-up examinations on the implementation of recommendations have also been carried out by the IAS on IMI JU'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 additional validations, particularly of new or modified processes or procedures that are assessed as having a significant impact on reliability of the accounting system at any time.

Independent observers are also engaged by IMI JU to monitor each Call evaluation. 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 the further improvement and fine-tuning of the processes. These reports are made public and identified actions are followed up and implemented by IMI JU in subsequent evaluations. In 2014, there were 5 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 JU 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 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 JU as well as on the operational efficiency of the organisation are systematically compiled and reported. The latter cover critical issues such as time to pay, time to grant and budget execution.

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

High-level management reporting

The Annual Work 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 meetings 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 E- TABLE OF ONGOING IMI PROJECTS

(as of 31 December 2014)

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	www.advance-vaccines.eu	vaccines
AETIONOMY	Organising mechanistic knowledge about neurodegenerative diseases for the improvement of drug development and therapy	www.aetionomy.eu	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
Combacte-MAGNET	Combatting Bacterial Resistance in Europe - Molecules against Gram Negative Infections		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
DRIVE AB	Driving re-investment in R&D and responsible antibiotic use	http://drive-ab.eu/	infectious diseases
EBiSC	European bank for induced pluripotent stem cells	http://www.ebisc.org/	stem cells
EBODAC	Communication strategy and tools for optimizing the impact of Ebola vaccination deployment (Compliance with vaccine regimens)		Ebola+ programme
EBOMAN	Manufacturing and development for rapid access Ebola Vaccine (EBOMAN) (Vaccine manufacture capability projects)		Ebola+ programme

EBOVAC1	Development of a prophylactic Ebola vaccine using an heterologous prime-boost regimen Phase I (vaccine development)		Ebola+ programme
EBOVAC2	Development of a prophylactic Ebola vaccine using an heterologous prime-boost regimen Phase II (vaccine development)		Ebola+ programme
EHR4CR	Electronic health record systems for clinical research	www.ehr4cr.eu	knowledge management
ELF	European Lead Factory	www.europeanleadfactory.eu	drug discovery
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	www.nd4bb-enable.eu	antimicrobial resistance
EPAD	European Prevention of Alzheimer's Dementia Consortium		Alzheimer's disease
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
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	http://www.imi-getreal.eu/	relative effectiveness
IMIDIA	Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes	www.imidia.org	diabetes
IPIE	Intelligent Assessment of Pharmaceutical in the Environment		green chemistry

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	http://www.precisesads.eu/	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
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

SPRINTT	Sarcopenia and Physical fRailty IN older people: multi-componenT Treatment strategies	http://www.mysprintt.eu/	geriatrics
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
WEB-RADR	Recognising adverse drug reactions	http://web-radr.eu/	pharmacovigilance

List of acronyms

Acronym	Meaning
AAR 2013	Annual Activity Report 2013
ABAC	Accrual Based Accounting System
ACE Program	Autism Centres of Excellence Program
AD	Alzheimer's disease
ADC	Apparent diffusion coefficient
AER	Average error rate
API	Application Programming Interface
ASD	autism spectrum disorder
AWP2014	Annual Work Plan 2014
BIT	Booking of IT material application
CASMI	Centre for the Advancement of Sustainable Medical Innovation
CDER	Centre for Drug Evaluation and Research
CDISC	Clinical Data Interchange Standards Consortium
CEDEFOP	European Centre for the Development of Vocational Training
CEOi	Global CEO Initiative
CFAST	Coalition for Accelerating Standards and Therapies
CFS	Certificates on Financial Statements
CNS	central nervous system
COPD	chronic obstructive pulmonary disease
C-Path	Critical Path Institute
CPD	Continuing professional development
CPTR	Critical Path to TB Drug Regimens
CRC	Australian Cooperative Research Centres

CRO	Contract research organisation
DG HR	Human Resources and Security Directorate General.
DG Internal Market and Services	Directorate General for Internal Market and Services
DG RTD	Directorate-General for Research and Innovation
DILI	Drug-induced liver injury
DIVI	Drug-induced vascular injury
DORA	Document Registry Application
DoW	Description of Work
DPO	Data protection officer
DPUK	Dementia Platform UK
E&T	Education & Training
EC	European Commission
ECA	European Court of Auditors
eCDR	electronic Career Development Report application
EDPS	European Data Protection Supervisor
EEG	Electroencephalograph
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHR	electronic health record
ELF	European Lead Factory
EMA	European Medicines Agency
eMA	Electronic Missions Application
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ENSO	Exploring New Scientific Opportunities
EoI	Expression of Interest
eTOXdb	eTOX rich preclinical database
eTOXsys	eTOX *in silico* toxicology prediction system
EU	European Union
EU-AIMS	
FDA	Food and Drug Administration
FLT	Fluorothymidine
fNIH	Foundation for the National Institute of Health
FP	Full Proposal
FP7	Seventh Framework Programme
FPP	Full Project Proposal
GAP	Global Alzheimer's Platform
GSK	GlaxoSmithKline
GWAS	genome-wide association study
H2020	Horizon 2020 is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness. For more information, click here: http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020
Helmsley Charitable Trust	Leona M. and Harry B. Helmsley Charitable Trust
HR	Human resources

HTA	Health Technology Assessment
IAC	Internal Audit Capability
IAC	Internal Audit Capability
IAPO	International Alliance of Patients' Organisations
IAS	Internal Audit Service
IAS	Internal Audit Service of the European Commission
IBS	Irritable bowel disease
ICC	Internal Control Coordinator
ICC	Internal Control Coordinator
ICH S 1	International Conference on Harmonisation's Safety (S) 1
ICS	Internal Control Standards
ILG	Industry Liaison Group
IMI 1 JU	Innovative Medicines Initiative 1Joint Undertaking
IMI 2 JU	Innovative Medicines Initiative 2Joint Undertaking
IMI JU	Innovative Medicines Initiative Joint Undertaking
iPS cells	Induced pluripotent stem cells
ISA	Information System for Absences
ITF	EMA Innovation Task Force
ITI-PF&S	Innovative therapeutic interventions against physical frailty and sarcopenia
JDRF	Juvenile Diabetes Research Foundation
JUs	Joint Undertakings
KPI	Key performance indicator
LEAP	Longitudinal European Autism Project
MAPPs	Medicines adaptive pathways to patients
MIT	Massachusetts Institute of Technology
MRI	Magnetic resonance imaging
MS	Multiple sclerosis
MTA	material transfer agreement
ND4BB	New Drugs for Bad Bugs
ND4BB	New Drugs for Bad Bugs
NEWDIGS	New Drug Development ParadIGmS
NIMH	National Institute of Mental Health
NMDA-Receptor	N-methyl-D-aspartate receptor
OECD	Organisation for Economic Co-operation and Development
OLAF	European Anti-Fraud Office
PAGE	Population Approach Group in Europe
PET	Positron emission tomography
PM	Person month
PMDA	Pharmaceuticals and Medical Devices Agency
PONDS	Province of Ontario Neurodevelopmental Disorders
PPP	Public-private partnership
PRO	Patient reported outcomes
PSTC	Predictive Safety Testing Consortium

QST	Quantitative sensory testing
R&D	Research and development
RA	Rheumatoid arthritis
RAE	Risk assessment exercise
RCSA	Risk and control self-assessment
RepER	Representative error rate
ResER	Residual error rate
SEND	CDISC SEND Controlled Terminology
SGGs	Strategic Governing Groups
SMEs	Small and medium-sized enterprises
SOFIA	Submission of Information Application
SOP	Standard operating procedure
SP	Short Proposal
SRG	States Representatives Group
SRG	States Representatives Group
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TB	Tuberculosis
TSD	Total sleep deprivation
TTG	Time to Grant
TTP	Time to Pay
UPSA	Ultrasound-based plaque structure analysis
VC	Venture capital
WHO	World Health Organisation
WP(s)	Work Package(s)

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