Amended Annual Work Plan and Budget for 2016

In accordance with Article 16 of the Statutes of the IMI2 JU annexed to Council Regulation (EU) No 557/2014 of 6 May 2014 and with Article 31 of the Financial Rules of the IMI2 JU.

The Amended Annual Work Plan will be made publicly available after its adoption by the Governing Board.

Annex to the Decision of the IMI2 JU Governing Board No. IMI2-GB-DEC-2016-04 approved on 19.04.2016

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1 INTRODUCTION

Most countries in the world are facing the same immense challenge: How to bring the latest scientific and technological advances, that are generated in our excellent research intensive institutions, to application in healthcare delivery systems, in a time efficient and cost effective manner. By fostering collaboration between the public and private sectors and proactively engaging the most relevant stakeholders, the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) represents a neutral platform for debates to occur and for real innovations to be developed and implemented so that citizens can benefit from the latest health related innovations. The IMI2 JU represents a unique collaboration model that is emerging as a world class reference of its kind.

2016 will be an exciting and challenging year. We will be working to engage with Associated Partners from other industry sectors (e.g. ICT, Imaging, MedTech, etc) and philanthropic organisations and other public funders to invite these players to invest with us on specific projects. We will engage increasingly with small and medium size enterprises that are key to the future of a dynamic and thriving health innovation system in Europe and we will reinforce collaboration with patient groups, regulators and those who pay for healthcare with a view to demonstrating the value that innovation brings.

Within the framework of the Strategic Research Agenda, we will further develop our existing programme portfolio in areas such as diabetes, infection control, immunology or neurodegeneration, as well exploring new areas such as advanced therapies, oncology and areas embracing the “one health” concept.

We will also continue to develop our “Big Data for Better Outcomes” strategy across all disease areas.

The Programme Office will manage a growing portfolio of ongoing projects. Those coming to an end will be subject to a comprehensive socio-economic impact study that aims at demonstrating the added value of IMI2 JU outputs. A sustainability scheme for projects coming to an end will also be developed in order to preserve and optimise the various assets IMI2 JU projects have generated. We will also implement an ambitious communication strategy that aims at improving transparency and clarity of our work and objectives to various audiences, including policy makers at European and national level.

The IMI2 JU will continue to ensure the delivery of high-quality work according to strict ethical standards, under the principle of sound financial management and with appropriate and balanced levels of controls. The organisation of the Programme Office will be reviewed towards more efficiency and cost-effectiveness, in a spirit of continuous improvement.

I look forward to an exciting and challenging year!

Pierre Meulien

Executive Director

2 ANNUAL WORK PLAN 2016

2.1 Executive Summary

Highlights of IMI2 JU activities In 2016 can be set out as follows:

- Launching two new calls for proposals based on scientific priorities set out in section 2.2.2.
- Best manage a growing portfolio of projects, under both the 7th Framework Research Programme and Horizon 2020.
- Expand the basis of external collaborations and partnerships to best meet the challenges of the biopharmaceutical environment and optimising the innovation framework.
- Implement an ambitious communication strategy to demonstrate, in a spirit of openness and transparency, the added value of the partnership to EU citizens. The results of the socio-economic impact study on completed IMI2 JU projects will also contribute to meeting this objective.
- Improve and upgrade various aspects of our operating systems, including best implementation of the call management process under Horizon 2020, effective transition to Horizon 2020 IT tools, review of the risk assessment and internal control framework and reorganisation of IMI Programme Office towards enhanced efficiency and cost effectiveness.
- Carry out and implement audits and controls over beneficiaries recipient of IMI2 JU funding and companies in-kind contributions.

2.2 Operations

2.2.1 Objectives & indicators - Risks & mitigations

The key objectives for IMI2 JU operations in 2016 are based on the overall objectives of IMI2 JU as set out in Article 2 of Regulation No 554/2014, and therefore IMI operational activity will ensure a smooth and efficient implementation of its objectives

Key objectives are as follows:

- Efficient management of Calls for Proposals preparation, evaluation and grant award processes
- Close monitoring of ongoing projects' achievements, in particular the efficient use of resources and the quality of scientific outputs, as well as contributing to the analysis and dissemination of results and outputs
- Reaching out to new stakeholders towards broadening the network of collaboration in the healthcare family
- Optimal use of the internal resources of IMI2 JU Programme Office, supported by efficient IT systems

Key performance indicators

Key Strategic Focus	Annual Objectives 2016	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2016 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
Portfolio	IMI's new calls for proposals support the implementation of the research priorities as set out in the Strategic Research Agenda and updated by the Governing Board	▪ Article 2(a) and 2(b) ▪ Article 1(c) in Statutes of IMI JU	▪ Article 2(a) ▪ Article 1(b) in Statutes of IMI2 JU	**KPI 1:** Target number of priority areas defined in IMI2 JU's Annual Scientific Priorities for 2016 that are addressed by IMI's calls for proposals launched in 2016	Extent of coverage of priority areas for 2016 as defined in Section 3.2.2	**KPI 1:** ≥4 priority areas from IMI2 JU's Annual Scientific Priorities for 2016
Scientific Output	IMI projects effectively deliver and disseminate high quality outputs	▪ Article 2(a) and 2(b)	▪ Article 2(a) and 2(b)	**KPI 2:** Target estimated percentage of IMI projects that are assessed by the Programme Office as having achieved at least 90% of pre-set deliverables by the last reviewed reporting period by the end of the year	Progress for each project is assessed by the responsible IMI Scientific Officers, on the basis of cumulative achievements reported from the project start date up to the last reviewed reporting period by the end of the year	**KPI 2:** ≥80% of IMI JU projects
				KPI 3: Target estimated average number of IMI publications[3] per EUR10 million of total IMI funding requested by the projects **KPI 4:** Target to measure extent to which IMI's average impact factor of journals in which IMI publications[5] have been published is higher than the EU average **KPI 5:** Target to measure extent to which the citation impact of IMI publications[5] is higher than the EU average	The main source of information is the independent bibliometric analysis and results as last compiled and reported to the Programme Office by an external contractor, applying internationally recognised standards and criteria. Latest available information from IT systems will be used for the calculation of the estimated requested IMI JU funding by the end of the year under review. The benchmarking analysis with other international funding bodies to be performed by external	**KPI 3:** ≥20 publications **KPI 4:** ≥10% higher than EU average **KPI 5:** ≥20% higher than EU average

[1] OJ L 30 of 4.2.2008
[2] OJ L159 of 7.6.2014
[3] Covering all publications resulting from IMI projects from the start of IMI JU up the end of the year under review.

Key Strategic Focus	Annual Objectives 2016	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2016 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
				KPI 6: Target to measure the extent to which IMIs bibliometric indicators compare with those of other international funding bodies. Target to compare the citation impact of IMI publications[5] with the one of other international funding bodies (**KPI 6.1**), Target to compare the percentage of highly cited papers of IMI programme with the one of other international funding bodies[4] (**KPI 6.2**)	contractor, applying internationally recognised standards and criteria	**KPI 6.1:** ≥15% higher than the average of sampled institutions **KPI6.2** ≥5% higher than the average of sampled institutions
Impact on regulatory framework and standardization	IMI projects translate key scientific discoveries into clinical practice and regulatory framework	▪ Article 2 ▪ Article 1(e) in Statutes of IMI JU	▪ Article 2 ▪ Article 1(b) in Statutes of IMI2 JU	**KPI 7:** Target to measure the number of scientific advice and qualified opinions initiated by the IMI projects at the EMA and FDA **KPI 8:** Target to measure the number of regulatory guidelines derived from IMI projects **KPI 9:** Target to measure new standards and best practices derived from IMI projects	The main source of information is the annual periodic reporting, as well as close follows up of the project by the respective Scientific Officers through attendance of the project annual meetings, and other exchanges Each Scientific Officer will report annually during the preparation of the Annual Activity Report If necessary, additional complementary information may also be collected as part of an annual survey of the consortia For KPI 8 and KPI 9, the methodology for capturing information and the baseline data for establishing the targets will be determined and compiled in 2016	**KPI 7:** ≥ 5 **KPI 8:** Baseline data will be collected in 2016 **KPI 9:** Baseline data will be collected in 2016

[4] Publications that belong to the world's top decile of papers for journal category and year of publication.

Key Strategic Focus	Annual Objectives 2016	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2016 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
Business development and sustainability	IMI projects increase EU competitiveness and foster innovation	▪ Article 2	▪ Article 2	**KPI 10:** Target to measure, on average, the number of patent applications filed and/or awarded to those IMI projects which have been reimbursed at least for the third year of implementation[5] **KPI 11:** Target to measure impact on EU competitiveness **KPI 12:** Target to measure the number of spin-off companies or foundations created as a result of IMI projects **KPI 13:** Target to measure the estimated number of reported Full-Time Equivalents (FTEs) based in the EU that can be considered as directly related to the IMI programme	The main source of information is the annual periodic reporting, as well as close follows up of the project by the respective Scientific Officers through attendance of the project annual meetings, and other exchanges. Each Scientific Officer will report annually during the preparation of the Annual Activity Report If necessary additional complementary information may also be collected as part of an annual survey of the consortia For KPI 11, the methodology for capturing this information from industry and other sources and the baseline data for establishing the target will be determined and compiled in 2016 The estimated total number of FTEs reported by the projects as being directly related to the IMI programme will be reported for KPI 13. The data will be collected directly from the consortia through SOFIA or via an annual survey	**KPI 10:** ≥2 patent applications per EUR 10 million of costs accepted and reimbursed by IMI JU.[6] **KPI 11:** Baseline data will be collected in 2016 **KPI 12:** 25% of finalised projects **KPI 13: ≥ 1500**

[5] During 2016, initial baseline data will continue to be collected and analysed on the number of patents resulting from IMI JU projects, particularly on the first finalised projects.

[6] The calculation will be based on the total value of interim and final payments made by IMI by the end of the year under review to projects that have completed at least the third year of implementation and the total amount will be divided by the cumulative number of patents filed and/or awarded to these projects.

Key Strategic Focus	Annual Objectives 2016	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2016 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
SME participation	IMI2 JU projects promote the participation of SMEs	▪ Article 2(e)	▪ Article 2(a) ▪ Article 1(c) in Statutes of IMI2 JU	**KPI 14:** Target percentage of participants in signed Grant Agreements that are SMEs **KPI 15:** Target percentage of overall budget for projects that has been allocated to SMEs	Calculation is based on the latest available data extracted from IMI IT applications. Participations in IMI projects may count the same organisation multiple times when the same organisation is involved in several projects in line with current practice All participations from the start of IMI up the end of the year under review are considered in this calculation	**KPI 14:** ≥20% **KPI 15:** ≥20%
Patient participation	IMI2 JU JU projects promote the involvement of patient organisations	▪ Article 2	▪ Article 2(a) ▪ Article 1(c) in Statutes of IMI2 JU	**KPI 16:** Target percentage of projects involving patients' organisations as consortium partners, members of Advisory Boards, Ethical Advisory Boards or on consultancy basis for topics of relevance as identified in the Call text **KPI 17**: Target to measure impact for patients	Calculation is based on the latest available data extracted from IMI IT applications for the project partners Participations in IMI projects may count the same organisation multiple times when the same organisation is involved in several project in line with current practice If necessary, additional complementary information may also be collected as part of an annual survey of the consortia. For KPI 17**,** the methodology for capturing this information and baseline data for establishing the target will be determined in coordination with the European Commission in Q1 2016	**KPI 16:** 100% **KPI 17:** Baseline data will be collected in Q1 2016
Impact on society	IMI2 JU JU projects address the unmet healthcare needs, e.g. chronic, emerging or diseases lacking effective treatment	▪ Article 2	▪ Article 2	**KPI 18:** Target to measure additional impact on society	For KPI 18, the evaluation methodology development is in progress and the baseline data for establishing the target will be determined in 2016.	**KPI 18:** Baseline data will be collected in 2016

Key Strategic Focus	Annual Objectives 2016	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2016 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
Information, communication and dissemination	The Programme Office raises the awareness of IMI JU and IMI2 JU among all target groups	▪ Article 1(g) in Statutes of IMI JU	▪ Article 1(i) in Statutes of IMI2 JU	**KPI 19:** Target number of average monthly visitors to the IMI2 JU website **KPI 20:** Target to measure the performance of communication activities	Average number of monthly unique visitors as reported by Google Analytics for the year under review For KPI 20, the methodology for capturing the information and the baseline data for establishing the target will be determined in 2016	**KPI 19:** ≥10 000 **KPI 20:** Baseline data will be collected in 2016 and used to determine the appropriate target
Efficiency of the Programme Office	The Programme Office meets the timeframe for Time to Grant (TTG) established by the EU for Horizon 2020	▪ N/A	▪ Article 17	**KPI 21:** Target timeframe for TTG of 245 days	Comply with the timeframe set out in the Horizon 2020 Rules for Participation (Article 20.2 in Regulation (EU) No 1290/2013) Average Time to Grant (TTG) for a two stage evaluation is defined as the time between the deadline for the submission of a Full Project Proposal and the signature of the grant agreement. This will be calculated annually for each grant agreement signed during the year under review	**KPI 21:** ≤245 days
	The Programme Office achieves high levels of performance in its annual budget execution	▪ Article 1(l) in Statutes of IMI2 JU	▪ Article 1(f) in Statutes of IMI2 JU	**KPI 22:** Annual budget execution target for commitment appropriations of running costs **KPI 23:** Annual budget execution target for commitment appropriations of operational costs **KPI 24:** Annual budget execution target for payment appropriations of operational costs	Extracted from annual figures compiled for IMI JU report on the budgetary and financial management	**KPI 22:** ≥95% **KPI 23:** ≥95% **KPI 24:** ≥95%

Key Strategic Focus	Annual Objectives 2016	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2016 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
	The Programme Office meets the maximum time limits for expenditure operations established by the EU			**KPI 25:** Annual Average Time to Pay (TTP) target for pre-financing payments to beneficiaries **KPI 26:** Annual Average TTP target for interim payments to beneficiaries	Comply with time limits as established in the EU's Financial Regulation (Article 92 in Regulation (EU, EURATOM) No 966/2012) and Article 32 of the IMI Financial Rules	**KPI 25:** ≤30 days **KPI 26:** ≤90 days

Risks & mitigations

The IMI2 JU is continuously monitoring risks at various levels. Below there is an overview of risks of strategic nature currently identified by the IMI2 JU together with mitigation measures.

Risk	Mitigation and risk response
POLICY OBJECTIVES AND GOVERNANCE	
1. The Council Regulation establishing IMI2 as a Joint Undertaking is based on the strategic principle that pharmaceutical research is equally co-funded by industry and the EU. This objective might be undermined if the in-kind contribution from industry does not match the financial contribution of the EU at the end of the programme.	(i) Level of in-kind contributions (committed and reported) are reported in the AARs. Evolution monitored by the Governing Board at each meeting; (ii) The Grant Agreement foresees a systematic monitoring of projects financial management through annual Periodic Reports, Interim Review; (iii) The Programme Office is systematically monitoring the trend of in-kind contribution through the IT tool SOFIA; (iv) Systematic audits of EFPIA companies are planned according to a risk-based plan.
2. IMI2 JU might not be able to cope with its operational and financial planning if the call topics and the related indicative budget are not timely proposed and defined through the annual planning cycle. As a consequence there could be delays in approving or implementing the AWP process and, finally, ineffective management of call process resulting in low response by stakeholders.	Risk partially out of the control of the Programme Office which is mitigating it through: (i) Extensive consultations with JU's Members; (ii) Reengineering of the planning and budgeting process and timing
SCIENCE DEVELOPMENT& PROGRAM MANAGEMENT	
3. Despite IMI2 JU's commitment to align to H2020 legal framework, its operating procedures for call and project management including the IT tools are not fully aligned. This gap might: (i) increase the workload of staff; (ii) put at risk the capacity of the JU to effectively manage call and project procedure, and (iii) produce errors with the additional risk of appeal and redress.	As a general rule IMI applies the legal framework set up for H2020. When adjustments are needed due to the particular procedures of the JU, justification is recorded.
4. Due to a lack of financial resources or conflicting relations among participants in individual consortia – particularly during negotiation phase or on IP issues – there could be a risk of late withdrawal of participants in specific projects.	These risks are partially out of control of IMI JU as they depend on the negotiation among participants when agreeing on the Consortium Agreement.

Risk	Mitigation and risk response
As a consequence, the kick-off of new projects may be delayed or expected deliverables and scientific results of on-going projects may not be fully achieved or met.	Actions are taken by IMI JU to mitigate these risks; in particular SOs and legal team assist closely all Consortia during the negotiations phase and when necessary propose alternative solutions to prevent and resolve possible disputes.
BUDGET & FINANCE MANAGEMENT	
5. Delays in setting budget work plans and budget may lead to cash flow shortage and difficulties in meeting financial and legal obligations.	Risk mitigated through: (i) Reengineering of the planning and budgeting process and timing (ii) Preventing late budget commitment/payment from EC or EFPIA through: - open and effective discussion at Governing Board level; - a compulsory planning of instalments planned in the Annual Financing Agreement.
6. Due to the current timetable of deadlines for periodic reports of individual projects, the workload in the Programme Office is not equally spread across the calendar year. As a result, there can be delays during peak periods when most reports are received and this has an impact in terms of time needed to finalise the analysis and acceptance of reports and financial statements and process payments.	(i) Peak periods are managed through an adequate back-up and a balanced plan (including adequate staff resources) to cope with the workload (ii) Review of timelines of periodic report submission
INFORMATION TECHNOLOGY	
7. Operational disruptions arising from shift to H2020 IT tool (SEP, SYGMA, COMPASS)	Phasing-in approach with EC teams for systems setting, taking into account IMI specificities (ongoing); Efficient and timely training of user communities users (external and internal)
HUMAN RESOURCES	
8. Current organisational structure of the Programme Office no longer adapted to the growth of staff, activities and evolving needs.	New organisational set up to be established and implemented in Q1/Q2 2016

2.2.2 Scientific priorities and Topics to be launched, for 2016

The Innovative Medicines Initiative 2 (IMI2) Joint Undertaking activities for 2016 are fully in line with the objectives as set out in article 2 of the IMI2 JU Regulation. In particular they aim at the development and implementation of pre-competitive research, innovation activities of strategic importance to the Union's competitiveness and industrial leadership or to address specific H2020 societal challenges, and in particular the challenge to improve European citizens' health and well-being.

These activities develop within the general framework of the Scientific Research Agenda (SRA) for IMI2 (see http://www.imi.europa.eu/content/imi-2). The latter identifies a setting of scientific priorities where IMI attempts to pilot new ideas in real life in a safe harbour environment that maximises collaboration and synergy of all stakeholders; drives innovation in business models to support the transition from blockbusters to personalised medicine by testing new approaches across multiple companies and projects simultaneously, and pilots new types of collaborations between companies with different innovation cycles to optimise the success in delivering IMI2 objectives. The SRA furthermore identifies data and knowledge management as key enabling technologies, as well as education and training, and excellence in clinical trial implementation as key implementation strategies.

The priorities identified for 2016 are fully aligned with the IMI2 SRA and will help in the achievement of IMI2 objectives. They include the development of clinical trial networks, the sharing of data to improve and facilitate more powerful data analysis and the generation of better tools, biomarkers and standards that will result in speeding up the clinical development of new treatments. In order to achieve its objectives the initiative continues to seek the involvement of a broader range of partners from different sectors e.g. biomedical imaging, medical information technology, diagnostic and/or animal health industries. The projects that will result from the 2016 priorities will generate results that will have a high impact and facilitate the maximum number of stakeholders to join forces. The outcome of the projects launched in 2016 should bring great benefit to patients especially children and adolescents. Projects will also engage with Regulatory agencies and other health bodies fostering the approval of research outcomes. Involving the wider community in this way should help to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with an expected high impact on public health.

Seven scientific priorities, broken down into several Topics, were identified for 2016, taking into account the advice provided by Strategic Governing Groups to the IMI2 JU Governing Board. As described in the following pages, each priority area will be implemented via the launch of one or more Topics, which will generate multi-stakeholder projects, potentially including (or driven by) Associated Partners. Further details regarding the expected multi-stakeholder projects are elaborated under the individual Topics. Topics for 2016 have been prioritized based on criteria that include highest impact on reducing attrition in drug development, speeding up patient access, improving health outcomes and enhancing the biomedical research ecosystem. Additional Topics for 2016 might also be considered at a later stage in the case of very urgent public-health needs, such as rapid response to emerging diseases. The Annual Work Plan 2016 would then be updated accordingly.

To implement the 2016 priorities, IMI2 will initiate two competitive Calls for proposals, each covering several Topics (see Table at the end of this section), with indicative predefined launch dates of respectively 06 April 2016 and 12 October 2016[7].

Topics launched on the basis of this Annual Work Plan 2016 will seek synergies with other on-going initiatives especially those funded under the Horizon 2020 Framework Programme and at the national level, and those identified by the European Strategy Forum on Research Infrastructures (ESFRI), to ensure the consistency of approaches and to avoid the duplication of effort and funding.

[7] Please see Article 1 (f) and (g) of the Statutes, annexed to the IMI2 JU Council Regulation

A. Diabetes/Metabolic disorders

Activities in this priority area should seek progress towards novel diagnostic and treatment paradigms for the mechanisms being involved and triggering the early onset and progression of diabetes (type 1 and type 2)/metabolic disorders and their complications. This should aim to enable an early diagnosis with predictive biomarkers, to allow the development of experimental medicine approaches to safe and efficacious treatments, considering also health system sustainability of treatment intervention.

Activities in 2016 will address the following Topics:

Non-alcoholic fatty liver disease (NAFLD):

1. Address the rising incidence of NAFLD and Non-alcoholic Steatohepatitis (NASH) (related to the convergent epidemics of obesity, insulin resistance and type 2 diabetes) by developing non-invasive diagnosis procedures that clearly differentiate between NAFLD and NASH and predict disease progression ultimately to enable early diagnosis and appropriate treatment and enhanced development of new therapies.

Diabetes:

2. Improvement of the management and prevention of hypoglycaemia by improving our understanding of the underlying cellular/molecular mechanisms and defects in counter-regulation; along with mobilising all stakeholders to better define the clinical occurrences and consequences of hypoglycaemia.
3. Increased understanding of Type 2 diabetes patients to facilitate the better design of future clinical trials for diabetes treatments. This objective could be helped by capturing information on subjects in the respective placebo arms of performed clinical trials (RCT´s) in diabetes allowing the building of a uniformly structured database. Such a database would allow the evaluation of the background therapy in T2D patients and possible association with any particular serious adverse events (SAE) as well as an evaluation of increased or decreased susceptibility to T2D progression.
4. Development of appropriate methodology to study anti-diabetic medications in children and adolescents with type 2 diabetes. Discussions and alignment with regulatory authorities on requirements for documenting efficacy and safety in this patient population, as well as development of a Clinical Trial Research Infrastructure suitable for performing this type of studies.

Expected impact:

- Prevention of late stage liver disease such as cirrhosis and hepatocellular carcinoma resulting from NASH
- Better management of hypoglycaemia and to reduce risks of cognitive impairment
- Speeding up development of new treatment options for paediatric populations for diabetes type 1 and diabetes type 2 by enhancing the infrastructure for paediatric and adult clinical trials,

Type of actions:
Research and Innovation Actions

B. Neurodegeneration and other Neuroscience Priorities

The priority area Neurodegeneration aims to address the high-unmet medical need for effective disease modifying, as well as, symptomatic interventions in neurodegenerative disorders in general and Alzheimer's disease (AD) in particular as well as relevant companion diagnostics. Furthermore there is still a high unmet need in the area of understanding, treating and managing chronic pain, while no evidence based treatments to treat the core symptoms of Autism are available so far. Last but not least the area of CNS (as well as that of safety pharmacology) suffers from poor reproducibility of preclinical data that significantly hampers further decision making in R&D.

Activities in 2016 will address the following Topics:

Alzheimer's Disease:

1. Collaboration and alignment of the many initiatives born in the aftermath of the G8 Dementia Summit Declaration8 focused on advancing the field of dementia research. Such collaboration is essential to avoid unnecessary duplication, allow for data and insight sharing and increase efficiency by making joint priority trade-offs.
2. Accelerating development of tau radioligands to enhance exploitation of Tau PET imaging that has the potential to serve as a target engagement biomarker for emerging tau therapies and to enable their use in AD clinical trials and in clinical practice (e.g., for patient selection and outcome measures)
3. New genes as AD modifiers
4. Characterize the pathophysiological remodelling of the healthy astrocyte into the diseased one in neurodegenerative diseases to determine if targeting astrocyte related molecular pathway is a viable strategy for developing innovative treatments for neurodegenerative diseases, e.g. by studying models systems such as iPS cells-based models,, defining relevant molecular pathways by different techniques and finding suitable targets to support astrocyte survival and function for further drug development.

Pain:

5. Measuring physiological and activity-based parameters remotely and continuously via unobtrusive on-body sensors or smartphones has the potential to revolutionise our ability to predict and pre-empt harmful changes in disease trajectory.
6. Addressing hurdles to monitoring effectiveness for different treatment options to gain real world data based on PROMs from existing registries (e.g. due to missing, invalid or incompatible data).
7. Better understanding of the pathways of chronic pelvic pain relevant to the clinical situation and an assurance that these are reflected in pre-clinical models to improve their translational value for clinical research
8. Definition and validation of clinical stratification markers, enabling an understanding of which subgroups of low back pain and osteoarthritis patients preferentially respond to which drugs and to improve translational trajectories for pain in musculoskeletal diseases
9. Delivery of pharmacologically validated and standardized pain pathway functional biomarkers in man, with accompanying back-translation to animals, will support dose setting in early clinical trials, positively impacting the outcome of Proof Of Concept studies and speeding the flow of new medicines to patients.

Autism Spectrum Disorders:

10. Address deficiencies in the current development pathways and improve the likelihood of success of clinical research in Autism Spectrum Disorders by enabling testing of scientific hypotheses and drug responses in relevant and validated patient (sub)groups using validated biomarkers, stratification markers and clinical endpoints, building on the achievements of other initiatives (e.g. IMI EU-AIMS) which have set standards in the field and would allow clinical development in the field and including comorbidities (e.g. epilepsy).

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8 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/265869/2901668_G8_DementiaSummitDeclaration_acc.pdf

Data Quality and Integrity in Preclinical testing

11. Reproducibility and relevance of research findings represent the pillars of the scientific method. For drug development, robust data and scientific rigor are key drivers for decision making, determining patent strength, time-to-market and consequently availability of new treatments to patients. Therefore approaches are needed to advance the quality and efficiency of Discovery R&D data by developing quality criteria for new and/or improved preclinical tests and a consensus for quality management recommendations in non-regulated R&D. A first pilot study will focus on the areas of Neuroscience and Safety. Such a study will enhance the quality of decisions made based on experimental data, while fostering education on data quality as a major contributor to enhance the quality culture in preclinical research.

Expected impact:

- The fostering of a global dementia research agenda that most efficiently uses the investments of all stakeholders.
- Assignment of new functional roles to other rare genetic variants implicated in disease causation.
- Validation of tools and platforms for discovery of new biological insights into AD understanding, beyond the CNS.
- Identification of novel pathways and targets for drug development aimed to modulate the astrocyte function.
- Accelerating tau tracers development and better integration of novel imaging techniques into pharma development
- improvement in the data quality of pre-clinical studies via the delivery of reliable and reproducible models with harmonised and standardised protocols and procedures; and significant contribution to the 3Rs
- Reducing attrition rates with more predictive translational models and stratification of patients responding to specific treatments to drive reinvestment into new treatment options for chronic pain.
- Modernise and optimise clinical development for CNS therapies.
- Alignment of international efforts on obtaining early ‘first in man’ proof of concept for compounds (both novel and repurposed) impacting on neural systems implicated in autism.

Type of actions:

Research and Innovation Actions; Coordination and Support Actions

C. Immunology

Autoimmune diseases cover over 100 distinct diseases and syndromes, together affecting approximately 5% of the population of Europe, with two-thirds of the patients being female. The burden of autoimmune disease crosses medical and scientific boundaries, and requires cross-functional collaboration by scientists and physicians with interests in diseases of widely differing organ systems.

The proposed work will focus on a key set of immune mediated disease or disease mechanisms where working in partnership will benefit the knowledge-base and accelerate delivery of drug treatments to patients. The proposed work will build on the knowledge-base and infrastructure present within the EU from ongoing research-based initiatives e.g. Eumusc.net, EMEUNET, EUSTAR, ERS/ELF, ECCO, BILAG, EUVAS and Euro Lupus OMERACT, BLUEPRINT as well as relevant IMI projects (BTCURE, PRECISESADS), which together have aggregated substantive information on disease phenotypes, biomarkers and other factors associated with disease progression in many autoimmune disorders in order to guide better patient treatments.

Activities in 2016 will address the following topics:

Immune Tolerance Therapies:

1. Address the low rate of clinical remission observed in Rheumatoid Arthritis patients by developing and testing novel immune tolerance therapies. The development of these immune tolerance therapies should be accompanied by the development of methodologies and 'companion diagnostics' that allow the stratification of patients based upon specific immune reactions in subsets of patients with RA and other relevant inflammatory disease including lupus and myositis.

Multiple Sclerosis (MS):

2. Identification of individuals with high risk of multiple sclerosis development and/or potential to transition to progressive forms of MS using real world data, together with biomarker analysis and modelling of clinical disease. A very early identification of people at risk for MS and a better characterization of their immunological phenotype may greatly increase options for earliest and more targeted intervention to potentially abrogate the disease process.

Epigenetics:

3. An improved understanding of the molecular pathways leading to the identification of new epigenetic and non-epigenetic therapeutic targets, biomarkers and diagnostics involved in immune mediated diseases. Approaches should be based upon mapping the epigenomes in disease tissue samples in immune mediated diseases and comparing these with both normal tissues and tissues from other disease.

Expected Impact

- Generation of tools and capabilities required to support precision medicine
- Increase the efficiency of the drug discovery and clinical development process
- Improved methods for recognition and diagnosis of autoimmune and inflammatory disorders and a range of treatment options
- Earlier availability of new, more cost effective therapies to patients most likely to benefit
- Advance the understanding of epigenetics of immune and inflammatory disease progression or during drug treatment, and potentially the identification of new drug targets

Type of actions:
Research and Innovation Actions

D. Infection control including vaccines

The antimicrobial resistance (AMR) has been declared a major global public health threat. In Europe 25,000 deaths were reported in 2007 as a result of AMR of which 2/3 being due to gram-negative bacteria. In the US deaths due to AMR is estimated to a minimum of 23 000 deaths per year. The clinical burden is associated with soaring treatment and societal costs with a cost of AMR being estimated at around 1.5 billion Euros per year only in Europe. Despite the recognised need for new antimicrobials the reality is that as a society we are faced with the potential situation where prescribers could have few, if any, therapeutic options to treat certain bacterial infections. Continued efforts are required if key barriers to the development and delivery of effective antibiotics are to be overcome.

Furthermore, it is well recognised that antibiotics can cause disruption of the beneficial intestinal microflora and that this allows colonisation and infection with for example the Gram-positive bacterium *Clostridium difficile*. The annual rate of *C. Difficile* infection has doubled since 2001, coincident with the emergence of hypervirulent strains. Over 500,000 new cases of *C. difficile* infection occur each year in the US and estimates suggest greater than 400,000 diagnosed *C. Difficile* events occur annually in Europe. This represents a substantial burden of morbidity, mortality, and healthcare resource consumption that calls for more effective prevention and treatment strategies.

Vaccination is one of the most valuable and cost-effective public health measures to prevent and control the spread of viral/bacterial infectious diseases responsible for high mortality and morbidity. It saves at least three million lives every year globally. Despite the outstanding progress, a significant number of infectious diseases and chronic disorders are still not preventable by vaccination and remain a major cause of death and morbidity worldwide. Research and development is required to address the changing risks associated with vaccination innovative solutions and to better understand drivers underpinning inconsistent utilization of available immunization measures.

Activities in 2016 will address the following topics:

Antibiotics and antimicrobial resistance:

1. Support the development of new antimicrobials and epidemiology studies, for bacterial (in particular multidrug resistant gram negative bacteria), viral or fungal infections including development of efficient models of enrolling patients to evaluate new compounds. A particular focus will be the research and development of approaches to the diagnosis and treatment of *C. difficile infections* to increase the understanding of the current burden of infection with *C. difficile* and to provide a clearer understanding of unmet needs and options for addressing them may also be considered.

Innovation in vaccines:

2. Strengthen the capacity to monitor the effectiveness of the yearly seasonal influenza vaccines to generate effectiveness data at the level of national influenza vaccination programmes across age, risk groups and vaccines allowing a better evaluation of performance of influenza immunisation programmes. Vaccine effectiveness studies are within the mandate of public health bodies. At the same time, upcoming EU regulation will require marketing authorization holders to conduct brand-specific influenza vaccine effectiveness studies. To avoid a situation where efforts are conducted in parallel by public and private organisations, there is scope for exploring a model for joint influenza vaccine effectiveness studies in Europe. The innovation would lie in the development of a governance model and guidelines for joint studies that would take into account both public health and industry needs.
3. Provide innovative solutions to understand and measure the maturation of the immune system, and to tackle emerging/unmet medical needs. Approaches will include the development of novel immunisation strategies and technologies, as well as, measures to assess the effectiveness and safety of new vaccines. Research should also lead to a better understanding of the drivers underpinning inconsistent utilisation of available immunisation measures as well as, to reduce the use of experimental animals.

Human challenge trials:

4. Develop consensus frameworks to facilitate human challenge trials and design improvements to deliver reliable and robust results, thus facilitating improved access to new or second-generation vaccines and drugs. Approaches should address currently unsolved ethical, regulatory and clinical issues related to trial design and execution.

Expected impact:

- A pipeline of promising new agents for tackling antibiotic-resistant bacterial infections
- Optimised/harmonised methods to collect, collate, share and analyse medico-socio-economic data on infectious and non-infectious disease
- Delivery of better vaccines in response to target group-specific needs
- Strengthened coordination across sectors and stakeholders resulting in improved structures and governance for joint action to tackle societal challenges
- Validated alternatives to animal testing and models
- Improved antibiotic stewardship, decreased risk of antimicrobial resistance, and better preservation of the microbiome
- Creation of a collaborative framework to tackle several major unsolved issues currently limiting capacity in the EU to conduct HCTs will act as a catalyst to stimulate further actions to improve drug and vaccine development
- Drive change for improving HCT design and promote use in accelerated drug or vaccine licensure, ensuring earlier access to new products for patients or for the at risk population
- Major impact on the improvement of public health

Type of actions:
Research and Innovation Actions

E. Translational Safety

There is still a critical need for tools and methods that will facilitate the prediction and monitoring of safety issues, contributing to the safety of patients before and beyond the launch of new products. A better understanding of toxicological findings for human risk assessment has to be built prospectively, but also via a retrospective review of clinical side effects and their relationship to non-clinical safety data. A major challenge to reliably predict, detect, monitor, and assess adverse drug reactions is the lack of sufficiently sensitive and specific biomarkers. Better preclinical models integrating the complexity of human biology for predicting safety issues, and understanding the molecular causes underlying it, are needed to reduce attrition in the development of novel drugs and enable the development of safety biomarkers for the management of risks in humans.

Activities in the area will build on progress and success from the portfolio of IMI projects on preclinical and clinical safety, from other relevant European and global initiatives to create synergies (e.g. US Critical Path Institute, HESI/ILSI, EPAA, IQ and NIH driven projects) and from data management initiatives, including Big Data approaches.

Activities in 2016 will address the following topics:

Models and platforms to improve the prediction of toxicity and safety:

1. Build upon progress from the portfolio of IMI projects on preclinical and clinical safety and from other relevant European and global initiatives to create synergies (e.g. US Critical Path Institute, HESI/ILSI, EPAA, IQ and NIH driven projects) and from data management initiatives, including Big Data approaches.
2. The development of new platforms that reflect the complexity of human organ physiology (e.g. 3D, or organ-on-chip models, single cell-type or co-culture, static or dynamic systems) to predict toxicity and safety during early drug development. In particular, liver, renal and cardiac safety will be studied using induced pluripotent stem (iPS) cells from subjects with a variety of phenotypes to understand better which patient subpopulations are at risk from rare safety issues. Assessment of such new models will include evaluation of the limitations with respect to *in vivo* organ function, which thereby will define their applicability and ideally, their regulatory acceptance for each context of use. Such approaches will also contribute to Replacement, Reduction and Refinement of animal use.
3. The identification of molecular targets and pathways (through e.g., integrated 'omics' approaches) underlying toxic phenotypes of drugs failed for safety reasons. The development of *in silico* and *in vitro* models representing these pathways which can be employed in early safety testing would be an important goal. This should lead to a reduced and refined use of animals, including the possibility for better prediction of suitable toxicology species.
4. The evaluation and optimisation of existing or new toxicokinetic techniques (such as imaging) and models with the aim of predicting adaptive and adverse changes based on in vitro assay results and modelled exposure data. Of relevance may also be studies of the pharmacokinetic interactions caused by mechanism- based, time-dependent and metabolite- mediated inhibition of drug metabolism and transport as well as relevant pharmacogenetic studies.
5. Improve the toolbox for preclinical safety evaluation and prediction of drugs for CNS toxicity addressing all aspects of neurotoxicity. Approaches should include the three types of effects particularly challenging in terms of preclinical prediction and translation to human situation: convulsions/seizures; psychological changes: memory or mood disorders, including depression and suicidality and drug abuse liability. Identification of safety biomarkers for better monitoring during clinical trials should be included.
6. Develop a generalized framework for dosing recommendations in specific populations using physiologic or pharmaco-statistical empirical modelling methods based on prior data for drugs with similar clearance mechanisms. It is important that such a knowledgebase would provide drug and population attributes where model-based approaches can be used to inform dosing recommendations. Results should address the lack of a regulatory framework to incorporate model-based dosing recommendations for specific populations. As a first step, approaches should be focused on specific areas such as renal and hepatic impairment populations as prototypes.

Biomarkers:

7. The identification and/or further validation of known and suggested new safety biomarkers representing different types of molecules, e.g. proteins and enzymes, but also nucleic-acids, including biomarkers which are easily translatable across preclinical species and human patients and are relevant to organs other than the liver and kidney, e.g. heart, pancreas, gastro-intestinal tract, brain etc. Biomarkers allowing longitudinal, non-invasive follow-up such as bioimaging should be included either for safety monitoring or for stratification of patients.

Expected impact:

- Progress in preclinical and clinical data analysis especially in the translation to humans
- Provide early drug discovery with disease relevant tools of a high translational value
- A more efficient use of biomarkers and bio-imaging
- Reduction, refinement and replacement of animal studies
- Impact in the area of mechanistic toxicology
- The delivery of improved cell based systems for use in translational safety assessment
- Significant improvement of patient safety in drug development and post marketing
- Inform regulatory science and decision making

Type of actions:
Research and Innovation Actions

F. Data and Knowledge Management

The increasing volume (terabytes/patient), diversity (clinical, GWAS/ RNASeq, eHR, 'omic, cytometry, imaging, pharmacology, pharmacovigilance etc.) and velocity (e.g. real time telemetric monitoring of patients, social media feeds, etc.) of biomedical data available creates significant opportunity for healthcare R&D. However, common data standards, as well as robust, production quality data and knowledge management (KM) solutions and services are essential if the full value of these data sets is to be realised in the development of innovative precision medicines. To respond to the challenges faced in healthcare R&D it will be necessary to collaborate on the development of novel enabling technologies and adaptive therapies to facilitate the efficient capture and interrogation of these data sets to ensure effective healthcare practices for patients.
Addressing these challenges will also be facilitated by significantly increasing access to Real World Evidence; enhancing the involvement and central role of patients - including citizen-controlled data repositories; extensions to the RADAR platform to include other diseases (e.g. Alzheimer's Disease') and monitoring methodologies; leveraging data management for the better standardization of biomarkers; and finally aligning existing DKM platforms towards more standardised methods of utilising pathways and other network data.
To ensure a harmonised approach it is foreseen that ongoing projects will require coordination/collaboration with European biomedical research infrastructures through the European Strategy Forum on Research Infrastructures (ESFRI).

Activities in 2016 will address the following topics:

Generation and exploitation of real world evidence:

1. Utilise the ongoing Big Data for Better Outcomes (BD4BO) programme to catalyse and support the evolution towards value based and more outcomes-focused and sustainable healthcare systems in Europe. This will be achieved by exploiting the opportunities emerging from the wealth of data from many evolving data sources to generate a body of evidence that will inform policy debates. The programme's objectives are to maximise the potential of large amounts of data from variable, quickly developing digital and non-digital sources.
2. Establish a core distributed data infrastructure to allow real world evidence data repositories to be combined to overcome the challenge posed by the sheer volume of data and number of repositories and enable the generation of a body of evidence that will inform policy debates.
3. Address the growing problem of multi-morbidity by developing programmes to support improved patient health literacy and understanding of multi-morbidity in context of patients' lives.
4. Extension of the RADAR programme to other disease areas by leveraging the RADAR-CNS platform to study cohorts of patients who suffer from other conditions such as chronic pain or Alzheimer's disease. This will allow the development of methods for real-time identification of behavioural and physiological patterns (bio-signatures) that culminate in relapse. Early detection and communication of "red flags" to patients, care-givers and providers can prompt help-seeking behaviour and deployment of just-in-time interventions that may prevent relapse episodes, effectively altering one's clinical trajectory.

Access, standards and interoperability:

5. Address the lack of industry-wide meta-standards needed to support the discovery and validation of high quality biomarkers by developing well-established, sustainable, industry-wide metadata standards to support tracking, moving, compiling, storing, harmonizing and reconciling biomarker data; support for data provenance; as well as, exchange data standards for all biomarker modalities to enable interoperability.
6. Make a significant portion of the data from IMI projects accessible and interoperable to improve the use of the data for biomedical research. Any approach should also identify sustainable solutions for hosting the data and providing access according to principles outlined in the Guidelines on Data Management in Horizon 2020.
7. Accelerate the interoperability of all databases (including non-IMI project databases) to allow queries within individual and across different databases. The development of these approaches will be facilitated by the identification industry relevant research and development questions that are best addressed with advanced linked data analysis methods like automated inferencing and reasoning.
8. Build the basis for a common European biomedical 'language' across all stakeholders in the biomedical and health care space by establishing a governance body and governance processes for all relevant metadata standards; implementing a sustainable European biomedical metadata registry under a broadly agreed governance structure and standardized tools to lower the barrier to adoption of standards

Support new research paradigms:

9. Advance network-based in silico approaches to get a better mechanistic understanding and hypothesis formulation in areas such as disease mechanisms and new disease associated genes, disease subtyping and patient stratification, biomarkers, as well as drug efficacy and drug induced side effects. These advances should be supported by improved network generation and management; benchmarking of algorithms and networks and visualization methodologies.
10. Speed up the process of drug discovery by facilitating the application of machine learning to predict biochemical activities of chemical structures making use of historical biological assay data. This will require the development of novel methodologies for compound activities that make use of biochemical activity data residing in distinct proprietary databases. Key to facilitating such sharing of data is the establishment of an honest broker that distributes resulting predictions to consortium members.

Expected impact:

- Robust KM solutions and operational excellence to allow integration and analysis of diverse datasets, addressing long-term sustainability, accessibility and reuse of generated research data for future studies
- Innovative IT/KM/analytical solutions required to support new clinical trial paradigms, biomarkers and monitoring devices
- Increased value and return on biomedical research investment through operational excellence and collaboration and reuse of public research infrastructures
- More cost effective, improved R&D processes enabled by fit-for-purpose KM infrastructures, leading to improved scientific insight and so downstream healthcare improvements for Europe
- Develop coherent and transparent framework to address data privacy and personal integrity issues inherent in the use of health records and personal genomic data
- Improved transparency of data re-use and impact on R&D
- Faster translation of insights from real world health data to biomedical research and development approaches

Type of actions:

Research and Innovation Actions

G. Other enablers of innovation

1. Sustainable pan-EU paediatric CT network (EUPCTN)

To advance the concept of precision or personalised medicines will involve the implementation of innovative clinical trials. This will require the establishment, training and maintenance of European networks of investigators within all EU countries with ample expertise and experience in designing and executing clinical trials for diagnosing, preventing and treating disease as required to support delivery of clinical trials that address the priority health areas underpinning the PPP. To be successful the networks should not only consist of hospitals with disease management expertise, but also individuals who are experts in clinical trial design, the regulatory and HTA framework as well as expertise in developing and delivering training.

Activities in 2016 will address the current lack of evidence based data for the optimal use of existing medicines in children by developing a large collaborative paediatric network that will facilitate the development and availability of new medicines for children. Such a network should also allow the expansion of knowledge about drugs currently in practice for the entire paediatric population by not only advising on how best to do the necessary research, but by actually helping to plan, conduct, and complete all types of clinical studies (phase 1-4) that can be used for regulatory review and approval.

Expected impact:

- Drive reinvestment into paediatric medicines development in Europe
- Transform the way that paediatric drug development programs are planned and executed.

Type of action:
Research and Innovation Action

2. Stakeholders' engagement in product life-cycle
If new scientific advances are to be implemented there is the need to adequately consider perspectives of all stakeholders in product life-cycle (from research to healthcare delivery) to optimise medicines pathways and deliver innovation that more efficiently address the burden of disease for individual patients and EU society at large.

Activities in 2016 will address the following topics:

Patient-Stakeholders engagement in product life cycle:

1. Overcome fragmentation, inconsistency, inefficiency, and underrepresentation in interactions between patients and healthcare R&D stakeholders characterised by establishing a standard of systematic and integrated patient involvement during the development and life cycle of medicines and associated products and services. There is a need to enable patient communities to have a voice (in qualitative and quantitative terms) in the research process and to include those who are under-represented, or may not normally participate in critical healthcare delivery decision-making.

Involvement of payers, regulators, HTA and medical practice in IMI2:

2. Provide a platform(s) to enable the transparent and coherent involvement of regulators, payers and HTA body representatives in a growing number of IMI projects when required. These horizontal platforms should enhance the generation and uptake of robust and relevant tools and results with impact on research, regulatory and medical practice, "service" many projects and facilitate the correct engagement of regulatory, HTA, payers and medical practitioners.

Expected Impact:

- Enable and enhance the representation and role of patient/healthcare consumer involvement in medicines R&D and assessment processes throughout the medicine life cycle to increase their efficiency and patient-centric relevance.
- Provide resources for sustainable involvement of regulators, HTA bodies that will facilitate anchoring experts in for medium-long term in host institutions and therefore facilitate moving knowledge to the "last mile" i.e. regulatory and medical practice.
- Create economies of scale and decrease administrative burden.

Type of actions:
Research and Innovation Action and Coordination and Support Action

3. Unlocking the Solute Carrier Gene-Superfamily for Effective New Therapies

The Solute carriers (SLC) family includes approximately 300 genes that provide instructions for making proteins called solute carriers. Proteins in the SLC family transport various molecules across the membranes surrounding the cell and its component parts. The SLC genes are often called a "superfamily" because they can be further categorized into dozens of smaller families based on the type of molecules their corresponding proteins transport. Defects in many of the solute carrier genes are implicated in human diseases. When a solute carrier protein does not function properly, a particular type of molecule might not be able to make its way efficiently into the cell or cell compartment (organelle) where it is needed. Alternatively, a substance may not be able to be removed from the cell for disposal or use elsewhere, and may accumulate to toxic levels. Solute carrier proteins are also of interest for drug development research, for example in facilitating the delivery of a drug to its intended target in the body. Despite being the largest family of membrane transport proteins, SLCs have been relatively under-utilized as therapeutic drug targets by approved drugs.

Activities in 2016 will address the generation of new tools and methodologies in order to exploit the SLC drug target potential for them to be subject of routine small molecule drug discovery programmes with comparable efficiency to “enabled” gene-families like GPCRs and kinases.

Expected Impact

- Establish broadly applicable knowledge and methods to allow drug discovery to be conducted “at will” for any SLC
- Generate a series of novel drug targets for the generation of novel therapeutics in important areas of disease such as cancer

Type of action:
Research and Innovation Action

Calls for proposals

Call number & indicative topics	Indicative Call launch timing	Indicative IMI funding (in EUR)[9]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners	Call process
Call 1 of 2016 **Diabetes/metabolic disorder** ▪ Non-alcoholic fatty liver disease (RIA) **Immunology** ▪ Immune Tolerance therapies (RIA) **Infection control including vaccines** ▪ Innovation in vaccines (Joint influenza vaccine effectiveness studies - RIA) ▪ Antibiotics and antimicrobial resistance (Addressing the clinical burden of clostridium difficile infection - RIA) **Translational safety** ▪ Models & platforms to improve the prediction of toxicity & safety (Next generation of electronic translational safety – RIA) **Neurodegeneration and other Neuroscience Priorities** ▪ Data quality and integrity in preclinical testing (RIA)	06 April 2016	58,328,000	59,328,000	Two-stage with predefined submission deadline
Call 2 of 2016 **Diabetes/metabolic disorders** ▪ Diabetes (RIA) **Neurodegeneration and other Neuroscience Priorities** ▪ Alzheimer's Disease (CSA) ▪ Pain (RIA) ▪ Autism spectrum disorders (RIA) **Immunology** ▪ Multiple Sclerosis (RIA) ▪ Epigenetics (RIA) **Infection control including vaccines** ▪ Human challenge trials (RIA) **Translational safety** ▪ Models & platforms to improve the prediction & toxicity & safety (RIA) ▪ Biomarkers (RIA)	12 October 2016	184,672,000	183,672,000	Two-stage Call with predefined submission deadline

[9] Based on estimate of total operational commitment appropriations available in 2016, as well as estimate of commitment appropriations to be carried over from 2015.

Call number & indicative topics	Indicative Call launch timing	Indicative IMI funding (in EUR)[9]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners	Call process
Data and Knowledge Management ▪ Generation and exploitation of real world evidence (RIA) ▪ Access standards and interoperability (RIA) ▪ Support new research paradigms (RIA) **Other enablers of innovation** ▪ Sustainable pan-EU pediatric CT network (EUPCTN) (RIA) ▪ Patient-stakeholders engagement in product lifecycle (RIA) ▪ Involvement of payers, regulators, HTA and medical practice in IMI2 (CSA) ▪ Unlocking the Solute Carrier Gene-Superfamily for Effective New Therapies (RIA)				
OVERALL TOTAL		**243,000,000**	**243,000,000**	

All proposals must conform to the conditions set out in section 2.3 to this Annual Work Plan, the H2020 Rules for Participation[10] and the Commission Delegated Regulation with regard to IMI2 JU[11].

In the context of the Calls for proposals set out in this Annual Work Plan, there is particular interest in ensuring partnership at the level of the selected projects between, on the one hand, EFPIA constituent entities or their affiliated entities and IMI2 Associated Partners and, on the other hand, other beneficiaries, due to the complementarity of expertise and resources. In order to better organise this complementarity of expertise and to avoid overlapping, IMI2 JU Calls for proposals may thus comprise two stages where participation of EFPIA constituent entities or their affiliated entities and other Associated Partners occurs at the second stage. This approach does not affect the use of IMI2 JU funding because they do not receive IMI2 JU funding in line with Commission Delegated Regulation 622/2014. Additionally, in such two-stage calls for proposals, participants from EFPIA constituent entities and affiliated entities and other Associated Partners are pre-defined in the individual topics (based on their commitment to contribute to the project) and do not apply at the first stage of the call. Rather, an applicant consortium presenting complementarities to the EFPIA constituent entities or their affiliated entities and other Associated Partners is selected from the first stage in open Call for proposals, and this group of participants is merged at the second stage with the EFPIA constituent entities or their affiliated entities and other Associated Partners.

This Annual Work Plan for 2016 therefore includes the additional condition for participation[12] for the two-stage calls for proposals. In such type of calls participants from EFPIA constituent entities and affiliated entities and other Associated Partners are pre-defined but do not apply at the first stage of the call.

Furthermore, this Annual Work Plan for 2016 includes the additional condition for participation[13] in the context of the IMI2 9th Call for proposals, 1st Call of 2016, (two-stage calls for proposals) under the scientific priority

[10] http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf

[11] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0622&from=EN

[12] Article 9(5) of the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020"

[13] Article 9(5) of the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020".

'Infection control including vaccines, Innovation in vaccines', where the application of the European Centre of Disease Prevention and Control (ECDC)[14], the National Public Health Institutes (NPHIs) and National Regulatory Agencies (NRA), hereafter jointly defined as Public Health and Regulatory Bodies (PHRBs) occurs at the second stage only. This condition is justified in consideration of the nature and objective of the action. The latter has as key objective to develop and validate a public-private joint effort to deliver influenza vaccine effectiveness data in Europe.

The generation of data on vaccine effectiveness lies within the mandate of national public health institutes that are evaluating the performance of national vaccination programmes. However, the submission of data on vaccine effectiveness to regulatory authorities is also an obligation of the vaccine marketing authorization holder. There is therefore scope for exploring collaboration in order to avoid duplication of efforts and to maximize value created by resources spent. In addition, there is significant potential for scientific progress by bringing experts from different stakeholder organisations together.

The consortium implementing the action has to include ECDC and a sufficient number of EU NPHIs and NRAs in order to meet the objectives. These organisations are required because of their specific and unique mandate given to them by the European Union and the EU national governments, respectively. These organisations have access to vaccination data that is required for carrying out the effectiveness studies requested under this topic.

Due to the unique role of ECDC NPHIs and NRAs, their inclusion in the selection process occurs at stage 2 - together with EFPIA companies – in order not to compromise an open and competitive selection process at stage 1. It is expected that PHRBs would not join more than 1 consortium, and the consortium with PHRBs on board would have a strong competitive advantage. The additional condition for participation of PHRBs at stage 2 will allow a fair, open and competitive selection process at stage 1. The call topic is therefore designed in a way to select a consortium at stage 1 that will have to propose the coordination and facilitation of the development and validation of the governance model of a joint influenza vaccine effectiveness platform.

The unique partners providing access to the national vaccination data that are required for implementing the studies will not compete during stage 1 but join only during stage 2 together with the EFPIA partners. Importantly, the same evaluation criteria, i.e. "Excellence", "Impact" and "Quality and efficiency of the implementation" apply to both stages in their different configuration according to the submission stage. This ensures that the participation of an organisation joining on the basis of the additional condition for participation, and its related impact on the proposal, is fully assessed against the entire set of evaluation criteria irrespective to of the stage when it joined the proposal.

Potential applicants to topics launched under this Annual Work Plan must be aware that, if exceptionally needed, appropriate and duly justified, the IMI2 JU may publish under a future Annual Work Plan another Call for proposals restricted to those projects already selected under this initial topics, depending on the outcome of the selected projects, in order to enhance and progress their results and achievements by extending their duration and funding. The detailed scope of the restricted Call must be detailed in the relevant Annual Work Plan.[15]

[14] http://ecdc.europa.eu/en/Pages/home.aspx

[15] Article 9(5) of the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020"

Budget

The forecast put forward in the draft annual budget plan for 2016 has been re-evaluated based on the currently available information.

A table overview of the operational budget for the financial year 2016 is set out below. The maximum Union financial contribution to the IMI2 JU for year 2016 is still subject to the approval of the 2016 Annual Financing Decision of the European Commission for IMI2 JU.

	Heading Title 3	Financial year 2016		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
30	* Operational expenditure	203,186,585	197,000,000	Grant agreements - Payments
30	Operational expenditure – carry over from 2015		-	To be determined at the end of 2015 based on final year budget execution

*Excluding amounts carried over from 2015

The amount carried over from previous years to 2015 budget commitment appropriations was of EUR 88.8 million.

The exact amount of appropriations to be carried over to 2016 will be specified once the budgetary year 2015 is closed and will be entered into the budget 2016 based on the Governing Board decision at the beginning of 2016.

A table overview of the 2016 draft budget is set out in Chapter 3 to this Annual Work Plan together with the staff establishment plan.

Strategic Governing Groups (SGGs)

Strategic advisory groups to the Governing Board (called **Strategic Governing Groups**) which were established by the Governing Board in 2014 will further develop their activities. Those were established in different thematic areas with the primary aim to make the process of topic development and gathering industry commitment more transparent, effective and strategic in various thematic areas as follows:

- immunology;
- diabetes and metabolic disorders;
- neurodegeneration;
- translational safety;
- Data and Knowledge management;
- infections control.

In 2016, consideration will be given to establishing a Strategic Governing Group on oncology.

A scientific member of the Programme Office has been allocated to each of the Strategic Governing Groups and will continue also in 2016 to support their activities.

The objectives of the SGGs include improving idea maturation and budget commitment processes for an efficient translation of the SRA into concrete proposals that can be developed into formal call topics through established IMI processes; the strategic coordination within and across portfolios of existing projects and programmes; ensuring the coherent planning and exploitation of results into research, regulatory and medical practice and providing the structures for review and integration of proposals from industry and third parties during the early stage of idea generation.

As the primary role of the SGGs is to make the process of topic development and gathering industry commitment more transparent, effective and strategic the SGGs advise the IMI Governing Board on the scientific portfolio strategy, scientific priorities and annual work plan for selected disease or/and thematic areas; research projects and programmes, as well as the type of call process that is most suitable and effective. They advise on outreach to/consultation with the scientific, patients, etc. communities. They also evaluate programmes and projects in light of evolving science and environment as well as on the basis on key milestones; formulate recommendations to expand or end activities and seek synergies and complementarities with other similar European and global initiatives. All activities related to allowing the SGGs perform these tasks and achieve their objectives are considered as eligible in-kind contributions.

2.2.3 Call management (planning, evaluation, selection)

Activities related to proposals evaluation and grant preparation

Key activities in 2016 will comprise the launch of two competitive Calls for Proposals implementing the 2016 Scientific Priorities with indicative launch dates of the 06 April 2016 and 12 October 2016.

In a single- stage submission evaluation procedure, from the initial publication of the Call for proposals the submission deadline will be approximately three months from the publication of the calls for proposals

In a two stage submission evaluation procedure, from the initial publication of the Call for proposals the submission deadline will be:

- for stage 1 approximately three months from the publication of the calls for proposals
- for stage 2 approximately eight months from the publication of the calls for proposals.

In addition, the evaluation of Short Proposals and Full Proposals submitted to Calls launched under the AWP in 2016 will be held according to the predefined timelines established in the relevant Call for Proposals.

Timelines for completion of the evaluation process and of preparation will be kept as lean as possible with the aim of completing signature of the Grant Agreements within applicable time to grant (TTG), in compliance with the Horizon 2020 framework, i.e. a maximum of eight months from the final date of submission of the full proposals[16].

To maximise the efficiency of the calls management, the IMI JU will continuously explore and implement simplification and improvement processes while maintaining the highest standards of the evaluation process.

2.2.4 Activities to support and monitor ongoing projects

65 ongoing projects will be running at different stages of their life cycle in 2016 and an overview is provided in the table below (status of projects as forecasted for 1st January 2016). All projects will submit to IMI a periodic report for the previous year summarising their progress and costs incurred. These reports form the basis for the Programme Office's ex-ante controls.

In addition to periodic reporting and associated feedback, IMI will continue to provide support and advice to the consortia, including on amendments to Grant Agreements.

IMI will organise 4 mid-term (interim) reviews for projects launched under IMI1 (Call 7 and 8) and the first reviews of IMI2 projects, namely projects in the Ebola + programme launched under IMI2 Call 2. IMI will adopt a policy on reviews to maintain the instrument of ex-ante control on the project performance as stipulated in the Grant Agreements under IMI1.

[16] Article 20 of the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020"

		Project periodic reports due in 2016						Of which	
IMI Calls	ongoing in 2016	1st RP in 2016	2nd RP in 2016	3rd RP in 2016	4th RP in 2016	5th to 7th RP in 2016	Total reports	finishing in 2016	Final report due 2016
1	6	0	0	0	0	6	6	5	5
2	8	0	0	0	0	8	8	6	6
3	7	0	0	0	7	0	7	0	0
4	7	0	0	0	7	0	7	1	1
5	1	0	0	0	1	0	1	0	0
6	2	0	0	0	2	0	2	0	0
7	2	0	0	2	0	0	2	1	1
8	4	0	4	0	0	0	4	1	1
9	4	1	3	0	0	0	4	0	0
10	1	1	0	0	0	0	1	0	0
11	8	8	0	0	0	0	8	0	0
IMI2C1	1	1	0	0	0	0	1	0	0
IMI2C2	8	8	0	0	0	0	8	2	1
IMI2C3	5	0	0	0	0	0	0	0	0
IMI2C4	1	1	0	0	0	0	1	0	0
IMI2C5	0	0	0	0	0	0	0	0	0
Total	**65**	**20**	**7**	**2**	**17**	**14**	**60**	**16**	**15**

A key task will be to continue maximising efficiency, facilitating, optimising, and monitoring the implementation of all these projects and seeking feedback for continuous improvement to IMI JU operations. To this end, further workshops to provide guidance on the management of financial and administrative aspects of the projects will be held for IMI beneficiaries. In addition, the IMI Programme Office will work with consortia on helping to communicate on project progress and achievements.

Furthermore, **interactions between projects** and sharing of best practices (including on sustainability plans) will be promoted by organising joint and cross-projects meetings and/or using various other channels. Many IMI projects are discussing how to sustain their results (tools, databases, guidelines, etc.) beyond the period of IMI funding. Cross-project meetings to discuss potential solutions for sustainability and to help inform IMI policy in this area are therefore considered important and the IMI Programme Office may facilitate the organisation of such meetings in 2016.

Several projects launched under IMI1 that are coming to the end of their funding period are requesting IMI to assist them in preparing for sustainability of their results (tools, databases, guidelines, etc.) beyond the IMI project duration. IMI2 JU has previously initiated a pilot exercise in order to ensure that potentially valuable assets are exploited to their maximum once the projects have been concluded. The necessary expertise in the development of business cases, and sustainability plans was identified through a consultancy study. The best practices identified by this process will be made available to all IMI projects. Based upon the learning from this study and feedback from the projects the IMI Programme Office will bring forward a policy document capturing how this may be best achieved. This policy document will be discussed with and approved by the IMI Governing Board. A key aim of this policy will be to help the consortia develop sustainability plans that are not based on continuous IMI funding. This may take the form of a call dedicated to ensuring the sustainability of key achievements/assets/outputs generated by the so-called IMI1 projects.

Cross project interactions

In order to share best practice between the projects and develop potential synergies a series of cross project meetings will be organised for both IMI funded and other initiatives. Cross project interactions are planned for but not restricted to the following areas:

Neurodegeneration - activities will be organised to facilitate links between projects in the portfolio of neurodegenerative diseases. In particular a cross meeting of actions under the IMI Alzheimer's Platform from IMI (AETIONOMY, EMIF AD, EPAD) and IMI 2 (project from IMI2 C5 T4) including a session with other related EU and national projects (HBP, JPND, DZNE, DPUK) where patients are invited

Psychiatry – a cross project meeting for IMI1 and IMI2 projects in Neuropsychiatry EU-AIMS (IMI) PRISM (IMI2) will be held including a session with other related National and EU projects where patients are invited.

Antimicrobial resistance – activities will be organised to facilitate links between projects under the New Drugs for Bad Bugs programme.

2.2.5 Monitoring and analysis of projects' results

All IMI projects will complete a periodic report in 2016 and these reports will be used to track progress against their stated objectives and deliverables as laid out in the description of the action. This reporting will also allow an assessment of project achievements and the impact of results. In addition to these ex-ante controls a combination of internal management information systems, external databases, independent evaluations and, if necessary, commissioned studies and surveys will be used to measure the progress and identify significant achievements of IMI projects. In addition, 15 projects will finish their IMI funding during 2016 and will submit their final reports. For those projects resulting from IMI2 calls launched in 2016 onwards this monitoring will be done using the functionalities of the Horizon 2020 IT infrastructures. The transition to using H2020 IT infrastructures will be completed in 2016.

It had been previously been proposed to develop an online platform that would allow for customisable, analytics on all project outputs. The feasibility of such an approach and value for money was found to be doubtful especially in the context of the transition to H2020 tools. IMI retains the option to explore this avenue if it is found that developments in the H2020 IT systems do not meet IMI's needs.

In 2016 the analysis of the IMI project scientific outputs in terms of publications and collaboration among IMI researchers will be continued. Where feasible monitoring and analysis approaches will be refined in line with observations from the ECA to ensure the highest possible standards.

2.2.6 Stakeholders' engagement and external collaborations

Given the important role of the IMI2 JU in facilitating collaboration between public and private sectors, consultation with and mobilisation of different stakeholders is key to the successful implementation of the IMI2 JU work plan. In order to do this requires the IMI2 JU to consult on future scientific priorities, explore synergies and avoid duplication of efforts. The IMI2 JU plans to facilitate external stakeholder engagement and collaboration through hosting regular meetings and workshops at which the various stakeholders can engage with each other, network and contribute to helping the IMI2 JU shape and achieve its objectives.

The costs for these meetings, workshops and collaborations will be met from the IMI2 JU running costs and will not require the launch of specific calls.

Patients

IMI recognises that patients can make a vital contribution to shaping research, make it more effective and more oriented to patient needs. Therefore, IMI's goal is to champion a patient centric-approach, encouraging all the projects that it funds to work in partnership with patients wherever possible.

Patients play an essential role when designing and implementing the IMI Strategic Research Agenda, sitting alongside researchers from public and private sectors, including the pharmaceutical industry, biotech companies, academia and regulators. This is why we wish to embed patient and their advocates at all levels; agenda setting for research in medical innovation, project planning, implementation, evaluation processes and content. Therefore the Programme Office will continue to actively engage with patients and promote patient involvement in its projects and activities.

Patients		
Objective		
To raise awareness of IMI's activities among patients and explain what IMI is doing for them. To ensure patient input in all aspects of IMI activities as a research-funding organisation, and particularly to promote their involvement in IMI projects.		
Planned activities		**Specific actions**
1	Organise one or two patient focus meeting(s) with an objective to provide patient perspective and input into the potential research topics in IMI.	Meeting(s) to be organised Q2 or Q3
2	IMI represented at least at 1 specific patient focused event.	Meetings to be identified and IMI to attend the most relevant
3	Continue to produce materials for promotion of patient involvement in IMI.	Produce relevant materials as needed.

Regulators

To advance the vision of delivering the right treatment to the right patient at the right time for priority diseases requires all sectors within the healthcare ecosystem to work together to build the environment and infrastructure that allows the full value of this innovation to be realised.

Since the beginning IMI has established collaboration with Regulators to ensure when relevant that development strategies such as novel biomarkers and patient focussed clinical endpoints, innovative trial designs, patient centred benefit/ risk and effectiveness/risk assessment, and alternative regulatory pathways address actual needs. IMI will continue to develop the framework to engage with all relevant Regulatory Agencies. It is important to expand the ongoing dialogue with other healthcare decision makers such as health technologies assessment bodies and payers.

Regulators		
Objective		
To continue to strengthen relations with regulatory agencies. in particular with EMA and FDA		
Planned activities		**Specific actions**
1	Ensure that IMI projects benefit from the regulators' input and maximize the impact of IMI projects outputs to progress regulatory science.	Annual IMI regulatory science summit with the EMA and FDA planned Q1 or Q2

2	Monitoring of the progress on actions points agreed at the annual meetings	TCs to be held throughout the year
3	Regular exchange of information with EMA and FDA on topics under development projects, including regular teleconferences.	TC every 2/3 months
5	Joint dialogue with EFPIA, the EMA and European Commission to further discuss the impact of the IMI projects on the EU regulatory environment, including the results from the IMI coordination and support action ADAPT-SMART looking at enabling implementation of Medicines Adaptive Pathways to Patients (MAPPs) within the current regulatory framework.	Regular teleconferences to be organised throughout the year
6	Continue raising awareness of the IMI consortia on the regulatory relevance of their activities, the subsequent regulatory processes to follow particularly with the qualification advice/opinions procedures, and on supporting early liaison with the regulators.	Survey to be organised Q1/Q2 Dedicated webinars to be organised throughout the year
7	Enhance dialogue with other decision-makers particularly Health Technology Assessment (HTAs), payers and other relevant EU-funded initiatives.	Develop a framework for dialogue, taking into consideration experience from the IMI coordination and support ADAPT-SMART

Small and medium Size Enterprises

15.6% of participants in IMI1 are SMEs and receive 13.5% of the IMI1 budget. In the coming year, IMI will continue to work with its founding members and other stakeholders to increase support to SMEs and increase SME participation in its projects. IMI JU will achieve this through the provision of targeted support and guidance disseminated through the dedicated helpdesk and IMI website, attendance at dedicated SME meetings and the organisation of an IMI focused meeting targeted specifically at SMEs. Discussions will be held to explore the organisation of a meeting focused on funding and networking opportunities with venture capital organisations and the investment arms of pharmaceutical companies.

SMEs		
Objective		
To increase awareness of SMEs to IMI funding opportunities and encourage SME applications to IMI Calls		
Planned activities		**Specific actions**
1	Collaborate with pan-European SME organisations to prepare a meeting focused on European funding opportunities	Meeting to be organised Q3
2	IMI represented at 3 specific European SME focused/bio-partnering events at least one of which is emerging European economy countries	Meetings to be held throughout the year

Health Care Professionals

In line with the aims and objectives of the SRA of IMI2 the Programme Office will enhance involvement of healthcare professionals in IMI activities with a view to engage all stakeholders in achieving the vision of delivering the right treatment at the right time to the right patient. This will focus on identifying the best channels to develop a framework for interacting with healthcare professionals. If progress is sufficient a dedicated meeting may be held in this area.

Funding Agencies

At a time when research funding is under intense pressure and in an effort to avoid the duplication of effort and the dilution of funding impact there is the need to explore with other funding agencies how best to align approaches especially in key areas of mutual interest. IMI will explore with other leading national and international funding agencies on the possibility of offering joint funding initiatives or schemes run in parallel with the aim of achieving complementary objectives.

Funders' Forum	
Objective	
To identify areas where joint funding schemes may be offered to increase the impact of research funding, to maximise the financial leverage possible and speed up the development of new medicines and treatments for patients.	
Planned activities	**Specific actions**
1 Collaborate with national and international funding agencies in developing an approach to allow the joint funding of research in areas of high medical need	Meeting to be organised Q4
2 Further develop EU-US collaboration on clinical trials related to antimicrobial resistance by organising a workshop with NIH/NIAID and others funders/initiatives	Workshop to be organised Q1 2016

External collaborations

Clinical Data Interchange Standards Consortium (CDISC)

The collaboration with the Clinical Data Interchange Standards Consortium (CDISC) will continue in 2016 for the benefit of IMI JU beneficiaries, in particular with the training activities by CDISC offered to partners of IMI consortia. In order to further facilitate implementation of data standards, in-depth trainings on CDISC standards and any other applicable standards, a consultancy session may be organised for the projects. Projects will be informed of any new data therapeutic area standards being developed through CFAST and novel data standards needed for the implementation of IMI Actions will, where possible, be developed according to a standards development methodology such as the process followed by CDISC. The latter will be discussed through participation in in the Scientific Advisory Committee of the Coalition for Accelerating Standards and Therapies (CFAST).

CDISC	
Objective	
To promote the adoption (and/or adaptation and/or development) of well-established data formats and content standards in order to ensure interoperability to quality standards. In particular, the implementation of CDISC standards for clinical trials data.	
Planned activities	**Specific actions**
1 Renew the Memorandum of Understanding between CDISC and IMI	Q1
2 Renew the IMI membership to CDISC. This membership extends the IMI membership (platinum) to a (gold) membership for the IMI beneficiaries.	Q3
3 Conduct an Introductory training to CDISC	Webinar Q3 or Q4
4 Inform projects of new Therapeutic Area standards being developed through CFAST. Ensure that new data standards needed for the implementation of IMI actions are developed according to a standards development methodology such as the process followed by CDISC.	Participation in the Scientific Advisory Committee of CFAST (Coalition For Accelerating Standards and Therapies)

Secondary use of data

Secondary use of data occurs when data is used for a purpose different from the purpose for which the data was initially collected. Enabling secondary use of medical data by healthcare professionals and researchers is important to improve the quality of health care and research effectiveness. At the same time, it is important to protect patient privacy and to ensure that no harm is done to a patient through the use of the data. It has proven difficult for research projects such as the projects funded by the Innovative Medicines Initiative to set-up an approach to deal with the secondary use of personal medical data which is common to all partners.

More importantly it is well recognized by such projects that is a recurrent challenge. IMI has produced a code of practice and remains committed to providing support to its projects via the regular updating of and communicating on this code of practice.

Secondary use of data	
Objective	
To provide a Code of Practice for the Secondary Use of Medical Data in Scientific Research Projects in the context of multi-national, multi-partner collaborations such as funded by IMI.	
Planned activities	**Specific actions**
Convene an expert panel (scientific, data protection and ethics) for the periodic review of the Code to ensure continued compliance with EU directives and regulations.	Meeting to be organised Q3 or Q4

Global Alliance for Genomics and Health

In the coming year IMI will determine whether a membership of the Global Alliance for Genomics and Health (GA4GH) can provide solutions for recurrent challenges in IMI projects. However, irrespective of the decision on membership IMI will still attend GA4GH meetings to capitalize on solutions found by other large projects in this area.

Global Alliance for Genomics and Health	
Objective	
Capitalize on solutions found by large projects for recurrent challenges such as sharing of patient-level genomic and clinical data	
Planned activities	**Specific actions**
1 Determine whether a membership to the Global Alliance for Genomics and Health (GA4GH) can provide solutions for recurrent challenges in the IMI projects.	Q1
2 Participation in the GA4GH meetings	Q2-4

C-PATH Institute

IMI will continue to collaborate with C-Path Institute notably with a potential fourth joint IMI & C-Path meeting scheduled in Q4 of 2016. IMI and C-Path Institute will work together on synergies and alignment and will seek to avoid duplication of efforts in these programmes, particularly in areas of common interest to advance regulatory science and leverage global biopharmaceutical development, as well as, in specific research areas between IMI & C-Path projects.

Collaboration will have a continued focus on the data standard space with a view to ensuring consistent remapping of respective data sets to enable leveraging the data on both sides. There will be regular exchange of information on topics under development and the results of ongoing projects

A focus of the interaction in the coming year will be on enabling a collaborative relationship on paediatrics particularly between the C-Path Global Paediatric Clinical Trials Network Pre-Launch Consortium and the future IMI 2 project derived from topic launched as part of Call 8. Furthermore, collaboration in the area of neuroscience and tuberculosis will continue in 2016.

C-PATH Institute	
Objective	
To collaborate with C-Path Institute to develop synergies and alignment of projects, as well as, seek to avoid duplication of efforts in these programmes	
Planned activities	**Specific actions**
Joint IMI & C-Path meeting	Meeting organised Q3 or Q4

NIH Institutes and Foundation for NIH (FNIH)

Collaboration will continue between the IMI EU-AIMS project and FNIH Biomarkers Consortium's Autism Initiative to align the two initiatives and achieve harmonized biomarkers qualification by EMA and FDA as well as link biobanking and clinical research initiatives.

In addition opportunities will be explored to align the IMI initiatives in areas such as diabetes and neurodegeneration with parallel initiatives launched as part of Accelerated Medicines Platform (AMP).

The Global CEO initiative for Alzheimer's Disease and the UK Dementia Platform

Collaboration will be strengthened between the global CEO initiative for Alzheimer's Disease, the medical Research Council-UK Dementia Platform (DPUK) and the IMI Platform for Alzheimer's Disease based upon the Global Alzheimer's Platform (GAP).

The CEO Initiative Alzheimer's Disease and Global Alzheimer's Platform	
Objective	
To align activities in the IMI2 priority area Neurodegeneration/Alzheimer's Disease to ensure synergy for future actions and to facilitate and monitor implementation of ongoing actions.	
Planned activities	**Specific actions**
1 Organize a joint meeting at AAIC2016 (Toronto July 2016 http://www.alz.org/aaic/) to align planned activities and monitor implementation of aligned activities in GAP and IMI project EPAD as well as related action generated by IMI2 (C5 T4)	Meeting organised Q3
2 Joint participation CEOi AD and IMI to activities developed as part of the Global Action against Dementia (https://worlddementiacouncil.wordpress.com/) of the World Dementia Council	Joint Participation to one key meeting during 2016, contribution to preparation of white papers and reports as relevant.

Advanced therapies

The objective is to make advanced therapies rapidly available to patients. An initial workshop took place in October 2015 with the aim to organize brainstorming meetings as a follow-up gathering multi-disciplinary expertise to address clinical translation hurdles in advanced therapies including regulatory models, business models, manufacturing and healthcare delivery systems. Call is foreseen in 2016.

Organization of dedicated sessions to IMI stem cell projects in specific international congresses is foreseen in order to give visibility to the projects and to promote IMI to the scientific community.

European induced pluripotent stem cell (EBiSC)

EBiSC phase 2 Funding:

IMI1 Call 8 aimed at the establishment of a European iPS cell bank that would provide researchers with access to quality-assured, well characterized iPS cell lines on a not-for-profit basis. The project was granted for three years period 2014-2016, with the provision that additional three years would be granted based on successful completion of defined milestones during the initial 3 years period. EBiSC has established a single access point for research grade, ethically sourced, quality controlled iPSC lines and associated data under standardized, unrestricted license terms. The first phase of the project will end Dec. 2016 therefore it is urgent to propose a funding solution for the continuation of EBiSC for the next coming year (2017-2019),so that the EBiSC Consortium can complete the operational/business plan for not for profit, self-sustainability. The external peer review at mid-term duration of the project has recommended securing funding for Years 4-6 to sustain EBiSC until it can become self-sustaining. A total budget of 16 million EUR (IMI-JU funding of EUR 8 million, combined with in-kind contribution equivalent to EUR8 million from EPFIA companies) would be needed.

Collaboration between StemBANCC and EBiSC

The goal of StemBancc is to achieve reprogramming of 500 subjects within the timeframe of the project. The objective of distributing hiPSC lines and sharing data with the scientific community is at the heart of StemBANCC. Negotiations with the IMI consortium EBiSC are currently progressing with the goal to set up a formal agreement to ensure cell lines and data distribution which is compliant with legal and ethical requirements. The success of the collaboration and the sustainability of material and data dissemination are clearly dependent on sustained funding of the EBiSC Consortium.

On this basis IMI and its founding partners will explore a solution for continuing these efforts.

Advanced Therapies	
Objective **Mobilise relevant stakeholders to address key challenges in making advanced therapies rapidly available to patients**	
Planned activities	**Specific actions**
1 Workshops gathering multi-disciplinary expertise to address clinical translation hurdles in advanced therapies including regulatory models, business models, manufacturing and healthcare delivery systems	Workshops organised Q1 and Q3
2 Organization of dedicated sessions to IMI stem cell projects in specific international congresses is foreseen in order to give visibility to the projects and to promote IMI to the scientific community.	Meetings held throughout 2016
3 Facilitate Collaboration between StemBANCC and EBiSC as well as other IMI and FP7 projects in the field.	Meetings held throughout 2016

One Health

IMI is considering the launch of a programme based on the OneHealth concept. The human and animal health companies should collaborate to reach common goals that would benefit humans, animals and the environment where they live. An initial Worksop has been organised in July 2015 by IMI and EFPIA. It included about 40 participants that represented animal and human health industries and participants of the European Commission DG Research and Innovation (RTD), DG Agriculture and Rural Development (AGRI) and DG Health and Food Safety (SANTE). There was high interest in future collaborations between the two industry sectors and many potential areas were proposed (e.g. antimicrobial resistance, vaccines, understanding diseases' mechanisms, regulatory issues and many others).

In 2016 a second Workshop will be organised to define areas where an OneHealth Programme would prompt synergies that would address unmet needs in human and animal health. It will be important that other initiatives are included in this meeting particularly ongoing EU-funded projects such as ADITEC and SAPHIR.

2.2.7 Socio-economic impact study

Described and set up under the AWP 2015, activities related to this study will continue during 2016. The objective of this first socio-economic evaluation is to identify and report on the socio-economic impacts of project outputs from IMI 1's completed or nearly-completed 2008 and 2009 Calls. The evaluation will connect the scientific and technology outputs already identified and previously reported with the longer-term, downstream impact measures of the type of healthcare ecosystem innovation that IMI activities represent. The evaluation will be carried out by the IMI2 JU with the assistance of independent experts, selected on the basis of a transparent process.

Pre-competitive research, such as that undertaken by the majority of the first IMI1 projects included in this evaluation, has a long lead time. One of the challenges for measuring this type of output is that most of the achievements made by the IMI projects under consideration are at the early stage in the R&D value chain.

The evaluation will look at short-term outcomes (2-3 years) such as improved scientific quality, enhanced knowledge production, network-based R&D capacity building, and human resources development. It will also consider mid-term impacts (4-5 years) and longer term outcomes, known as 'wealth and health' benefits. Mid-term impacts indicators will include concrete results on biomarker validation/toxicology test, big data and shared IT infrastructures, improved knowledge transfer and communication.

Longer term impact indicators willl include improved economic performance reflected in increased competitiveness at European and even global level, better investment in the pharma sector and new medicines/treatments for patients.

The identification and subsequent analysis of the relevant data from the project outputs will be performed by an independent expert panel whose conclusions will be reviewed and tested by an external research organisation. The experts will meet at regular intervals during this pilot evaluation process, which starts in mid-September 2015 and will be completed by the end of April 2016. A preliminary report will be drafted (for internal use) in January 2016, with the final report being signed off by the expert panel and ready for publication by the beginning of May 2016.

This first evaluation will be a pilot exercise in order to establish a model for identifying and measuring this type of impact of completed projects. The evaluation will also produce a set of relevant KPIs for future evaluation purposes. The final report will be disseminated to all stakeholders, including policy makers at the European level.

2.3 Call management rules

All proposals must conform to the conditions set out in the H2020 Rules for Participation (http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf and the Commission Delegated Regulation with regard to IMI2 JU http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0622&from=EN.

The following general conditions shall apply to the IMI2 Calls for Proposals:

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

By way of derogation[17] from Article 10(1) of Regulation (EU) No 1290/2013, only the following participants shall be eligible for funding from the Innovative Medicines Initiative 2 Joint Undertaking:

(a) legal entities established in a Member State or an associated country, or created under Union law; and

(b) which fall within one of the following categories:

(i) micro, small and medium-sized enterprises and other companies with an annual turnover of EUR 500 million or less, the latter not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities' within the meaning of Article 2(1)(2) of Regulation (EU) No 1290/2013 shall apply *mutatis mutandis*;

(ii) secondary and higher education establishments;

(iii) non-profit organisations, including those carrying out research or technological development as one of their main objectives or those that are patient organisations.

(c) the Joint Research Centre;

(d) international European interest organisations.

In accordance with Article 10(2) point (a) of the Regulation (EU) No 1290/2013, in case of participating legal entity established in a third country, that is not eligible for funding according to point (a) above, funding from the IMI2 JU may be granted provided the participation is deemed essential for carrying out the action by the IMI2 JU.

ADMISSIBILITY CONDITIONS FOR GRANT PROPOSALS, AND RELATED REQUIREMENTS

Part B of the General Annexes[18] to the Horizon2020 Work Programme 2016– 2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

Page limits will apply to proposals as follows:

- At stage 1 of a two-stage call, the limit for short proposals is 30 pages;
- For a single stage call, as well as at stage 2 of a two-stage call, the limit for full proposals is 70 pages.

[17] Pursuant to the Commission Delegated Regulation (EU) No 622/2014 of 14 February 2014 establishing a derogation from Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in 'Horizon 2020 — the Framework Programme for Research and Innovation (2014-2020)' with regard to the Innovative Medicines Initiative 2 Joint Undertaking

[18] http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016-2017/annexes/h2020-wp1617-annex-ga_en.pdf

ELIGIBILITY CRITERIA

Part C of the General Annexes to the Horizon 2020 Work Programme 2016– 2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

Under all two-stage submission procedures the following additional condition applies:

The participants from EFPIA constituent entities and affiliated entities and other Associated Partners which are pre-defined in the topics - under the section 'Industry consortium' - of a call for proposals do not apply at the stage 1 of the call. The applicant consortium selected from the stage 1 of the Call for Proposals is merged at the stage 2 with the EFPIA constituent entities or their affiliated entities and other Associated Partners.[19]

Furthermore, in the context of the IMI2 9th Call for proposals, 1st Call of 2016, (two-stage calls for proposals) under the scientific priority 'Infection control including vaccines, Innovation in vaccines', the following additional condition applies:

The European Centre of Disease Prevention and Control (ECDC) and the EU National Public Health Institutes (NPHIs) will join the applicant consortium selected from the stage 1 only during stage 2, together with the participants from EFPIA constituent entities and affiliated entities. This condition is justified in consideration of the nature and objective of the action. The latter has as key objective to develop and validate a public-private joint effort to deliver influenza vaccine effectiveness data in Europe. The generation of data on vaccine effectiveness lies within the mandate of national public health institutes that are evaluating the performance of national vaccination programmes. However, the submission of data on vaccine effectiveness to regulatory authorities is also an obligation of the vaccine marketing authorization holder. There is therefore scope for exploring collaboration in order to avoid duplication of efforts and to maximize value created by resources spent. In addition, there is significant potential for scientific progress by bringing experts from different stakeholder organisations together.

The consortium implementing the action has to include ECDC and a sufficient number of EU national public health institutes in order to meet the objectives. These organisations are required because of their specific and unique mandate given to them by the European Union and the EU national governments, respectively. These organisations have access to vaccination data that is required for carrying out the effectiveness studies requested under this topic.

Due to the unique role of ECDC and national public health bodies, their inclusion in the selection process occurs at stage 2 - together with EFPIA companies – in order not to compromise the open and competitive selection process at stage 1. It is expected that ECDC and NPHIs would not join more than one consortium, and as such their participation as of stage 1 would significantly limit the open competition between potential applicants. A proposal not having ECDC and NPHIs on board would have a significant competitive disadvantage. The additional condition for participation of ECDC and NPHIs at stage 2 will allow a fair, open and competitive selection process at stage 1. The call topic is therefore designed in a way to select a consortium at stage 1 that will propose the coordination and facilitation of the development and validation of the governance model of a joint influenza vaccine effectiveness platform. The unique partners providing access to the national vaccination data that are required for implementing the studies will not compete during stage 1 but join only during stage 2 together with the EFPIA partners.

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

Part D of the General Annexes to the Horizon2020 Work Programme 2016– 2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

TECHNOLOGY READINESS LEVELS (TRL)

Part G of the General Annexes to Horizon2020 Work Programme 2016– 2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

[19] Article 9(5) of the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020"

EVALUATION

Part H of the General Annexes to the Horizon2020 Work Programme 2016– 2017 shall apply *mutatis mutandis* for the actions covered by this Work Plan with the following additions:

The relevant call texts launched under this Work Plan must specify whether the Call for proposals is a single-stage or two-stage Call, and the predefined submission deadline.

Award criteria:

Experts will evaluate the proposals on the basis of criteria of "Excellence", "Impact" and "Quality and efficiency of the implementation" according to the submission stage and type of action, as follows:

Type of action	Excellence	Impact	Quality and efficiency of the implementation*
RIA and IA **1st stage** **evaluation**	The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the call for proposals and referred to in the IMI2 annual work plan: ▪ Clarity and pertinence of the proposal to meet all key objectives of the topic; ▪ Credibility of the proposed approach; ▪ Soundness of the concept, including trans-disciplinary considerations, where relevant; ▪ Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art; ▪ Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders	The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level: ▪ The expected impacts of the proposed approach as mentioned in the call for proposals ▪ Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant; ▪ Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges; ▪ Improving European citizens' health and wellbeing and contribute to the IMI2 objectives[20].	The following aspects will be taken into account: ▪ Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget; ▪ Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal. ▪ Appropriateness of the proposed management structures and procedures, including manageability of the consortium.

[20] Article 2 of the Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (O.J. L169 of 7.6.2014)

Type of action	Excellence	Impact	Quality and efficiency of the implementation*
RIA and IA **Single stage, and 2nd stage** **evaluation**	The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the call for proposals and referred to in the IMI2 annual work plan and is consistent with the stage 1 proposal: ▪ Clarity and pertinence of the proposal to meet all key objectives of the topic; ▪ Credibility of the proposed approach; ▪ Soundness of the concept, including trans-disciplinary considerations, where relevant; ▪ Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art; ▪ Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.	The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level: ▪ The expected impacts of the proposed approach as mentioned in the call for proposals; ▪ Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant; ▪ Enhancing innovation capacity and integration of new knowledge; ▪ Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges; ▪ Improving European citizens' health and wellbeing and contribute to the IMI2 objectives;[20] ▪ Any other environmental and socially important impacts; ▪ Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.	The following aspects will be taken into account: ▪ Coherence and effectiveness of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and budget; ▪ Complementarity of the participants within the consortium (where relevant); ▪ Clearly defined contribution to the project plan of the industrial partners (where relevant); ▪ Appropriateness of the management structures and procedures, including manageability of the consortium, risk and innovation management and sustainability plan.

Type of action	Excellence	Impact	Quality and efficiency of the implementation*
CSA **1st stage** **evaluation**	The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the Call for proposal and referred to in the IMI2 annual work plan: Clarity and pertinence of the proposal to meet all key objectives of the topic Credibility of the proposed approach; Soundness of the concept, including trans-disciplinary considerations, where relevant; Quality of the proposed coordination and/or support measures. Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.	The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level: The expected impacts of the proposed approach as mentioned in the Call for proposal; Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant. Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges; Improving European citizens' health and wellbeing and contribute to the IMI2 objectives[21].	The following aspects will be taken into account: Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget; Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal. Appropriateness of the proposed management structures and procedures, including manageability of the consortium.
CSA **Single stage and 2nd stage** **evaluation**	The following aspects will be taken into account, to the extent that the proposed work corresponds to the topic description in the Call for proposal and referred to in the IMI2 annual work plan and is consistent with the stage 1 proposal: Clarity and pertinence of the proposal to meet all key objectives of the topic;	The following aspects will be taken into account, to the extent to which the outputs of the project should contribute at the European and/or International level: The expected impacts of the proposed approach as mentioned in the Call for proposal; Added value from the public private partnership approach on R&D, regulatory, clinical and health care practice as relevant	The following aspects will be taken into account: Coherence and effectiveness of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and budget; Complementarity of the participants within the consortium (where relevant);

[21] Article 2 of the Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (O.J. L169 of 7.6.2014)

Type of action	Excellence	Impact	Quality and efficiency of the implementation*
	Credibility of the proposed approach; Soundness of the concept, including trans-disciplinary considerations, where relevant; Quality of the proposed coordination and/or support measures. Mobilisation of the necessary expertise to achieve the objectives of the topic and to ensure engagement of all relevant key stakeholders.	Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges; Improving European citizens' health and wellbeing and contribute to the IMI2 objectives[22]. Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.	Clearly defined contribution to the project plan of the industrial partners (where relevant); Appropriateness of the management structures and procedures, including manageability of the consortium, risk and innovation management and sustainability plan.

The scheme above is applicable to a proposal in a single-stage submission procedure, as well as in a two-stage submission procedure. At each evaluation stage of the two-stage submission procedure, the relevant evaluation criteria and threshold apply.

These evaluation criteria include scores and thresholds. Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the above table. For all evaluated proposals, each criterion will be scored out of 5. Half marks may be given.

For the evaluation of first-stage proposals under a two-stage submission procedure, the threshold for each one of the two first criteria (‘excellence’ and ‘impact’) will be 3. There is no overall threshold. For the evaluation of second-stage proposals under a two-stage submission procedure; the threshold for individual criteria will be 3. The overall threshold, applying to the sum of the three individual scores, will be 10. For the evaluation of proposals under a single-stage submission procedure, the threshold for individual criteria is 3. The overall threshold, applying to the sum of the three individual scores, is 10.

Following each evaluation stage, applicants will receive an ESR (Evaluation Summary Report) regarding the respective evaluated proposal.

The full evaluation procedure is described in the IMI2 Manual for submission, evaluation and grant award in line with the H2020 Rules for Participation.[23]

Where appropriate and duly justified, IMI 2 JU calls for proposals may follow a two-stage process.

Under the single-stage evaluation process, evaluated proposals will be ranked in one single list. Best-ranked proposals, in the framework of the available budget, will be invited to prepare a Grant Agreement.

[22] Article 2 of the Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (O.J. L169 of 7.6.2014)

[23] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/Manual_for_submission_evaluation_grant%20award_2014.06.26.pdf

Under the two-stage evaluation procedure, and on the basis of the outcome of the first stage evaluation, the applicant consortium of the highest ranked short proposal (first stage) for each topic will be invited to discuss with the relevant industry consortium the feasibility of jointly developing a full proposal (second stage). The applicant consortia of the second and third-ranked short proposals (first stage) for each topic may be invited for preliminary discussions with the industry consortium if the preliminary discussions with the first ranked proposal and the industry consortium fail. In such case, the first applicant consortium and the industry consortium shall be responsible for jointly notifying the IMI2 JU if the preparation of a joint full proposal is not feasible. This notification must be accompanied by a joint report clearly stating the reasons why a joint full proposal is considered not feasible. Upon acknowledgement and after consideration of the specific circumstances, the IMI2 JU may decide to invite the next-ranked applicant consortium in priority order, i.e. the second ranked proposal is contacted only after failure of preliminary discussions with the first ranked, and the third ranked after the second ranked.

Under the two-stage evaluation procedure, contacts or discussions about a given topic between potential applicant consortia (or any of their members) and any member of the relevant industry consortium are prohibited throughout the procedure until the results of the first stage evaluation are communicated to the applicants.

As part of the panel deliberations, the IMI2 JU may organise hearings with the applicants to:
- clarify the proposals and help the panel establish their final assessment and scores, or
- improve the experts' understanding of the proposal.

INDICATIVE TIMETABLE FOR EVALUATION AND GRANT AGREEMENT

	Information on the outcome of the evaluation (single stage, or first stage of a two-stages)	Information on the outcome of the evaluation (second stage of a two stages)	Indicative date for the signing of grant agreement
Single-stage	Maximum 5 months from the submission deadline at the single stage.	N/A	Maximum 8 months from the submission deadline.
Two-stages	Maximum 5 months from the submission deadline at the first stage.	Maximum 5 months from the submission deadline at the second stage.	Maximum 8 months from the submission deadline at the second stage.

BUDGET FLEXIBILITY

Part I of the General Annexes to the Horizon2020 Work Programme 2016– 2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

FINANCIAL SUPPORT TO THIRD PARTIES

Part K of the General Annexes to the Horizon2020 Work Programme 2016– 2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

SUBMISSION TOOL

Unless otherwise stipulated in the relevant Call Conditions of the specific Call, the IMI electronic submission tool **SOFIA** (Submission OF Information Application) is to be used for submitting a proposal in response to a topic of this Call; no other means of submission will be accepted. Proposals may be finalised and re-opened online until the 'Submit' button is pressed.

To trigger the admissibility check, eligibility check and the evaluation, firstly the 'Finalise' button and secondly the 'Submit' button must be pressed in SOFIA by the Call submission deadline.

Access to the IMI electronic submission tool SOFIA for the first time requires a request to access to the tool.

It is expected that during 2016, the IMI2 JU will be able to make use of the H2020 IT tools. As soon as the H2020 proposal submission IT tool will be available for applicants to IMI2 calls launched in 2016 this will be stipulated in the Call Conditions of the relevant Calls for proposals. See also section 2.4.3.1.

OTHERS

For proposals including clinical trials/studies/investigations, a specific template to help applicants to provide essential information on clinical studies in a standardised format is available under:

http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_CallDocs/ClinicalTrialInfoTemplateIMI_v201602.docx. In the first stage of a two-stage evaluation procedure, this template should not be submitted. However, applicants may integrate relevant aspects of this information in their short proposal (within the page limit). In the second stage of two-stage evaluation procedure involving clinical studies, the use of this template is mandatory in order to provide experts with the necessary information to evaluate the proposals. The template may be submitted as a separate document.

Ethical issues should be duly addressed in each submitted proposals to ensure that the proposed activities comply with ethical principles and relevant national, Union and international legislation. Any proposal that contravenes ethical principles or which does not fulfil the conditions set out in the H2020 Rules for Participation, or in the IMI2 Call for proposals shall not be selected. [24]

In order to ensure excellence in Data and Knowledge Management consortia will be requested to:

1) Disseminate scientific publications on the basis of open access[25] (see "Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020").

2) Include a Data Management Plan outlining how research data will be handled during a research project, and after it is completed, as part of the full proposal (see "Guidelines on Data Management in Horizon 2020" providing guidance for the collection, processing and generation of research data). In order to ensure adherence to the legislation concerning protection of personal data, controlled access digital repositories and data governance will need to be considered.

3) Use well-established data format and content standards in order to ensure interoperability to quality standards. Preferably existing standards should be adopted. Should no such standards exist, consideration should be given to adapt or develop novel standards in collaboration with a data standards organization (e.g. CDISC).

4) Disseminate a description of resources[26] according to well-established metadata standards such as the Dublin Core (ISO15836) in order to make the resources included and generated by the IMI Actions discoverable for metrics and re-use.

Full proposals must contain a draft plan for the exploitation and dissemination of the results.

Applicants intending to submit a proposal in response to the IMI2 JU Calls should also read the topic text, the IMI2 JU Manual for submission, evaluation and grant award, and other relevant documents[27] (e.g. IMI2 model Grant Agreement).

[24] Article 19 of Horizon 2020 Framework Programme, and Articles 13 and 14 of the Horizon 2020 Rules for Participation

[25] Article 43.2 of Regulation (EU) No 1290/2013 of the European Parliament and of the Council laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006

[26] Examples of Resources are (a collection of) biosamples, datasets, images, publications etc.

[27] http://www.imi.europa.eu/content/documents#calls_for_proposals_-_imi_2_programme

2.4 Support to Operations

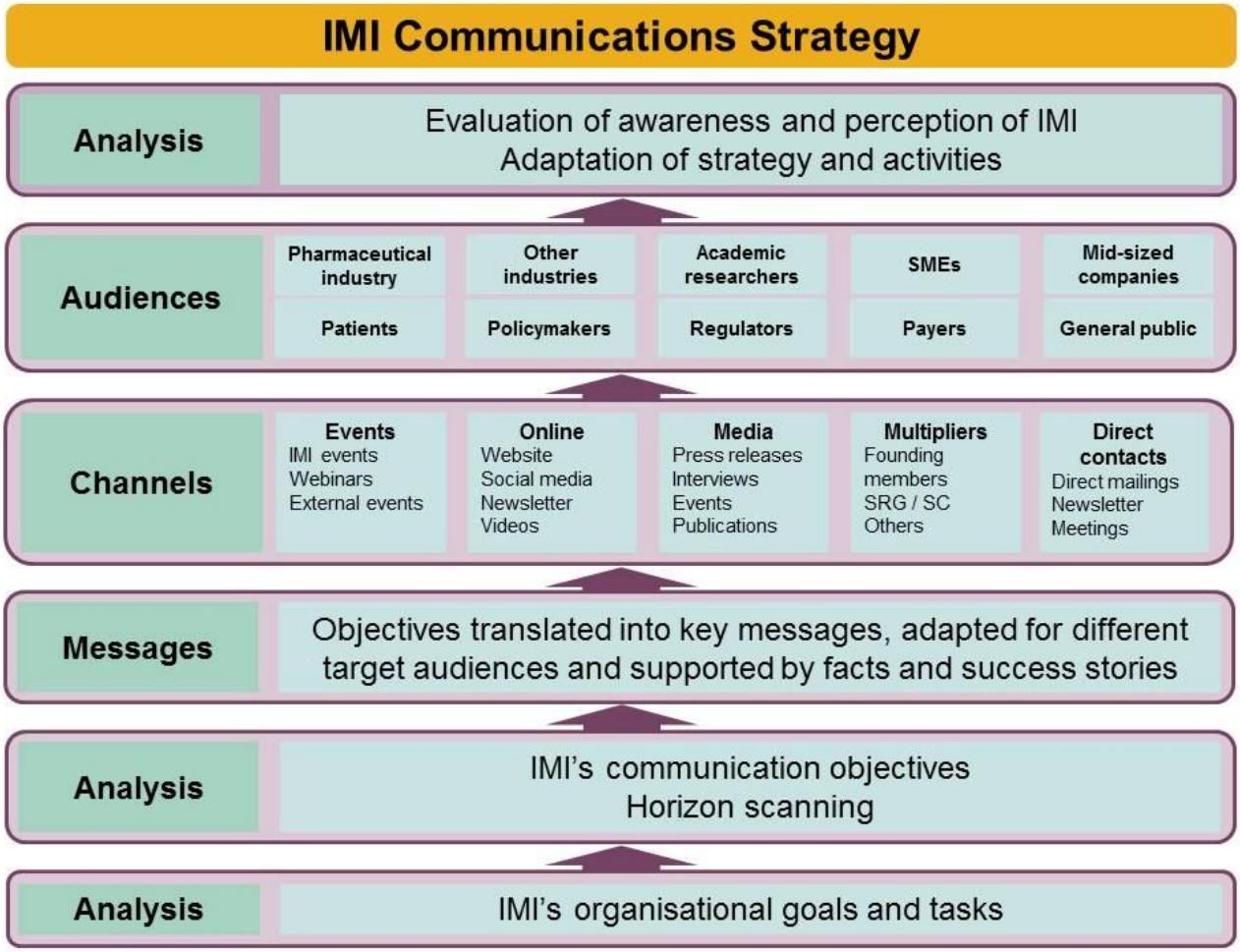
2.4.1 Communication and events

Communication activities

IMI's Communications Strategy has the following objectives.

- Promote IMI and raise awareness levels and perception of IMI among all target groups.
- Attract the best researchers from relevant target groups to apply for funding under IMI 2 Calls for proposals.
- Increase the engagement of patients in IMI's activities.
- Increase the engagement of SMEs in IMI's activities.
- Gain support for IMI among key groups of policymakers and opinion leaders.

The strategy is summarised in the diagram below, and implementing it will form the core of IMI's communications activities in 2016.



Implementing this strategy will drive the core of the communications team's activities throughout 2016. At the same time, as an ongoing exercise, IMI monitors developments in relevant fields (health and research policy, drug development, medicines research) to ensure its strategy, including the objectives, as well as the key messages, audiences and channels, remain relevant. This includes IMI's strategy for patient engagement, which is the result of collaboration between the IMI and science teams and is discussed in section 2.2.6.

In addition, a priority in 2016 will be to update the strategy to take account of the arrival of two new external relations team members. The timing of this exercise will depend on the arrival dates of the new staff.

For this update, the following activities have been identified as priorities:

Expand IMI's strategy for outreach to policymakers and opinion leaders

Just under half of the Members of the European Parliament (MEPs) from the 2009-2014 European Parliament were re-elected in the elections held in 2014. As a result, many of the MEPs with whom IMI had built relationships, and half of the MEPs who voted on (and so are familiar with) the IMI 2 legislation, are no longer there.

As the European Parliament and Council have oversight of IMI's accounts through the discharge procedure, it is important for them to understand IMI and its goals and activities as well as how it works. Throughout 2015, IMI has developed the framework of a strategy for outreach to this important group, including mapping of key stakeholders, drafting of key messages, and creation of extensive materials and information resources. Most importantly, IMI has started reaching out to this group via different channels and at different levels.

An important goal for 2016, especially with the arrival of a new staff member with expertise on outreach to policymakers, would be the further development, refinement and proactive implementation of this strategy.

Develop an IMI strategy for outreach to SMEs

Under IMI 2, in line with the goals of the wider Horizon 2020 programme, it is expected that SMEs will receive 20% of the budget. So far, although IMI has proven to be a good tool for SMEs, they still only account for 15% of participations and just under 14% of the budget so far. This suggests that additional measures are needed to increase their participation and to this end, a priority for 2016 would be the creation of a specific SME engagement strategy, drafted jointly by the science and communication teams.

Redesign the IMI website and newsletter

The current IMI website was launched in autumn 2010. Although the information in it is up to date and the number of visitors continues to rise, the technology behind the website is no longer up-to-date and certain features that have been added to the website in recent years are difficult to edit and do not work reliably. In addition, there are a number of bugs in the newsletter module. A revamped website would allow IMI to adopt the latest web technologies, eliminating existing bugs and making updating the website simpler and less time-consuming. It would also allow IMI to align the website with IMI's wider visual identity (currently, the site only has the new logo). Redesigning the website will be a major exercise that will take up a significant proportion of the team's time for some months.

Develop IMI success stories

Success stories are an important element of IMI's communications with all key target groups. Gathering success stories and tailoring them to different audiences, messages and formats is an ongoing goal for the communications team and will be the one of the core tasks of the writer/editor to be hired in 2016.

Events

IMI already has a number of events planned for 2016, and more will be added to the list depending on other activities (e.g. timing and topics of Calls for proposals).

- Webinars on Call topics and rules and procedures (held at time of Call launches) – webinars are a key element in IMI's efforts to promote Calls for proposals and encourage groups to apply.
- BIO 2016 (June, San Francisco, US) – BIO is one of the most important trade shows and exhibitions for the biotech sector, and is well attended by groups from Europe. IMI will have a spot and some sessions at the European Commission's stand. A proposal for a conference session has also been submitted.

- Stakeholder Forum – holding a Stakeholder Forum is a requirement of the legislation behind IMI. This event draws a wide audience and is an opportunity for IMI to present and discuss its activities, successes and plans with stakeholders.
- IMI Scientific Symposium – a scientific meeting dedicated to showcasing the scientific achievements of IMI projects is foreseen. It may be held in conjunction with other IMI events such as the Stakeholder Forum.
- European Parliament events – Events to raise IMI's visibility at the European Parliament are an important part of IMI's efforts to reach out to policymakers.
- Local events – Events held in the Member States are a good opportunity to reach out to both potential applicants and policymakers and local press.

Additional events may be added, depending on IMI's evolving priorities and the timing of Calls for proposals.

2.4.2 Procurement and contracts

In order to reach its objectives and adequately support its operations and infrastructures, IMI will allocate funds to procure the necessary services and supplies. To make tender and contract management as effective and cost-efficient as possible, IMI makes use as much as possible of multi-annual framework contracts and inter-institutional tenders. Most essential framework contracts IMI is using will be running beyond 2016.

Three of the larger framework contracts of IMI expired in 2015. Consequently, the framework contract for ex-post audits will be replaced by a framework contract of the European Commission. The IMI will finalize the joint JUs awarding procedure for FWC interim service launched in 2015 as an open procedure. The estimated amount of the Framework Contract (FWC) for 4 year duration for the 6 JUs is EUR 200 000. The framework contract for the provision of meeting and event services expired by the end of 2015, a new tender procedure will then be launched.

Additionally, IMI will launch low-value procedures to procure the necessary services for implementing its communication activities. Regarding the event organisation support, IMI intends to join the upcoming framework contract of the Commission when available, it will otherwise launch a tender procedure.

IMI will earmark a total budgetary envelope of EUR 1 120 000 for procurement needs in 2016.The table below provides a summary of the tenders planned for 2016 and related procurement procedure expected to be used, the estimated budget and expected timing for publication.

Subject	Expected procedure	Max estimated amount (EUR)	Indicative timing of publication
Meeting and event facilities	Multiannual Framework Contract (FWC)	800 000	Q1
Professional printing services	Multiannual Framework Contract (FWC)	130 000	Q1
Promotional materials	Multiannual Framework Contract (FWC)	60 000	Q1/2
Event organisation support	Multiannual Framework Contract (FWC)	130 000	Q1/2
Total		1 120 000	

2.4.3 IT and logistics

IMI information and communications technologies (ICT) strategic objective is to deliver value to the business and to be a key enabler of new business initiatives with the goal of supporting and shaping the present and future of IMI. Operations and administration information systems and infrastructure aim at making all IMI processes simpler and more efficient. A strong element in achieving this goal will be the rollout of the use of the full suite of Horizon 2020 IT tools for the management of IMI2, from the launch of calls for proposals to the follow-up of the grants.

In order to achieve the afore-mentioned goal IMI IT will focus its 2016 activities on three sections:

i. business operations information systems,

ii. collaboration, communication and administration management information systems and

iii. infrastructure, security and office automation support.

2.4.3.1 Business operations information systems

In order to support IMI core business two applications have been until now available to end-users and IMI staff and stakeholders; the Submission of Information Application (SOFIA) tool for the management of IMI calls, projects and related processes, and Qlikview, which is a reporting tool with a variety of tailor-made dashboards, enabling the analysis of scientific and financial data regarding IMI calls and project.

In 2016, IMI will start using European Commission's IT tools related to Horizon 2020, such as SEP, COMPASS and SyGMA. The current plan is to use SEP for **IMI2** calls from March 2016 and SyGMA/COMPASS for **IMI2** projects from June 2016. However, in order IMI to be fully operational regarding IMI2 projects two developments are necessary:

1. Migration of data of IMI2 projects from SOFIA to SyGMA, which is expected to take place in Q3 2016
2. Extraction of IMI2 data from CORDA and import to Qlikview, which is also expected to take place Q3 2016
3. On the other hand, since IMI1 projects will continue running until 2020 the following developments are foreseen for SOFIA application:
4. Enhancement of the application regarding performance, usability and user interface in order to improve the end-user experience (Q1 – Q4 2016)
5. Maintenance (continuous) of the application with helpdesk support, bug fixes and implementation of service requests (Q1 – Q4 2016)

Last but not least, the following developments are foreseen for Qlikview, the IT tool for statistics generation.

6. Addition of reports based on the needs of external, for example SRG, and internal stakeholders, improvement of currently available dashboards and training of staff (Q1 – Q3 2016)

2.4.3.2 Collaboration, communication and administration management information systems

IMI has well established collaborative platforms to provide support to the Governance Bodies, namely the Governing Board, the Scientific Committee, the States Representatives Group and the newly formed Strategic Governance Groups. These platforms will be maintained and updated both from a content and operations point of view.

Furthermore, a number of web-based applications, related to human resources management, time management, mission management, document management, incident management and internal communications are available to IMI staff.

The following developments are foreseen in 2016 in order to safeguard the continuous improvement and increase of scope of the afore-mentioned systems:

1. Enhancement of the applications regarding performance, usability and user interface in order to improve the end-user experience (Q1 – Q4 2016)

2. Maintenance (continuous) of the applications with helpdesk support, bug fixes and implementation of service requests (Q1 – Q4 2016)
3. Migration of the back-end system due to end of product life of current version (Q1 – Q2 2016)
4. Reengineering of IMI's website in order to use up-to-date technologies, which are expected to improve the interaction with the site, potentially reduce the need for custom-made software components and increase security. This project is expected to take place with the close collaboration of IMI's Communication team (Q4 2016)
5. Assessment of the practicality of current document repository application to support the automation of IMI's administrative processes compared to commercial off-the-shelf products with applied workflows. This initiative is driven by the concept of paperless office towards IMI would like to move in 2017 (Q4 2016)

2.4.3.3 Infrastructure, security and office automation support

IMI shares IT infrastructure, related IT operations and office automation support with other JUs that are also located in the same premises. In the context of the common infrastructure the following activities are foreseen for 2016, which are expected to provide with efficiency gains in the operation of the organisation:

a. Transfer of the fixed telephony infrastructure to the new provider under the corresponding EC framework contract (Q2 2016)

b. Transfer of the TESTA network infrastructure to the new provider under the corresponding EC framework contract (Q1 – Q2 2016)

c. Implementation of a backup-as-a-service (BaaS) solution, i.e. online backup system, in order to improve the backup strategy of the JUs and the recovery point objective serving the requirements of the business continuity planning (Q1 – Q2 2016)

d. Definition of the strategy and architecture related to common IT infrastructure to be implemented in 2017 due to end of life of currently used hardware (Q2 – Q3 2016)

e. Alignment of office automation software licenses that JUs had initially purchased with the current situation based on headcounts and repartition keys (Q2 – Q3 2016)

f. Maintenance (continuous) of the common infrastructure and networks and end-user office-automation support covering incidents, service requests and improvements (Q1 – Q4 2016)

Moreover, IMI utilises an online infrastructure in order to host its business operations information systems, and the collaboration, communication and administration information systems mentioned above. The following activities are anticipated to take place in 2016 in the context of the dedicated infrastructure.

g. Cyber-capability assessment addressing existing protocols, personnel, tools, governance, controls, security architecture and delivery systems in order to improve the **level of confidence** for accessing the applications, and **level of security** for electronic data protection. (Q1 – Q2 2016)

h. Maintenance (continuous) of the online infrastructure (Q1 – Q4 2016)

2.4.4 Human Ressources

Together with well-defined workflows and processes, human resources management is at the heart of IMI's Programme Office organisational efficiency, namely through:

- adequate recruitments and staff performance assessment;
- balanced workload allocation and clear teams coordination;
- learning and development opportunities;
- clear organisational culture and open communication;
- inter - JU cooperation.

In 2016, the work plan will be implemented around four main themes:

Staffing

The staffing needs of IMI Programme Office will be carefully assessed, under the direction of the Governing Board, along the growth projection as set out in IMI2 JU Legislative Financial Statement.
Human Resources team will implement the selection and recruitment actions accordingly.

A traineeship scheme will be implemented in 2016.

Organisation development

Changes of staff population, including at management level, associated with the development of IMI2 JU and related Horizon 2020 objectives and obligations will take place adapting the organisational structure to further enhance effectiveness and flexibility, in a spirit of continuous improvement.
Human Resources will be fully associated to these activities, particularly by advising management on means to enhance operational efficiency and effectiveness, through the following:

- identify activities required to achieve organisational objectives;
- assignment of duties and responsibilities to best achieve fulfilment of objectives and tasks;
- establishment of clear and efficient reporting lines and set up necessary delegations of authority;
- enhancement of co-ordination between the different activity cluster areas.

These will be looked at with particular attention in 2016, under the leadership of the new Executive Director.

HR management

As part of HR core functions, the team will deal with issues related to people such as performance management and assessment, safety, compensation and benefits, employee motivation, communication, administration, training and rights and entitlements. The IMI programme office plans also to implement a promotion/reclassification scheme for the staff.

Apart from the day-to-day management of administrative workflows and process the HR function will deal and follow up in particular with:

- Full implementation of the new EU Staff Regulation through the adaptation of the EC implementing rules to the specificities and size of IMI2 JU and their adoption by the Governing Board;
- The performance management of the work environment to enable staff members to perform to the best of their abilities including a rational learning and development policy for better efficiency and staff retention.

Inter-JU cooperation

The efficiency and cost effective management of IMI2 JU is also based on a close collaboration with other Joint Undertakings through flexible arrangements and experienced mechanisms of combining expertise for specific tasks. In 2016, IMI will be willing to go further through pooling of human resources, sharing of IT tools and common IT infrastructure and common approach on implementing rules of the Staff Regulation.

2.4.5 Administrative budget and finance

*Draft Budget Plan 2016**

The forecast put forward in the draft annual budget plan for 2016 has been re-evaluated based on the available information.

The budget of administrative expenditure has increased by 6.74% in 2016 compared to 2015, mainly due to increase in staff expenditures and given the growing number of projects and audits. A comparison table of the financial years 2015 and 2016 is set out hereinafter.

	Heading Title 1	Financial year 2015	Financial year 2016	Evolution	Comments
Chapter		Budget EUR	Budget EUR	%	
11	Staff in active employment	4,392,760	4,893,000	11.39	3 new positions of Temporary Agents in 2016 3.5% promotion and indexation
12	Staff recruitments - miscellaneous expenditure	20,000	20,000	-	
13	Missions and duty travels	190,000	190,000	-	
14	Sociomedical structure	230,000	230,000	-	
17	Representation	20,000	20,000	-	
	Title 1 - Total	**4,852,760**	**5,353,000**	**10.31**	

	Heading Title 2	Financial year 2015	Financial year 2016	Evolution	Comments
Chapter		Budget EUR	Budget EUR	%	
20	Office building and associated costs	870,000	660,000	-24.14	Reduce of works to fit out floors 6&7 carried out in 2015.
21	Information technology purchases	561,000	560,000	-0.18	
22	Office equipment (movable property and associated costs)	153,000	153,000	0.00	
23	Current administrative expenditure	123,000	123,000	0.00	
24	Telecommunication and postal expenses	67,000	68,000	1.49	
25	Expenditure on formal meetings	158,000	158,000	0.00	
26	Running costs in connection with operational activities	291,640	300,000	2.87	Increase of number of workshops, meetings and events due to increase of number of projects.

	Heading Title 2	Financial year 2015	Financial year 2016	Evolution	Comments
27	External communication, information and publicity	625,000	625,000	0.00	
28	Service contracts	580,000	780,000	34.48	Increase due to additional risk-based audits.
29	Expert contracts and cost of evaluations	600,000	700,000	16.67	Increase of evaluations and experts due to increase of number of projects and new activities such as Socio Economic Impact.
	Title 2 - Total	**4,028,640**	**4,127,000**	**2.44**	
	Total Running Costs	**8,881,400**	**9,480,000**	**6.74**	

* It is without prejudice to the outcome of the procedure with the Budgetary Authority

The operational budget is covered under section 2.2.2.

A table overview of the 2016 draft budget is set out in Chapter 3 to this Annual Work Plan together with the staff establishment plan.

Financial Management

During 2016, the finance team will continue with its day to day activities of initiation, verification and payments of invoices and cost claims, creation of commitments, recovery orders, and analysis of periodic reports and negotiations of financial and administrative parts of projects. These activities will be conducted in a timely manner that will be monitored through corporate KPIs, in particular payment times and budget execution.

Best practice and highest quality standards will be ensured through the availability of a Manual of Financial Procedures that is under regular revision. In addition, knowledge dissemination will be further developed through the development of further guidance and the tenure of several financial workshops, in particular targeting beneficiaries, with the aim to reduce errors in financial reporting.

Preparatory work will start for implementing changes to the IMI financial rules, and the recourse to external audit firms to check and validate IMI accounts and review transactions.

2.4.6 Data protection

Objectives	**To promote a culture of data protection at IMI2 JU** **To support projects in establishing common minimum requirements for protecting and sharing personal data**
Planned Activities	To promote a culture of data protection at IMI2 JU: ▪ training and advising ▪ continue to implement the internal procedure for handling notifications and, where applicable, prior checking notifications to the European Data Protection Supervisor (EDPS) ▪ participate on the EU network for Data Protection Officers and implement best practices ▪ follow-up progress and analyse potential impact of the new EU framework for data protection To support projects in establishing common minimum requirements for protecting and sharing data: ▪ advising ▪ follow-up on recommendations addressed to IMI by the European Data Protection Supervisor
Expected results	**To ensure that personal data is protected and that Regulation (EC) 45/2001 is complied with.** Actions: 1. train newcomers 2. inform IMI staff on data protection matters during internal meetings 3. provide advise upon request 4. support the preparation of internal notifications 5. prepare prior-checking notifications and/or their updates 6. attend EDPS and Data Protection Officers meetings

2.5 Governance

Key objectives

- Further develop an IMI strategic orientation and related objectives.
- Ensure that activities are in line with and support IMI strategic orientation.
- Further improve the efficiency and effectiveness of the IMI's governance activities.
- Promote and maintain a positive reputation among stakeholders and partners as a key facilitator of healthcare research.

Planned Activities

- Support to the Governing Board, Scientific Committee, States Representatives Group and management.
- Align planning activities (strategy, annual work plans and related budget) and the following monitoring and reporting activities.
- Improve responsibilities and accountability.
- Enhance communication and transparency.

IMI will continue to provide support to the Governing Board, the Scientific Committee, the States Representatives Group, and the Stakeholders' Forum and their working groups.

The **Governing Board** gathers representatives of IMI2 JU members. It has the responsibility for overseeing the operations of the IMI2 JU and the implementation of its activities. It will meet at least twice.

The **Scientific Committee** is an advisory body to the Governing Board. It will meet at least twice. The Scientific Committee will be consulted on the Annual Work Plans, will advise on Call texts and will participate to interim reviews. Based on IMI2 legal framework, the Chair of the Scientific Committee may participate to the meetings of the Governing Board on issues of specific interest to the Committee.

The **States Representatives Group** will be consulted on the Annual Work Plans and will receive the evaluation outputs. At least two meetings of the States Representatives Group are foreseen for 2016. The Chair will participate in Governing Board meetings.

Expected results

- Streamlined governance activities

Actions:

- Preparation of plans, reports, briefings, decisions.
- Organisation of consultations and assessment of the input.
- Organisation of meetings and presentations.
- Implementation of decisions and recommendations.
- Coordinate information across governance structures.

2.6 Internal Control framework

The objective of the IMI2 internal control system in place is to ensure the adequate management of the risks relating to the legality and regularity of the underlying transactions. Internal Control framework is designed to ensure that operational activities are implemented in an effective and efficient way; that legal and regulatory requirements are met, that financial and other management reporting is reliable, and that assets and information are safeguarded. This is achieved via a combination of systems, procedures, and supervision, notably including the monitoring of financial performance and transaction checks. The implementation of recommendations from audits by the European Court of Auditors and the Commission's Internal Audit Service, and ex ante and ex post controls, also play a key role in this area.

The priority objective is to implement and maintain an effective internal control system so that reasonable assurance can be drawn that (1) resources assigned to the activities are used according to the principles of sound financial management (2) risk of errors in operations is minimised and (3) the control procedures put in place give the necessary assurance concerning the legality and regularity of the underlying transactions.

A particular challenge for the year will be to assess the Internal Control Standards (ICSs) capability to reflect the evolving needs of the JU and better meet the expectations of its members and stakeholders in terms of efficiency, effectiveness and flexibility. In this view a revision of the standards may also be considered and planned on a multiannual basis, in order to orient the IMI2 JU toward a quality management system.

The following ICSs have been prioritised by management for the year 2016:

- **ICS 3 and ICS 7 (Staff allocation and Organisational structure)**

  Programme developments and changes of senior management have a significant impact on the way IMI should be organised in order to continue to meet evolving organisational and stakeholder needs and expectations. It is therefore proposed to maintain the priority of the standards related with staff allocation and recruitment (ICS 3) as well as on the effectiveness of the operational structure (ICS 7).

- **ICS 8 (Processes and procedures)**

  IMI's internal operating procedures are also being duly revised and updated to reflect the new environment and requirements of H2020. In 2016 this will also require close monitoring and management supervision in order to ensure that the changes adhere to the new applicable legal and procedural provisions and requirements and that the appropriate measures are being taken to continue to safeguard the interests of IMI.

- **ICS 13 (Accounting and financial reporting)**

  The transition towards a new modalities of accounting services performed by DG Budget associated with relevant changes at management level with a new Budget Officer and a new Audit Manager suggest to focus on the procedure ensuring the reliability and completeness of the accounting information as well as the production of accounts which give a true and fair image of IMI JU's financial performance and position (assets and of budgetary implementation).

The focus points will be:

- Establishing and monitoring the annual action plan for the implementation of the JU internal control system taking into account the standard prioritised above and the recommendations resulting from internal and external audits, other reviews and evaluations;
- Maintaining an integrated and systematic risk management process including the performance of an annual full risk assessment exercise and keeping up to date a JU Risk Registers with the critical and significant risks;
- Reporting on IMI2 JU's compliance with the ICSs and on the overall effectiveness of the internal control framework. The results of this exercise will also contribute to the annual reporting and declaration of reasonable assurance of the Executive Director.

2.6.1 Financial procedures

Financial Rules are the point of reference for the principles and procedures governing the establishment and implementation of the IMI2 JU budget and the control of its finances. Alignment of internal procedures involves also a continous process.

The objective for 2016 will be the revision of internal procedures in order to increase simplification (cutting red tape, speeding up procedures, in particular the time-to-grant, and shifting the focus from paperwork to performance) and ensuring enhanced sound financial management. In this view the Programme Office will revise the Manual of Procedures for financial operations to incorporate new organisational needs and H2020 programme implementation requirements.

2.6.2 Ex-ante and ex-post controls

IMI ex-ante and ex-post controls aim to ensure that the actions financed from the budget are effectively carried out and implemented correctly.

The overall objective of the *ex-ante* controls is to ascertain that the expenditure is in order and complies with the provisions applicable and that the principle of sound financial management has been applied.

In this view the *ex-ante* controls embedded within IMI2 JU management and financial processes aim at verifying the coherence among supporting documents requested and any other information available. Each operation shall be subject at least to an *ex ante* control based on a desk review of documents and take into consideration the available results of controls already carried out, as well as risks identified relating to the operational and financial aspects of the operation.

Furthermore, a particular challenge for 2016 will be to streamline *ex ante* controls by accomplishing implementation of the Action Plan of IAS Audit on Grant Management; and to integrate/ accommodate with the legal and procedural changes of H2020 programme.

In parallel, the IMI2 Programme Office will carry on with the implementation of its Ex-post Audit Strategy for FP7 to verify that operations are correctly implemented by launching new audits including risk based audits where necessary. The relation between ex-ante and ex-post controls will be reinforced by developing further the tools and criteria for applying risk based controls.

The priority action is to ensure implementation of audit findings, the correction or recovery of funds unduly paid. Errors of a systematic nature will also continue to be extended to cover unaudited financial statements ('Forms C') of the same participants.

During 2016 the Strategy will be updated to reflect changes and developments. With the experience gained from the program to date, the revision aims at improving the cost-efficiency of the ex-post audit approach while applying sufficient coverage to maintain the residual error rate below 2%.

In addition, IMI2 will continue liaising with the Common Support Centre (CSC) for the implementation of H2020 Ex-post Audit Strategy and the development of working arrangements that are appropriate for IMI2's size and specificities. The first audits of H2020 grant agreements will be launched in the second half of 2016 in collaboration with the Common Audit Service of the European Commission.

The seven risk-based audits of in-kind contributions by EFPIA companies that were launched in late 2015 will be finalised in 2016. The program of risk-based reviews of EFPIA companies' methodologies and contributions will be continued with new audit launches. Audits on the in-kind contributions are followed-up by corrections to the reported amounts and reviews of revised certificates of methodology, where required.

2.6.3 Internal and External Audits

Audit enviroment is an assurance and accountability pillar within IMI2 internal control framework since it provides reasonable assurance about the state of effectiveness of risk management and control processes and serves as a building block for the annual Declaration of Assurance of the Executive Director.

The Audit Manager will coordinate audits carried out by IMI2's internal and external auditors and will follow up and asses the implementation of the Internal Audit Service of the European Commission (IAS) and the Court of Auditors (ECA) audit recommendations with the objective to confirm the effective implementation .

The IAS will continue performing internal audit function and implement the Strategic Internal Audit Plan 2015-2017. Internal audit engagement in 2016 will focus on Horizon 2020 Grant process (from the identification of the call topics to the signature of the grants agreement).

In parallel, during the year 2016, the Audit manager will coordinate and support audit visits of the Court of Auditors and contribute to the overall coorporate objective of receiving a positive statement of assurance. ECA will audit and issue opinions on the reliability of IMI2 JU's 2015 annual accounts as well as the legality and regularity of the underlying transactions.

The Audit Manager will continue to examine and evaluate risk management, control and governance processes of the IMI2 Joint Undertaking to provide the Executive Director with independent assessment and consulting aimed to add value and improve IMI2 JU's operations. Priority is given to management support and advice throughout dischange process.

2.6.4 Anti-Fraud strategy

Anti-fraud measures are an essential part of sound financial management required under the EU Financial Regulation, safeguards to financial interests of the Joint Undertaking's and contribute to its reputation. Throughout 2016 IMI will implement its anti-fraud Action Plan in line with the Common Anti-Fraud Strategy of the Research Family.

Within the existing internal control framework IMI's anti-fraud activities will focus on specific objectives and pro-active actions for fraud protection, early detection and immediate correction taking into account the specific needs and nature of the JU as a Public-Private Partnership.

IMI actions will cover the following four elements:

- Minimising the opportunities for internal and external fraud ensuring that effective counter-fraud measures are in place and provide an appropriate response when fraud occurs;
- Raising awareness about fraud risk across the JU as well as among partners and beneficiaries;
- Conducting fraud risk analysis and reviews especially in areas considered vulnerable to fraud;
- Train the staff disseminating relevant reports within the JU as appropriate and maintaining operational contacts with the European Anti-fraud Office (OLAF).

3 BUDGET YEAR 2016

STATEMENT OF REVENUE				
	Heading Revenue	**Financial year 2016**		**Comments**
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
10	European Commission contribution (including EFTA contribution)	207,926,585	201,740,000	Commitment appropriations include EUR 4,740,000 for running costs and EUR 203,186,585 for operational costs. Payment appropriations include running costs of EUR 4,740,000 and operational costs of EUR 197,000,000.
	Title 1 - Total	**207,926,585**	**201,740,000**	
20	EFPIA contribution	4,740,000	4,740,000	EFPIA contribution to IMI JU running costs.
	Title 2 - Total	**4,740,000**	**4,740,000**	
	Total EC and EFPIA contribution	**212,666,585**	**206,480,000**	

STATEMENT OF EXPENDITURE				
	Heading Title 1	**Financial year 2016**		**Comments**
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
11	Staff in active employment	4,893,000	4,893,000	Salaries
12	Staff recruitments - miscellaneous expenditure	20,000	20,000	Miscellaneous expenditure on staff recruitment: travel expenses, etc.
13	Missions and duty travels	190,000	190,000	Mission expenses
14	Sociomedical structure	230,000	230,000	Other staff costs: training, language classes, medical service, interim staff
17	Representation	20,000	20,000	Representation, receptions and internal meetings (EC/EFPIA)
	Title 1 - Total	**5,353,000**	**5,353,000**	

	Heading Title 2	Financial year 2016		Comments
Chapter		Commitment Appropriations (CA)	Payment Appropriations (PA)	
20	Office building and associated costs	660,000	660,000	Rent, works, common/IMI charges and parking. Additional costs: indexation, insurance, water/gas, electricity, heating, maintenance + repairs, security and surveillance.
21	Information technology purchases	560,000	560,000	IT purchases, software licences, software development, IMI website.
22	Office equipment (movable property and associated costs)	153,000	153,000	Purchases and rental of office equipment, maintenance and repair.
23	Current administrative expenditure	123,000	123,000	Office supply. Literature, subscriptions, translation services, bank charges and miscellaneous office expenditure.
24	Telecommunication and postal expenses	68,000	68,000	Data communication such as telephone, video conferences and postal services.
25	Expenditure on formal meetings	158,000	158,000	Official meetings such as SRG, Scientific committee, Governing Board and working groups created by GB.
26	Running costs in connection with operational activities	300,000	300,000	Expenditure in connection with research activities and objectives of IMI (workshops, meetings and events targeting IMI projects).
27	External communication, information and publicity	625,000	625,000	External communication and events such as Info Days, stakeholder forums.
28	Service contracts	780,000	780,000	Studies, audits.
29	Expert contracts and cost of evaluations	700,000	700,000	Costs linked to evaluations, expert contracts.
	Title 2 - Total	**4,127,000**	**4,127,000**	
	Total Running Costs	**9,480,000**	**9,480,000**	

	Heading Title 3	Financial year 2016		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
30	Implementing the research agenda of IMI JU	203,186,585	197,000,000	Grant agreements - Payments
	Title 3 - Total	**203,186,585**	**197,000,000**	
	Total EC and EFPIA contribution	**212,666,585**	**206,480,000**	

3.1 Staff Establishment Plan 2016

Grade	Amended Establishment Plan 2015			Year 2016											
				Posts evolution						Organisational evolution			Establishment Plan 2016		
				Promotion / Career advancement			Turn-over (departures/arrivals)			New posts (per grade)			Requested (Draft Budget)		
	PERM	TEMP	TOTAL	Officials	TA-LT	TA-ST	Officials	TA-LT	TA-ST	Perm	TA-LT	TA-ST	Perm	TA	Total
AD16															
AD15															
AD14		1	1											1	1
AD13															
AD12		2	2											2	2
AD11		4	4											4	4
AD10															
AD9		3	3											3	3
AD8		7	7											7	7
AD7		5	5											5	5
AD6															
AD5		7	7											10	10
Total AD		**29**	**29**											**32**	**32**
AST11															
AST10															
AST9															
AST8		1	1											1	1
AST7															
AST6															
AST5															
AST4															
AST3		5	5											5	5
AST2															
AST1															
Total AST		**6**	**6**											**6**	**6**
SC6															
SC5															
SC4															
SC3															
SC2															
SC1															
Total SC		**0**	**0**											**0**	**0**
Overall Total		**35**	**35**											**38**	**38**

Contract Agents		
Grade	2015	2016
CA FG IV	2	2
CA FG III	6	6
CA FG II	1	1
CA FG I	0	0
Total CA	**9**	**9**

LIST OF ACRONYMS

Acronym	Meaning
AAIC 2016	Alzheimer's Association International Conference
ABAC	Accrual Based Accounting System
ACE Program	Autism Centres of Excellence Program
AD	Alzheimer’s disease
AD (HR)	Administrator
ADC	Apparent diffusion coefficient
AER	Average error rate
AMR	Antimicrobial Resistance
API	Application Programming Interface
ASD	Autism spectrum disorder
AST	Assistant
AWP2016	Annual Work Plan 2016
BIT	Booking of IT material application
CA (Budget)	Commitment Appropriation
CA (HR)	Contractual Agent
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
CRC	Australian Cooperative Research Centres
CRO	Contract research organisation
CSC	Common Support Centre
DG AGRI	Directorate-General Agriculture and Rural Development (European Commission)
DG HR	Directorate-General Human Resources and Security (European Commission)
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission).
DG RTD	Directorate-General for Research and Innovation (European Commission)
DG SANTE	Directorate-General for Health and Food Safety (European Commission)
DILI	Drug-induced liver injury
DIVI	Drug-induced vascular injury
DORA	Document Registry Application
DPO	Data protection officer
DPUK	Dementia Platform UK
E&T	Education & Training
EBiSC	European induced pluripotent stem cell
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
EUPCTN	Sustainable pan-EU paediatric CT network
ESFRI	European Strategy Forum on Research Infrastructures
eTOXdb	eTOX rich preclinical database
eTOXsys	eTOX *in silico* toxicology prediction system
EU	European Union
FDA	Food and Drug Administration
FG	Function Group
FLT	Fluorothymidine
FTE	Full-Time Equivalent
FWC	Framework Contract
fNIH	Foundation for the National Institute of Health
FP	Full Proposal
FP7	Seventh Framework Programme
FWC	Framework Contract
GA	Grant Agreement

GAP	Global Alzheimer's Platform
GB	Governing Board
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
HCT	Human challenge trials
Helmsley Charitable Trust	Leona M. and Harry B. Helmsley Charitable Trust
HR	Human resources
HTA	Health Technology Assessment
IAC	Internal Audit Capability
IAPO	International Alliance of Patients' Organisations
IAS	Internal Audit Service of the European Commission
IBS	Irritable bowel disease
ICC	Internal Control Coordinator
ICH S 1	International Conference on Harmonisation's Safety (S) 1
ICS	Internal Control Standards
ICT	Information Communications Technology
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
KM	Knowledge Management
KPI	Key performance indicator
LEAP	Longitudinal European Autism Project
MAPPs	Medicines adaptive pathways to patients
MEP	Member of the European Parliament
MRI	Magnetic resonance imaging
MS	Multiple sclerosis
MTA	Material transfer agreement
NAFLD	Non-alcoholic fatty liver disease
NASH	Non-alcoholic Steatohepatitis
ND4BB	New Drugs for Bad Bugs
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
PA	Payment Appropriation
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
SC	Scientific Committee
SEND	CDISC SEND Controlled Terminology
SGGs	Strategic Governing Groups
SMEs	Small and medium-sized enterprises
SLC	Solute carriers
SOFIA	Submission of Information Application
SOP	Standard operating procedure
SP	Short Proposal
SRA	Strategic Research Agenda
SRG	States Representatives Group

SWOT	Strengths-Weaknesses-Opportunities and Threats analysis
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TA	Temporary Agent
TB	Tuberculosis
TSD	Total sleep deprivation
TTG	Time to Grant
TTP	Time to Pay
UPSA	Ultrasound-based plaque structure analysis
US	United States
VC	Venture capital
WHO	World Health Organisation
WP(s)	Work Package(s)

Tel +32 (0)2 221 81 81 • Fax +32 (0)2 221 81 74 | infodesk@imi.europa.eu • www.imi.europa.eu • twitter: @IMI_JU
Postal address: IMI JU • TO56 • 1049 Brussels • Belgium | Visiting address: Ave de la Toison d'Or 56-60 • 1060 Brussels • Belgium