Annual Work Plan and Budget for 2017

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 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-2016-32 approved on 23.12.2016

Last update: 07.12.2016

IMI reference: IMI2/INT/2016-03375

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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.

In 2017, we will continue to engage with Associated Partners from other industry sectors (e.g. ICT, imaging, medical technology, etc.) and philanthropic organisations and other public funders to invite these players to invest with us on specific projects. We will engage more with small and medium-sized enterprises (SMEs) that are key to the future of a dynamic and thriving health innovation system in Europe. We will also 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 (SRA), we will further develop our existing programme portfolio in areas such as diabetes, infection control, immunology and neurodegeneration, and explore 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 year 2017 will also mark the completion of the interim evaluation of IMI2 JU. In this context, particular attention will be given to monitoring the impact and added value of IMI’s completed and ongoing projects.

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.

Pierre Meulien

Executive Director

2 Annual Work Plan Year 2017

2.1 Executive Summary

The main goals of f IMI2 JU in 2017 can be set out as follows:

- Launching two new Calls for proposals based on scientific priorities set out in section 2.2.2
- Successfully manage a growing portfolio of projects, under both the Seventh Framework Programme for Research (FP7) and Horizon 2020 (H2020).
- Expand the basis of external collaborations and partnerships to best meet the challenges of the biopharmaceutical environment and optimise 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 IMI1 projects will also contribute to meeting this objective.
- Contribute to the interim evaluation of IMI2 JU due to be completed by 30 June 2017, with conclusions and observations reported by the Commission to the European Parliament and to the Council by 31 December 2017.
- Improve and upgrade various aspects of our operating systems, including implementation of the Call management process under Horizon 2020, effective transition to the 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 that receive of IMI funding and companies' in kind contributions.

2.2 Operations

2.2.1 Objectives & indicators - risks & mitigations

The key objectives for IMI2 JU operations in 2017 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, including 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 (KPIs)

IMI2 JU assesses its performance of the basis of the KPI framework adopted by the GB on 13 January 2016. In 2017 KPIs will be further reviewed to ensure better alignment with IMI2 JU objectives and H2020 cross cutting and common to all JUs KPIs.

Key Strategic Focus	Annual Objectives 2017	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2017 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
Portfolio	IMI2 JU'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 2017 that are addressed by IMI's calls for proposals launched in 2017	Extent of coverage of priority areas for 2017 as defined in Section 2.2.2	**KPI 1:** ≥4 priority areas from IMI2 JU's Annual Scientific Priorities for 2017
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 IMI2 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	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 IMI2 JU funding by the end of the year under review.	**KPI 3:** ≥20 publications **KPI 4:** ≥10% 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 2017	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2017 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
				KPI 5: Target to measure extent to which the citation impact of IMI publications[5] is higher than the EU average **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**)	The benchmarking analysis with other international funding bodies to be performed by external contractor, applying internationally recognised standards and criteria	**KPI 5:** ≥20% higher than EU average **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	**KPI 7:** ≥ 5 **KPI 8:** Baseline data will be collected in 2017 **KPI 9:** Baseline data will be collected in 2017

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

Key Strategic Focus	Annual Objectives 2017	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2017 Target
		73/2008 of 20.12.2007[1]	557/2014 of 6.05.2014[2]			
					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 2017.	
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 2017 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 2017 **KPI 12:** 25% of finalised projects **KPI 13: ≥ 1500**

[5] During 2017, 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 2017	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2017 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 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 2017	**KPI 16:** 100% **KPI 17:** Baseline data will be collected in Q1 2017
Impact on society	IMI2 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 2017.	**KPI 18:** Baseline data will be collected in 2017

Key Strategic Focus	Annual Objectives 2017	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2017 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 2017	**KPI 19:** ≥10 000 **KPI 20:** Baseline data will be collected in 2017 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 2017	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2017 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	▪ Article 1(l) in Statutes of IMI2 JU	Article 1(f) in Statutes of IMI2 JU	**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

Risks are a strategic element of planning activities as their identification enables management to customise their objectives and corresponding actions. This section gives an overview of the corporate risks identified by the Programme Office against the overall objectives of IMI2 JU as set out in Article 2 of Regulation No 554/2014 and the above key objectives for 2017.

These conclusions are based on the outcomes of the **annual risk assessment exercise** 2016-2017 performed by the Internal Control and Risk Manager for IMI2 JU management as a proactive process – adjuvant to the definition of the annual work plan. The goal of the annual risk assessment exercise is to identify and assess events that could pose a threat to the achievement of its objectives and determining how the corresponding risks should be managed.

This exercise has identified a number of possible operational and financial risks that can affect (i) the strategies employed by management to implement corporate policies or (ii) internal administrative processes, IT systems, resources and financial management. Risks are mapped through a risk register which provides information on their nature and the required mitigating actions.

At an operational level each functional area produces and manages an **operating risk register** (ORR) with the risks that they might face when implementing the Annual Work Plan.

At corporate level, management makes an assessment of the major cross-sectional risk factors identified at operational level and merges them with the strategic risks that may challenge the achievement of IMI2 JU objectives. These risks are included in the **strategic risk register** (SRR), directly managed at senior level and complemented by an appropriate risk mitigation plan.

Both registers are monitored by the Programme Office to effectively anticipate and mitigate the risks, ensuring that the work plan remains up to date and effective.

The overall assessment of the exercise 2016-2017 shows that some threats tend to persist within the JU. This is because certain risk factors are correlated with the specific objectives of IMI as public-private partnership established to support activities that carry a high level of uncertainty such as the development and implementation of pre-competitive research and innovation in the pharmaceutical sector, mobilising resources and bringing together dissimilar stakeholders such industry, academia, SMEs, patient organisations and regulators.

At the corporate level, in particular, some risks are typically associated with IMI2 JU's mission and strategic objectives and have therefore to be accepted as such and addressed in a way that allow the JU to reduce or partially transfer their impact where needed.

This is the case of the risks that a project fails to achieve all or part of the research objectives envisaged or lacks the capacity to exploit the results and assets generated.

Similarly, IMI2 JU has to cope with the risk that the programme ends with an imbalance between members' contributions and/or unsatisfactory leverage of private contributions.

Operational risks escalated at corporate level mainly consist of specific threats to the internal processes that may affect the IMI2 JU's effectiveness if not appropriately controlled. In this view, finalising the reorganisation of the Programme Office and providing the necessary human and technical resources will be decisive for reinforcing IMI2 JU's performance.

Among the 12 risks identified at corporate level at the end of the exercise 2016-2017, the following four can be considered as critical and are reported hereafter in line with the requirement of the IMI2 JU Internal Control Standard 6 on risk management:

1. Potential negative external perception of IMI2 JU added value and recurrent criticism might undermine the PPP model

In the context of the H2020 JUs mid-term review process and the path towards the next Framework Programme, IMI2 JU will be exposed to a higher degree of scrutiny from all stakeholders. A potential negative external perception of IMI's added value/impact could undermine the continuity of the PPP model after 2020.

2. Risk of imbalance between the contributions committed by Founding Members at the end of the program

IMI2 JU is a partnership based on the principle that pharmaceutical research is equally funded by EFPIA companies and the EU. This strategic objective might be undermined in case of imbalance between EU

funding and industry in-kind contribution and weak participation at the end of the program. A mitigation plan has been part forward with the aim at ensuring optimal industry commitment.

3. The planned leverage of private resources (beyond EFPIA) committed to IMI2 JU might be challenging to achieve.

The PPP model developed by H2020 as a tool for increasing research investment in the biopharmaceutical sector may be challenged in case of limited leverage of private resources committed by Associated Partners, and insufficient external collaboration and partnerships. However, as also indicated in the SWOT analysis agreed by the Governing Board this risk is also an opportunity for the JU and should be tackled by promoting IMI's project achievement and increasing its visibility at international level.

4. Risk of delays and ineffective management of the ex-ante control process and operational expenditure

There is an increasing risk of ineffective performance of the ex-ante controls of cost claims due to the increasing backlog in the treatment of periodic and final reports for IMI1 and IMI2 JU projects, the limited resources available in the IMI2 JU financial team.
These circumstances may generate a significant delay of payments with consequently insufficient budget execution and finally, potential business discontinuity of financial processes undermining the internal effectiveness and the reputation gained by the IMI2 JU.

In this context the Governing Board and the IMI2 JU Programme Office have taken a number of actions and measures to mitigate and manage any possible negative effect. These include the implementation of an ambitious communication strategy to demonstrate, in a spirit of openness and transparency, the added value of the partnership to EU citizens. At the same time, opportunities to enhance international cooperation, with targeted actions by area, are being addressed within the auspices of the Governing Board.

Concerning IMI performance, particular attention will be given to the organisational structure as well as staff allocation and financial management. This is considered crucial by management in order to ensure that the structure and resources of the JU continue to meet evolving organisational objectives and needs. Moreover, management will ensure that annual targets and objectives as well as key performance indicators are updated and coordinated with responsibilities and tasks also revised to reflect changing strategic priorities.

In turn, continuous measures are to be taken to strengthen both IMI2 JU operational procedures, increasing the resources available in some specific areas, improving the approach used for topic development, project monitoring and reporting as well as for IT management.

Finally, an external event such as Brexit should be included in the risk assessment given its potential impact on the strategy and programme implementation of IMI2 JU. UK stakeholders have largely contributed to the success of IMI success so far[7]. The consequences of Brexit are unpredictable at this point in time but will require monitoring and assessment within the EU's broader political agenda.

[7] As at 30/09/2016, in IMI2 JU 27.5% of participating EFPIA companies are based in UK (11 out of 40) as well as the 32.3% of beneficiaries (73 out of 226) while IMI2 funds allocated to those UK beneficiaries represent 40.3% of the total IMI contribution.

2.2.2 Scientific priorities for 2017

The IMI2 JU activities for 2017 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 and innovation activities of strategic importance to the EU's competitiveness and industrial leadership, and address specific H2020 societal challenges, in particular that to improve European citizens' health and well-being.

These activities will be developed within the general framework of the Scientific Research Agenda (SRA) for IMI2 (see http://www.imi.europa.eu/content/research-agenda). The SRA identifies a set of scientific priorities where IMI attempts to pilot new ideas in real life in a safe harbour environment that maximises collaboration and synergies among all stakeholders; drives innovation in business models to support the transition from blockbusters to personalised medicines by testing new approaches across multiple companies and projects simultaneously; and pilots new types of collaboration between companies with different innovation cycles to optimise the success in delivering IMI2 JU 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 2017 are fully aligned with the IMI2 SRA and will help with the achievement of IMI2 JU objectives. They include the development of clinical trial networks; the sharing of data to improve and facilitate more powerful data analysis, insight generation and the creation of better tools, biomarkers and standards that will result in accelerating 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, diagnostics and/or animal health industries among others. The actions that will result from the 2017 priorities will generate results that will have a high impact and facilitate the maximum number of stakeholders to join forces. The outcome and impact of these actions should bring great benefit to patients and society at large. There will also be engagement 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.

IMI has identified eight scientific priorities, broken down into several topics, for 2017, 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 actions, potentially including (or even driven by) Associated Partners. Further details regarding the expected multi-stakeholder actions are elaborated under the individual topics. Topics for 2017 have been prioritised based on criteria that include the highest impact on reducing attrition in drug development, speeding up patient access, improving health outcomes and enhancing the biomedical research ecosystem. Additional topics for 2017 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 2017 would then be updated accordingly.

To implement the 2017 priorities, IMI2 JU 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 5 April 2017 and 9 November 2017 [8].

Topics launched on the basis of this Annual Work Plan 2017 will seek synergies with other ongoing initiatives especially those funded under Horizon 2020 and at the national level, and those identified by the European Strategy Forum on Research Infrastructures (ESFRI), to ensure the consistency of approaches, to leverage other funding initiatives and to avoid duplication of effort and funding.

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

A. Diabetes/Metabolic disorders

The activities in this priority area should seek progress towards novel diagnostic and treatment paradigms for the mechanisms involved in and triggering the early onset and progression of (type 1 and type 2) diabetes/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 the sustainability of treatment interventions for health systems.

Activities in 2017 will address the following topics:

Diabetic cardiomyopathy:

1. Diabetic patients have a 2-4-fold increased risk of suffering from heart disease and their prognosis regarding cardiac failure is much worse compared to non-diabetic individuals. Death from cardiovascular disease (CV) is the leading cause of mortality for diabetic patients. Diabetes itself is an independent risk factor for CV disease, as the risk remains increased even after correcting for hypertension and ischemic heart disease. Meta-analyses of large clinical trials with diabetic patients have shown that despite strict glycaemic control there were no significant differences between intensified glucose lowering therapy and standard treatment considering non-fatal stroke and CV and all-cause mortality. As a consequence of this lacking correlation between tight glycaemic control and overall mortality, the regulatory guidelines today make for each novel antidiabetic drug candidate a CV outcome study mandatory to obtain approval.
   The aim of this topic is to unveil the underlying mechanisms of diabetic cardiomyopathy and its impact on CV mortality in diabetic patients.

A clinical reference baseline database in support of flexible clinical trial designs in the area of metabolic diseases:

2. Major problems to determine a clear and unequivocal assessment of the benefits and advantages of novel drug candidates to treat type 2 diabetes in clinical drug trials are caused among other factors by the heterogeneity of the type 2 diabetes population, the lack of understanding of the impact of the multidrug treatment of diabetic patients on clinical outcomes, the lack of understanding of the incidence of safety outcomes which are not treatment-related and potentially inherent to the disease. The aim of this topic is to create a pooled database of safety data collected from the placebo/standard of care arms of clinical drug trials performed in type 2 diabetes patients by industry and clinical institutions involving all relevant key study details such as: inclusion/exclusion criteria, standard of care, length of follow up, demographic data and patient medical history, safety data etc. The participating partners will provide full access to the respective databases to extract fully anonymized patient information to build a reference baseline database of individuals with diabetes and metabolic disorders to enable flexible and stratified clinical trial designs.

Involvement of the microbiome in the context of metabolic disorders: mechanistic understanding of the role of the microbiota-induced immunoregulation in the ethiopathogenesis of diabetes and metabolic disorders

3. The incidence of diabetes and obesity has reached epidemic dimensions. Increased food intake and sedentary lifestyles are two major contributing and driving factors behind the development and progression of these metabolic diseases. The underlying biochemical mechanisms with the involvement of a variety of genetic and environmental influences are only marginally understood. In the past years increasing evidence was found that the gut microbiota plays a major role in the development of obesity and diabetes. Gut microbiota can increase energy production from ingested food and contribute to low-grade inflammation and regulation of fatty acid tissue composition; changes in gut microbiota composition can impact key metabolic pathways like insulin secretion and incretin production. Therefore, the link between obesity and diabetes and the microbiome is well documented, but the underlying mechanisms, the individual contribution of the various factors, the diversity regarding ethnic and inter-individual differences are not known. This topic aims to elucidate the role of the microbiome in the development and progression of metabolic diseases. This could be a first step in a more and broader microbiome programme.

Expected impact of the topics:

- Options for improved treatment of diabetic patients to decrease their risk for CV morbidity and mortality, via a better understanding of diabetic cardiomyopathy and the identification of reliable markers for its diagnosis and risk.
- Enabling of stratified clinical trials with novel antidiabetic drug candidates to assess their CVD risk
- Potential impact on the criteria for approval of novel antidiabetic drugs (alternative to CV-outcome trials).
- Facilitating the design and interpretation of rationally designed stratified clinical trials via the better understanding and scientific base of the diabetes and metabolic disorders population.
- A faster evaluation of the benefit and benefit/risk relationship of novel treatment options.
- Identification of key contributing pathways involving the microbiome with the potential to find efficacious and causative therapeutic options to treat and/or prevent diabetes and metabolic disorders.
- Potential high impact on future guidelines to treat diabetic and obese individuals.
- Potential high impact on public health regarding population morbidity and mortality and public healthcare costs.

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 and symptomatic interventions, as well as relevant companion diagnostics, for neurodegenerative disorders in general and Alzheimer's disease (AD) in particular. The priority addresses the following themes: 1) increasing disease aetiology understanding for new drug target identification & validation; 2) development of translational model systems and identification/validation of biomarkers; 3) increasing the understanding of the blood/brain barrier in health and disease; 4) improving clinical trials including primary/secondary prevention; 5) better patient access.

Furthermore there is still a high unmet need in the areas of understanding, treating and managing pain. The pain priorities address the following themes: 1) increase disease aetiology understanding for new drug target identification & validation; 2) translational models and biomarkers; 3) clinical trial methodologies.

More specifically activities in 2017 will address the following topics:

Neurodegeneration - Alzheimer's disease:

1. Coordination and Support Action for collaboration and alignment of the many initiatives (including but not limited to IMI-AD platform) devised in the aftermath of the G8 Dementia Summit Declaration[9] focused on advancing the field of dementia research. Collaboration is essential to avoid unnecessary duplication, allow for data and insight sharing, and increase efficiency by making joint priority trade-offs.
2. Tau imaging. 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 clinical practice (e.g. for patient selection and outcome measures).
3. New genes as Alzheimer's disease modifiers. Identification of new genes as Alzheimer's disease modifiers: In order to identify novel, validated targets a platform should be developed that covers new biological and phenotypic approaches for improved disease understanding based on systems biology.
4. Immune system and Alzheimer's disease. Further explore the role of the innate immune system in neurodegeneration, complementing the TREM2/CD33 activities launched in 2016.
5. Early markers of progression in Alzheimer's disease. Identification of early markers of progression of AD to facilitate recruitment into - and read out of - clinical trials.

Neurodegeneration - Parkinson's disease:

6. Personalised treatment. Support the development of innovative personalised treatments for Parkinson's disease using a biomarker approach.
7. Mitochondrial deficiency. Explore mitochondrial deficiency as a potential key factor in the neurodegenerative process underlying Parkinson's disease.

Biomarkers in neurodegeneration:

8. Participate in- and build on- global biomarker development efforts, and validate translational biomarkers for decision making in clinical trials of disease-modifying agents in neurodegenerative diseases.

Blood-brain barrier:

9. Better understanding the blood-brain barrier in health and disease, and identification of innovative brain delivery systems.

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

Pain:

10. Identification and validation of novel pain targets / pathways with disease-modifying potential: analysis of tissue samples from pain patients using omics-scale technologies to increase disease understanding; development of new platforms to facilitate future drug screening.
11. Validation and standardisation of methods to measure neuronal activity in pain: In patients, employ e.g. electrophysiological measurements, fMRI, QST, and test biomarkers to achieve a better understanding of which (sub)-groups of patients preferentially respond to which drugs, and back-translation of the measures into preclinical models to improve translational trajectories for chronic pain.
12. Clinical endpoints in headache medicine: Exploration and validation of clinical endpoints in abortive and preventive migraine trials in adult and paediatric populations. Abortive migraine trial endpoints: pain freedom, associated migraine symptoms, migraine-associated disability, quality of life, real-world evidence for functional outcome or treatment preference. Preventive migraine trial endpoints for chronic and episodic migraine: reduction of headache days, reduction in migraine-associated disability, quality of life and real-world evidence of functional outcome and treatment preference. Planning work for a framework for clinical biomarkers of disease, disease progression, and treatment response.

Expected impact of the topics:

- The fostering of a global dementia research agenda that most efficiently uses the investments of all stakeholders.
- Assignment of new functional roles to rare genetic variants implicated in disease causation.
- Validation of tools and platforms for discovery of new biological insights into Parkinson's and Alzheimer's disease understanding, and beyond the central nervous system compartment
- Accelerating tau tracers development and better integration of novel imaging techniques into pharma development
- More efficient, cost-effective and successful use of Parkinson's and Alzheimer's disease model systems in support of the development of novel therapies
- Better understanding of the functioning of the blood-brain barrier in health and disease, and how it may be manipulated to aid therapy
- 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.
- Improved understanding of pain mechanisms and increasing feasibility for drug development paving the way to new disease-modifying treatment options.
- Reducing attrition rates with optimised methods to assess pain phenotypes and innovative clinical trial paradigms to drive reinvestment into new treatment options for chronic pain.
- Increase predictive validity and translational value of animal models of chronic pain.
- Better definition of clinical endpoints in acute migraine episodes and in chronic migraine.

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 Europe 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, ULTRADD, BioVacsafe), 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 2017 will address the following topics:

Inflammatory bowel disease:

1. Development of biologic therapies has greatly transformed the ability of physicians to treat inflammatory bowel disease (IBD), but current therapies, while effective at controlling established inflammation, tend to lose efficacy over time in many patients. It is currently unclear why patients lose response despite initially responding well to treatment. Therefore, this topic will specifically study the remission phase of disease to elucidate the mechanisms that cause loss of remission and to determine if there are systemic, endoscopic, and/or stool biomarker(s) that will predict IBD flares effectively. As such, this topic will address the unmet medical need for early indicators of IBD flares and for a mechanistic understanding of IBD flares and potentially guide towards the development of evidence based treatment sequences aimed at long term remission.

Fibrosis

2. Fibrotic diseases are diverse in nature but share common molecular and cellular drivers. At present, significant gaps exist in our understanding of this group of diseases, particularly relating to immune-fibrotic cross talk. Immune based approaches relating to treatment of fibrotic conditions have met with limited success. There is a lack of tools to assess disease progression, and limited acceptance of non-invasive markers to monitor disease progression. The topic will focus on common underlying mechanisms that offer the opportunity to explore cross disease approaches including but not limited to immune-fibrotic pathways and cross talk, biomarkers, patient stratification and in particular the identification of rapid progressors in addition to experimental medicine approaches across different disease settings.

Systemic lupus erythematosus

3. Systemic lupus erythematosus (SLE) is associated with multiple symptoms such as rash, arthritis and fatigue and affects multiple organ systems. The various symptoms and organ systems affected by SLE are often responsive to different therapies. Most disease activity measures in SLE are global measures, such as the SLE Disease Activity Index (SLEDAI) and British Isles Lupus Activity Group (BILAG), and are not sensitive indicators of changes in individual symptoms or disease manifestations. Drug approval in SLE has been slow, partly because most therapies under study have used global measures of disease activity or composite indices as primary study endpoints. The topic will focus on the implementation of activities that will enable the implementation of clinical trial endpoints and therefore better clinical trials ultimately improving the quality of therapies for patients.

Sjögren's syndrome

4. Sjögren's syndrome is one of the more prevalent autoimmune disorders that presents as primary Sjorgen's syndrome (pSS) or secondary (sSS) in association with other autoimmune disorders. Unlike many other autoimmune diseases, Sjögren's syndrome lacks universally accepted classification criteria. Primary Sjögren's syndrome affects exocrine glands leading to sicca symptoms of the eyes and the mouth. Systemic (fatigue) and extraglandular (e.g. arthritis or lung) manifestations also often develop. A negative impact on quality of life is substantial, mainly due to the disabling

fatigue. In addition, about 5% of pSS patients develop B cell lymphomas. Besides symptomatic treatments, no effective disease modifying treatment has been approved. Moreover, as there are no industry-sponsored studies that have been able to show a disease-modifying effect, and with the growing interest in conducting clinical trials in pSS, specific, sensitive and validated outcome measures have become a necessity to develop effective therapies. The major scope of this topic will be the development and optimisation of pSS-related outcome measures including clinical and laboratory data (biomarkers), patient reported outcomes (PROs) and imaging modalities.

Epigenetics

5. The scope of this topic will be 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 on mapping the epigenomes in disease tissue samples in immune mediated diseases and comparing these with both normal tissues and tissues from other disease. Advances in epigenetic mapping technologies will now allow these to be applied to ever smaller quantities of samples such that we can start to realise the ambition of being able to study disease samples available from well characterised patients enrolled on clinical studies provided as industry in-kind contribution. The topic will allow an increase in understanding of disease pathways and provide insights into the importance of epigenetic dysfunction in disease along with the identification of new targets (epigenetic and other), disease biomarkers and epigenetic correlates of disease status.

Microbiome research

6. The topic will focus on understanding the impact of the microbiome on immune disease development and how learnings can be applied across therapeutic areas. This could be a first step towards the creation of a broader microbiome research programme.

Disease deconstruction and target identification

7. The topic will aim to deconstruct the pathways leading to manifestation of immune diseases via genomic or disease biomarker analysis that will ultimately lead to the identification of a series of key targets within the disease area. The topic will focus on the implementation of activities that will ultimately lead to the precompetitive identification of new drug targets within key disease areas including, but not limited to, type 1 diabetes (T1D), fibrosis, osteoarthritis (OA), rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), respiratory diseases and Sjögren's disease. The topic will also develop ways to prosecute newly identified targets via the use of tool molecules, or drug repositioning with clinical trial cohorts.

Expected Impact of the topics

- 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.
- An understanding of the role of the microbiome in immune disease that can open to novel drug pathways and target discovery.

Type of actions:

Research and Innovation Actions

D. Infection control including vaccines

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 (2013 CDC report: http://www.cdc.gov/drugresistance/threat-report-2013/). 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.

Because of their low unit cost for individuals (albeit high societal cost) and improved clinical outcome, antibiotics were overused in the past century which resulted in the pandemic spread of highly resistant bacterial clones. Because of the increased bacterial resistance we need a paradigm shift in the way we deliver care and prescribe antibiotics. Personalized medicine based on novel and rapid diagnostic strategies should help achieving this paradigm shift by identifying those patients who really need antibiotics, and by helping to select the narrow-spectrum antibiotic of choice.

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. In addition, immune- and host-based biomarkers which can predict the response to vaccination are lacking. 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 2017 will address the following topics:

Antimicrobial resistance – antibiotics and diagnostics:

1. One of the most challenging aspects of antibacterial drug development is the execution of late stage clinical trials. Therefore, the ND4BB programme is successfully building a clinical trial network under the IMI project Combacte-NET, and running several large scale clinical trials with new treatments against some of the most difficult to treat multi-drug resistant pathogens. For more standard trials with new antibiotics, trial sites are still established de novo and disassembled after the completion of the trial, incurring time delays and expense in the start-up and shut down of activities. Activities in 2017 will therefore aim at further progressing the idea of an ongoing network that can test more than a single, novel antibacterial agent in a “semi-contemporaneous time frame”. The key paradigm change will be a change in the way we run clinical trials. This is especially true for non-inferiority trials with clinically approved comparator drugs. The goal is to establish an ongoing network that can conduct trials with multiple drugs (comparators and novel agents). It is estimated that this could save up to 40% of the expense of these trials.
2. As narrow spectrum anti-infective agents continue to progress into clinical use this must be accompanied by the development and use of rapid, point of care diagnostics. The goal is to facilitate the development and accessibility of novel diagnostics which will enable a more rational, reduced and targeted approach to antimicrobial use. In addition, the aim will also be to develop new innovative evaluation techniques to demonstrate the value of diagnostics for impacting antimicrobial resistance and to develop new economic models to incentivize the discovery, development and use of new diagnostics for use now and in the future.

Innovation in vaccines:

3. Innovative solutions to understand and measure the maturation of the immune system and to tackle emerging/unmet medical needs are needed. 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.
4. Stronger knowledge of the epidemiology of infectious diseases and a deeper understanding of the outcomes of infectious diseases in the elderly (morbidity, mortality, etc.) are needed. The goal is to improve understanding of the epidemiology of infectious diseases in the elderly, the mechanisms

behind the immune responsiveness and the contribution of extrinsic factors (such as nutrition, physical exercise, co-morbidities and pharmaceutical treatments, etc.).

5. Coordination and Support Action. The IPROVE (Innovation Partnership for a Roadmap on Vaccines in Europe) roadmap (http://www.euvaccine.eu/news-events/news/iprove-roadmap-launched-16-march) on vaccines in Europe has been developed through a collaborative effort of the leading vaccine experts in Europe. A coordination and support action (CSA) is planned to address the key challenges and gaps identified in relation to e.g. vaccines R&D, awareness, education and training, and regulatory pathways.

Emerging infectious diseases:

6. In light of the recent outbreaks of e.g. Ebola and Zika virus infections it is clear that there is a need for improved preparedness and faster response to emerging infections. The aim is to support the development of new platforms that facilitate rapid deliveries novel and improved diagnostics, vaccines and treatments for these infections.

Expected impact of the topics:

- A pipeline of promising new agents for tackling antibiotic-resistant bacterial infections.
- Improved antibiotic stewardship, decreased risk of antimicrobial resistance, and better preservation of the microbiome.
- An ongoing clinical trial network that has the prospect of faster trials with reduced expenses and better comparative data
- Novel and rapid diagnostics and new business models for improved access and use
- 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.
- Improved preparedness and faster response to emerging infectious diseases
- Major impact on the improvement of public health.

Type of actions:

Research and Innovation Actions and Coordination and Support Action

E. Translational safety

Translational safety is a key priority for the IMI2 JU programme. Translational safety activities aim at improving the safety assessment of pharmaceuticals through innovative and more predictive preclinical and clinical evaluations. The goal is to optimise the translatability to the 'real life' situation of the safety assessment paradigms and ultimately to improve the safety profile of drugs delivered to patients. In order to create synergies and avoid redundancies, activities in the translational safety area will connect with any other IMI projects relating to safety (including data management), and other relevant European and global initiatives (e.g. US Critical Path Institute, The Health and Environmental Sciences Institute/International Life Sciences Institute (HESI/ILSI), Innovative Questions (IQ) and National Institutes of Health (NIH)-driven projects).

Topics brought forward in 2017 will aim at tackling safety-related attrition during drug development by better bridging preclinical and clinical areas, and as a result, should bring safer medicines to the market. Therefore, the topics planned focus on two extremes of the R&D process: on one side, on the improvement of the toolbox used during early phases of preclinical evaluation; and the other side, on clinical evaluation at late stages. The final idea is still to connect both preclinical and clinical areas through translational, integrative approaches.

Reduce safety-related attrition during drug development

1. Reducing neurotoxicity. Adverse effects of drugs on the central and peripheral nervous system are not uncommon during clinical development and post-marketing surveillance, in the context of either recommended use or misuse/abuse. However, neurotoxicity is poorly predicted by preclinical studies during R&D process, leading to a substantial attrition rate, including post-marketing surveillance (figures for attrition, though variable according to sources, are typically in the range of 5-25%). It is envisaged to bring forward a topic focused on delivering improved preclinical tools and strategies, at every step of the R&D process, using an integrated approach that would combine in silico, in vitro and in vivo models. Efforts in this area have typically concentrated on new chemical entities. Recent information however suggests that biologics (especially monoclonal antibodies) should be included in approaches undertaken.
2. Translational microphysiological systems. Over 30% of candidate drugs are stopped in clinical trials due to toxicity. Frequently these toxicities were either undetected in preclinical models or the models underestimated clinical toxicity margins that ultimately prevented clinical progression. Therefore, there is the urgent need to identify and characterize alternative models with better predictive capacity. Microphysiological systems (MPS) using cells derived from different species capable of predicting drug-induced toxicities earlier in drug discovery process would be of tremendous benefit. However, although many MPS have been developed the performance of these systems, their appropriate context of use, and their translational potential have not been established particularly in organs such as kidney and the intestine. The aim of the topic launched under this priority will be to understand better the translational potential of novel MPS systems for both organs types with the aim of deriving predictive quantitative toxicological information from these models not possible in traditional cell culture models.
3. Biomarkers for toxicities. The early and reliable prediction, detection, monitoring and assessment of adverse events are key to improving patient safety and reducing late-stage attrition in drug development. A major challenge to detecting and managing these toxicities is the lack of sufficiently sensitive and specific biomarkers. The aim of the topic will be to deliver biomarkers that fulfil these criteria. To accelerate the process important starting points will include biomarkers that already have data associated with the aim e.g., biomarkers that have received regulatory Letters of Support, but not yet full qualification from EMA and FDA. The scope of the work will include the generation of data that will allow the full qualification of biomarkers studied.

Better protect patients, launch safer medicines

4. Toxicities in women of childbearing age. Women of childbearing age are often required to take medicines to treat conditions that affect them during pregnancy. While reproductive and embryofetal developmental (EFD) studies are conducted routinely to determine potential teratogenic and/or toxic effects associated with foetal exposure and the presence of medicines in breast milk, the predictivity of these studies has limitations. Alternative ways of characterizing disease and compound mediated embryofetal risks and risks to the new-born and infants during lactation are therefore urgently needed. The overall objective of this priority area will be to bring forward topics that will result in optimised, reliable and timely information on reproductive risks of medications used in women of childbearing age.

5. Dosing in specific populations. The term specific population has been used to describe patient attributes that may require alterations in the course of therapy when compared to typical patients; examples include renal and hepatic impairment, children, elderly, and pregnancy. These populations are often excluded or under-represented in pivotal trials. 50% to 80% of new molecular entities do not have explicit dosing recommendations for severe renal and hepatic impairment, respectively. Thus, dosing recommendations for some specific populations may lag for years without assurance that they will ever be studied. Modelling and simulation (M&S) approaches offer the opportunity to bridge this gap. Therefore, topics will be brought forward to establish a framework for developing models, criteria for establishing adequacy of predictions, and a drug development-regulatory framework for incorporation of derived dosing recommendations into product labels.
6. Human metabolism, disposition and pharmacokinetics. Many compounds in drug development fail sooner or later because of undesirable pharmacokinetics (PK), insufficient efficacy, and/or safety concerns that were not foreseen even after having a plethora of data available from animal studies. Therefore, it would be highly desirable that information on **human metabolism, disposition and pharmacokinetics** (PK) could be evaluated early and directly in humans. However, this requires general acceptance of advanced analytical methodologies that bring new opportunities to the field. A topic is envisaged that will generate the necessary evidence to support the use of advanced analytical methodologies that would enable earlier testing of compounds in humans.

Expected Impact of the topics

- Improved preclinical models of toxicity
- Qualified safety biomarkers
- Decrease the risk presented to patients by novel pharmaceuticals
- Better protect volunteers or patients involved in clinical trials with drugs acting on nervous system
- Reduce dependence on animal models to investigate intestinal and renal toxicities
- Better understanding of the reproductive risks of medications used in women of childbearing age
- Develop new methodologies to better address the risks of adverse foetal outcomes due to disease and medication during pregnancy and lactation
- Models and a drug development-regulatory framework for incorporation of derived dosing recommendations into product label

Types of action:

Research and Innovation Actions

F. Data and Knowledge Management

The increasing volume (terabytes/patient), diversity (clinical, genome-wide association study/RNA sequencing, electronic heath records, 'omic, cytometry, imaging, pharmacology, pharmacovigilance etc.) and velocity (e.g. real time telemetric monitoring of patients, social media feeds, wearable devices in healthy subjects etc.) of biomedical data available creates significant opportunity for healthcare research & development (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 methods 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 (http://www.radar-cns.org/) 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 while ensuring the regulatory requirements of this data is complied with fully.

To ensure a harmonised approach it is planned that ongoing projects will require coordination/collaboration with European biomedical research infrastructures through the European Strategy Forum on Research Infrastructures (ESFRI).

Activities in 2017 will address the following topics:

Establishing a sustainable legacy of IMI data assets:

1. Establish a sustainable legacy of the IMI data assets. Develop solutions to make a significant portion of the data from IMI projects hosted in a sustainable way, accessible and interoperable. The activities include making the wealth of data generated during IMI-1 and IMI-2 projects Findable, Accessible, Interoperable, and Re-usable (FAIR).

Access, standards and interoperability:

2. Biomedical metadata registry. Develop well-established, sustainable, industry-wide metadata standards to support tracking, moving, compiling, storing, harmonizing and reconciling biomarker data to accelerate the interoperability of all databases (including non-IMI project databases), and allow queries within individual and across different databases. Interoperability should be supported by developing tools and methods to confirm data provenance as well as exchange of data standards for all biomarker modalities.
3. Coordination and Support Action for building the basis for a common European biomedical 'language' across all stakeholders in the biomedical and health care space. This should be achieved by establishing a governance body and governance processes for all relevant metadata standards and by implementing a sustainable European biomedical metadata registry under a broadly agreed governance structure and standardized tools to lower the barrier to adoption of standards.

Development of enabling platforms to support new research paradigms:

4. Life science networks. Develop advanced 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, drug efficacy and drug induced side effects.
5. OpenPhacts Reasoning Engine. Tools and methods will be developed to facilitate the application of machine learning to predict biochemical activities of chemical structures making use of historical biological assay data.
6. Big Data for Better Outcomes (BD4BO): Use big data approaches for optimization of care pathways and improving outcomes for patients' multi-diseases/multi-morbidities; investigate how big data could support better outcomes for rare cancers, with the example of neuro-endocrine tumours;

develop a real world big data registry for better respiratory disease outcomes. Projects under the BD4BO programme will be required to conclude collaboration agreements[10] with each other.

7. Distributed Data Network. Activities will aim at establishing a core distributed data infrastructure to allow real world evidence data repositories to be combined for overcoming 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. This project will be part of the BD4BO programme and therefore beneficiaries participating in this action will be required to conclude collaboration agreements[10] with the beneficiaries of other BD4BO which are complementary to it in order to coordinate the work under the complementary grant agreements.
8. RADAR-Alzheimer's. Extend the Remote Assessment of Disease And Relapse RADAR programme to other disease areas by leveraging the RADAR platform for central nervous system (RADAR-CNS) to study cohorts of patients who suffer from other conditions such as chronic pain or Alzheimer's disease. Projects under the RADAR programme will be required to conclude collaboration agreements[10] with each other.
9. Personal health data ecosystem. Build data management systems that can provide individuals with ownership of their own health care data. Such systems should allow the evaluation of the opportunities of using the personal health ecosystem to realize their true potential in human research and clinical practise.
10. Adaptive designs: Develop solutions to improve the adoption of adaptive methods in R&D process.

Digital solutions for better compliance and adherence:

11. Develop approaches to help monitor and improve medication compliance by creating a multi-stakeholder network which will establish common processes, standards and guidelines for a digital patient platform with approved medicines information and map trusted sources and needs for additional information.

Expected impact of the topics:

- Stable legacy: enabling IMI data assets security (time and policy) and accessibility.
- An improved understanding: through maximising the utility of individual studies.
- To allow the development of new scientific insights to support and accelerate medicines development; by fulfilling the ethical responsibility to extract most value for contributing patients and by permitting combined, cross study analyses.
- The improved data sharing and interpretation: by developing and supporting independent, agreed and stable public-private standards; by developing and providing common interfaces reducing the threshold for data access to researchers and system interoperability.
- A strengthened community of informatics and knowledge management professionals.
- 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.
- An 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.
- Improve compliance and adherence to prescribed medicine.
- Create structure and guidance for information on medicines and related topics.

Type of actions:

Research and Innovation Actions and Coordination and Support Actions

[10] IMI2 Grant Agreement article 41.4: Relationship with complementary beneficiaries — Collaboration agreement.

G. Oncology

IMI via its strategic area oncology aims to foster a significant progress towards the extension and quality improvement of patients living with advanced cancer.

The mission and vision is to define research initiatives that will aspire to effectively double the following parameters: 1) progression-free survival / overall survival; 2) number of patients able to access innovative personalized medicines; 3) speed of drug development; 4) treatment tolerability, and 5) cost effectiveness in cancer drug development .

Activities in 2017 will address the following topics:

Beyond patient stratification:

1. Gathering large amounts of longitudinal diagnostic and treatment information for a greater understanding of signalling networks, how the function of these networks is altered by treatment, and how cells adapt to pharmacological treatment, including resistance mechanisms vs. escape for checkpoint. The high quality, integrated datasets obtained should be used to profile tumours and deeply interrogate tumour microenvironment and the patient immune system over time.

Increasing context specificity:

2. Develop new ways to study clinically and preclinically the “contextual space” of a tumour. This will require complex studies to test different drugs in different context and different indications to systematically explore and predict contextual dependencies.

Immune oncology:

3. Develop patient selection tools to identify responder populations for immune oncology (IO), IO-IO treatment combinations and / or IO targeted therapy.

Cell free DNA – liquid biopsy:

4. Explore the potential of cell free tumour DNA (cfDNA) assessment, as an alternative to classic biopsies.

Big data in oncology:

5. Creation of a centralized repository of data from patient populations affected by solid tumours (sequencing, RNA expression, protein profiling, metabolite and methylation profiling) capable of storing and processing sample information in a consistent fashion. This should be accompanied by efforts in standardisation of laboratory testing and data. This will facilitate patient access to the most advanced and appropriate treatment; speed up the enrolment of patients with rare genetic variants in clinical trials; allow the development of new clinical and molecular endpoints, and the generation of new hypotheses, methodologies and exploratory algorithms. Other elements of the solution are the establishment of an appropriate data architecture and software tools. Analytic and visualization tools allowing deeper exploration of the data are also required, as are ways for inclusion of other sources of information, such as patient reported outcomes, health economic and real world evidence of treatment.

Expected impact

- New approaches in drug development/ combination strategies for drugs in development to facilitate patient access to innovative treatments.
- Novel and better defined clinical and molecular endpoints.
- Better, more robust and higher quality screening tools and methods.
- A large positive impact in treatment outcomes, to support the adequate reimbursement of innovations in this field.
- A better understanding of the microenvironment of tumours and its dynamics, including tumour immunology.
- An outcomes-focused data platform to empower policy makers and clinicians to optimize care for patients with solid tumours

Type of actions:

Research and Innovation Actions

H. Other enablers of innovation

European screening centre

There is a growing need for a better translation of exciting biology concepts into tangible and refined chemical assets. These assets (e.g. chemical lead structures) are needed as tools for a better understanding of disease mechanisms as well as starting points for the future development of novel medicines. Pharmaceutical companies have their own compound libraries, as well as screening and medicinal chemistry facilities. Major academic centres have also started to establish their own libraries and screening activities, e.g. in the European Open Screen initiative (http://cordis.europa.eu/result/rcn/173234_en.html). These distributed activities have nevertheless shown their limitations, calling for a more coordinated approach bringing together public and private expertise in this area. The IMI project European Lead Factory (https://www.europeanleadfactory.eu/) established over the last four years is already showing the value of such a central, coordinated approach.

Activities in 2017 will address the following topic:

1. This topic will address the need for suitable chemical assets in complex diseases by the design of an enlarged high quality compound library, based on the work done in the European Lead Factory project, screening facilities with a strong focus on innovative biology, and a structured approach for qualification of the resulting hits. In particular, a further important value creating step towards tangible chemical assets is envisaged: Hit-to-Lead (H2L) workflow for selected programs enabling participants to jump start lead optimization projects and helping to further boost public private partnerships post the IMI funding period.

Expected impact:

- Generate a central European hub for screening and hit profiling for public and private partners
- Foster the translation of novel biology in disease areas with high unmet medical need into *highly valuable* chemical assets.

Type of action:

Research and Innovation Action

2. Facilitating the translation of advanced therapies to patients in Europe

Recent advances in biomedicine are now opening the door to new treatment approaches for diseases with high unmet medical need. These approaches include advanced therapy medicinal products (ATMPs) such as products based on genetic engineering, innovative cell-based therapies and tissue-engineered products. However, numerous factors and challenges complicate the translation from research into patient access of ATMPs.

Activities in 2017 will address the following topics:

1. Improving preclinical studies of ATMPs. Develop solutions, including tools and methods to address the key challenges in the area of preclinical development of ATMPs. This could include demonstration of proof of concept in relevant animal models, the study of new and effective approaches for delivery of ATMPs, the assessment of established vector systems and development of new enhanced vectors, as well as development of new approaches based on targeted gene editing. For improving the reproducibility of preclinical studies an increased understanding of all impacting factors and a joint effort towards standardisation, including development of the relevant regulatory science should be aimed for.
2. Novel approaches for clinical study of ATMPs. Address the issues raised from clinical exploratory studies to demonstrate safety and proof of concept/initial efficacy of ATMPs, as well as from confirmatory studies. The approach used should allow the incorporation of aspects of evidence, and effectiveness and the interpretation of the data in the context of clinical meaningfulness. This will require an organic study of the clinical condition and patient populations with the perspective of a

case-by-case basis and/or specific categories. Issues to be addressed include the development of primary and secondary endpoints, the interpretation of preclinical to clinical translatability using potential biomarkers and surrogate markers (of pathophysiology and of evidence of clinical effectiveness), and the mapping and inventory of the type of data available via clinical use programmes (registries, hospital exemption, compassionate use) in Europe.

3. ATMPs manufacturing. Address the challenges of manufacturing of ATMPs. This will require developing common best practices and 'automated' production platforms, highly sensitive analytical tools/methods and scaled down/micro assays. Manufacturing knowhow and education specific for the ATMP business, regulatory sciences and Current Good Manufacturing Practice (CGMP) related to ATMP usage should also be developed.
4. Vector technology platform for ATMPs. Establish a common technology platform for the production of specific vectors with respect of all aspects of the current regulatory standards on safety, stability, robustness and validation. This should be based on innovative production, analytical tools and equipment and achieved by combining in-depth knowledge of cell biology, culture technology and innovative solutions in bioprocessing technology and bioreactor engineering.
5. Immunogenicity of ATMPs. Explore how cells can be genetically re-engineered of to lower immunogenicity.
6. European stem cells facility. Establish a single central processing facility for inducible pluripotent stem (iPS) cell technology, building on the foundational infrastructure created by the IMI EBiSC project. The solution should become operationally self-funding within 5-7 years, and should couple quality control with cell line expansion, in order to standardise production workflow from sample procurement to cell line qualification.
7. Patient access to ATMPs. Build a knowledge base on health technology assessment (HTA) and hospital exemption (HE) implications of ATMPs. This should include the study of ways for development of health systems provisions for innovative reimbursement and payment mechanism, and the facilitation of the delivery of ATMPs through select centres of excellence to optimise cross-border health care delivery.

Expected impact of the topics

- To enhance research and development of advanced therapies in Europe as a fully-fledged industrial activity to make the EU more competitive and make advanced therapy products available to all patients in need.
- To facilitate translation from preclinical studies to the clinic and contributing to the 3Rs via development and validation of novel robust preclinical models and increased data reproducibility.
- A more consistent and reproducible manufacturing of ATMPs.
- A significant (not just incremental) acceleration in the progress of this field via development of standardised technological platforms, tools, biobanks (especially for iPS cells) and databases.
- A powerful public private innovation platform for addressing efficiently all challenges in the pathway from science to healthcare systems and patients, including price and reimbursement implications.

Type of action:

Research and Innovation Actions

Calls for Proposals

Call number and indicative topics[11]	Indicative Call launch timing	Indicative IMI2 JU funding (in EUR)[12],[13]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners	Call process
Call 1 of 2017 *Diabetes/metabolic disorder* ▪ Diabetes cardiomyopathy (RIA) *Neurodegeneration and other Neuroscience Priorities* ▪ Neurodegeneration - Alzheimer's Disease: Coordination and Support Action (CSA) ▪ Neurodegeneration – Alzheimer's Disease: Immune system and Alzheimer's Disease (RIA) ▪ Blood-Brain Barrier (RIA) *Immunology* ▪ Inflammatory Bowel Disease (RIA) ▪ Epigenetics (RIA) ▪ Disease deconstruction and target identification (RIA) *Translational safety* ▪ Reduce safety-related attrition during drug development: Reducing Neurotoxicity. (RIA); Translational MicroPhysiological Systems (RIA); Biomarkers for toxicities (RIA) ▪ Better protect patients, launch safer medicines: Toxicities in women of childbearing age (RIA) *Data & Knowledge Management* ▪ Establishing a sustainable legacy of IMI data assets (RIA) ▪ Development of Enabling Platforms to support new research paradigms: RADAR Alzheimer's (RIA); BD4BO multi-morbidities (RIA); Distributed data network (RIA) ▪ Digital solutions for better compliance & adherence (RIA) *Oncology* ▪ Beyond Patient stratification (RIA) ▪ Increasing context specificity (RIA) *Other Enablers of innovation* ▪ European Screening Centre (RIA) ▪ Facilitating the translation of Advanced Therapies: European Stem Facility (RIA)	5 April 2017	89,019,335	89,019,335	Two-stage call with predefined submission deadline Indicative Call deadline for Short proposals: 18 July 2017 Indicative Call deadline for Full Proposals: 23 January 2018 Research and Innovation Actions (RIA) & Coordination and Support Actions (CSA)

[11] Potential applicants are pre-informed that one or more topic(s), if exceptionally needed, may be subject to a restricted follow-up Call for proposals to be launched by IMI 2 JU at a later stage. This follow-up Call for proposals may be restricted to the consortium already selected under such topic, in order to enhance their results and achievements. The consortium will be entitled to open to other beneficiaries as appropriate. The detailed scope of the restricted Call shall be described in the relevant Annual Work Plan.

[12] Based on estimate of total operational commitment appropriations available in 2017. This is without prejudice to commitment appropriations to be carried over from 2016 to 2017 (to be determined early 2017).

[13] The maximum possible rate of co-financing is 100 %.

Call number and indicative topics[11]	Indicative Call launch timing	Indicative IMI2 JU funding (in EUR)[12],[13]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners	Call process
Call 2 of 2017 *Diabetes/metabolic disorder* ▪ Database for clinical trials in Metabolic disorders (RIA) ▪ Microbiome & Metabolic Disorders (RIA) *Neurodegeneration and other Neuroscience Priorities* ▪ Neurodegeneration - Alzheimer's Disease: Tau imaging (RIA); New genes as Alzheimer's Disease Modifiers (RIA); Early markers of progression in Alzheimer's Disease (RIA). ▪ Neurodegeneration - Parkinson's Disease: Personalised treatment (RIA); Mitochondrial deficiency (RIA) ▪ Biomarkers in neurodegeneration (RIA) ▪ Pain (RIA) *Immunology* ▪ Fibrosis (RIA) ▪ Systemic lupus erythematosus (RIA) ▪ Sjögren Syndrome (RIA) ▪ Microbiome research (RIA) *Infection control including vaccines* ▪ Antimicrobial resistance – antibiotics and diagnostics (RIA) ▪ Innovation in vaccines (RIA) ▪ Innovation in vaccines (CSA) ▪ Emerging infectious diseases (RIA) *Translational safety* ▪ Better protect patients, launch safer medicines: Dosing in specific populations (RIA); Human metabolism, disposition and pharmacokinetics - early and direct evaluation (RIA) *Data & Knowledge Management* ▪ Digital solutions for better compliance & adherence (RIA) ▪ Access, Standards and Interoperability: Biomedical Metadata Registry (RIA); Coordination and Support Action (CSA) ▪ Enabling Platforms to support new research paradigms: Life science networks (RIA); OpenPhacts Reasoning Engine (RIA); BD4BO rare cancers (RIA); BD4BO respiratory diseases (RIA); Personal health data ecosystems (RIA); Adaptive designs (RIA) *Oncology* ▪ Immune Oncology (RIA) ▪ Cell Free DNA-Liquid Biopsy (RIA) ▪ Big data in oncology (RIA)	9 November 2017	89,019,336	89,019,336	Two-stage call with predefined submission deadline Research and Innovation Actions (RIA) & Coordination and Support Actions (CSA) Indicative Call deadline for Short proposals: 13 February 2018 Indicative Call deadline for Full Proposals: 24 July 2018

Call number and indicative topics[11]	Indicative Call launch timing	Indicative IMI2 JU funding (in EUR)[12],[13]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners	Call process
Other Enablers of innovation ▪ Facilitating the translation of Advanced Therapies (RIA)				
OVERALL TOTAL		**178,038,671**	**178,038,671**	

Budget

A table overview of the operational budget for the financial year 2017 is set out below.

Heading Title 3		Financial year 2017		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
30	Operational expenditure	178,038,671	196,782,634	EC contribution to grant agreements - Payments
30	Operational expenditure		2,831,000	EFPIA companies and Associated Partners contributions to grant agreements - Payments
30	Operational expenditure – carry over from 2016(estimate)			To be determined at the end of 2016 based on final year budget execution

A table overview of the 2017 draft budget is set out in Chapter 3 to this Annual Work Plan.

2.2.3 Call management (planning, evaluation, selection, …)

Activities related to proposals evaluation and grant preparation

Key activities in 2017 will comprise the launch of two competitive Calls for proposals implementing the 2017 scientific priorities with indicative launch dates on 5 April 2017 and 9 Nov 2017. 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. As of 2017 all IMI2 JU calls and evaluations will utilise the H2020 participant portal and Horizon 2020 IT infrastructures.

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 2017 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.[14]

To maximise the efficiency of the calls management, the IMI2 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

78 ongoing projects will be running at different stages of their life cycle in 2017 with additional projects coming online during the year when Call 8 Ebola+ (3rd and 4th cut-off), Call 9 and Call 10 (launched in 2016) complete their evaluation cycles. All projects will submit to IMI2 JU 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, IMI2 JU will continue to provide support and advice to the consortia, including on amendments to Grant Agreements.

IMI will organise 8 mid-term (interim) reviews for projects launched under IMI1 JU (Calls 10 and 11) and IMI2 JU (Calls 1 and 3).

		Project periodic report due in 2017						Of which	
IMI Calls	ongoing in 2017	1st RP in 2017	2nd RP in 2017	3rd RP in 2017	4th RP in 2017	5th to 7th RP in 2017	Total reports	finishing in 2017	Final report due 2017
1	0	0	0	0	0	1	1	0	0
2	1	0	0	0	0	1	1	2	1
3	7	0	0	0	0	7	7	5	5
4	7	0	0	0	0	7	7	7	6
5	1	0	0	0	0	1	1	1	0

[14] 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 report due in 2017						Of which	
IMI Calls	ongoing in 2017	1st RP in 2017	2nd RP in 2017	3rd RP in 2017	4th RP in 2017	5th to 7th RP in 2017	Total reports	finishing in 2017	Final report due 2017
6	2	0	0	0	0	2	2	1	0
7	2	0	0	0	2	0	2	0	1
8	4	0	0	4	0	0	4	0	1
9	4	0	1	3	0	0	4	2	2
10	1	0	1	0	0	0	1	0	0
11	8	0	8	0	0	0	8	0	0
IMI2 C1	1	0	1	0	0	0	1	0	0
IMI2 C2	8	0	8	0	0	0	8	5	1
IMI2 C3	5	1	0	0	0	0	1	0	0
IMI2 C4	1	0	1	0	0	0	1	1	0
IMI2 C5	6	6	0	0	0	0	6	0	0
IMI2 C6	4	0	0	0	0	0	0	0	0
IMI2 C7	8	0	0	0	0	0	0	0	0
IMI2 C8	2	2	0	0	0	0	2	0	0
IMI2 C9	6	0	0	0	0	0	0	0	0
Total	**78**	**9**	**20**	**7**	**2**	**19**	**57**	**24**	**17**

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 IMI2 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.

2.2.5 Monitoring and analysis of projects' results

All ongoing IMI projects will complete a periodic report in 2017 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, 24 projects will reach their project end date and finish their IMI funding during 2017. Of these, 17 of these are expected to submit their final reports before the end of 2017. For projects resulting from IMI2 JU calls launched in 2017 onwards this monitoring will be done using the functionalities of the Horizon 2020 IT infrastructures.

In 2017 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 European Court of Auditors (ECA) to ensure the highest possible standards.

2.2.6 Stakeholders' engagement and external collaborations

In 2017 IMI will continue to develop its relationships and engagement with stakeholders such as patients, regulators, payers and healthcare professions to ensure that its outputs are aligned with and address the needs of society. Given their importance in driving employment and innovation in the European economic area IMI JU will continue its engagement with SMEs and encourage their participation in IMI projects. As the healthcare challenges that face society are global the IMI JU will also explore interactions and seek synergies with non-EU organisations when appropriate. Particularly important will be developing relationships with regulatory agencies outside of Europe and in areas where the setting of internationally accepted standards will benefit progress in healthcare research. When appropriate, collaborations with other non-EU organisations will be sought.

Patients

IMI recognises that patients benefit from research and development and can make a vital contribution to shaping research, making it more effective and more oriented to patient needs. The involvement of patients in research also builds their confidence in the research and development process. In addition, this engagement and interaction may provide IMI additional opportunities to communicate its role and mission. Therefore, IMI's goal is to champion a patient centric-approach at all levels and especially 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 IMI wishes to embed patients 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. Namely IMI will:

- ensure that patient engagement and the role for patients is considered at the idea generation and topic writing stage;
- communicate on patient engagement needs and opportunities at call launch;
- identify the most effective channels of communicating the call to patients and other relevant organisations;
- identify and communicate on best practices of patient engagement in IMI projects;
- facilitate patient engagement in consortia.

IMI will organise at least one patient focus meeting with an objective to provide patient perspective and input into the potential research topics in IMI. IMI will also be represented at least at 1 specific patient focused event.

The aim of these activities is 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 projects. IMI will continue to produce materials for the promotion of patient involvement in IMI.

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 its inception IMI has established collaboration with regulators to create an interface between science and regulation, in particular to explore how the current state of science could support the evolution of the regulatory paradigms as enablers of innovation for the benefits of patients. IMI will therefore continue to develop this framework to engage with all relevant regulatory agencies.

To continue to strengthen relations with regulatory agencies, in particular with EMA and FDA, IMI will continue a regular exchange of information with EMA and FDA on research projects, topics under development and strategic vision for collaborative research conducted under IMI to engage in dialogue with regulators as enablers of innovation. This dialogue will also further discuss the impact of IMI project results on the EU regulatory environment, including how they are enabling the implementation of Medicines Adaptive Pathways to Patients (MAPPs) within the current regulatory framework. In addition, IMI will organise a regulatory summit with the EMA and FDA.

To ensure that IMI projects benefit from the regulators' input and maximize the impact of IMI project outputs to progress regulatory science, IMI staff will continue to support topic writers at the stage of a topic development. IMI staff will also work with IMI consortia to raise awareness of the regulatory relevance of their activities and the subsequent regulatory processes to follow, particularly with the qualification advice/opinions procedures. IMI will also support early liaison with the regulators.

IMI will develop a framework for dialogue with other decision makers particularly health technology assessment (HTAs), payers and other relevant EU-funded initiatives, taking into consideration experience from the IMI coordination and support action ADAPT-SMART.

SMEs

Small and medium-sized enterprises (SMEs) are the backbone of Europe's economy representing 99% of all businesses in the EU. They play a valuable role in bringing forward innovative solutions to help tackle key societal challenges. IMI recognises this important role of SMEs and will continue to work with its founding members and other stakeholders to increase support to SMEs and increase SME participation in its projects.

In 2017, the IMI SME strategy will be finalised and implemented. The first implementation step will be to encourage increased SME participation in IMI call topics by clearly highlighting activities to be carried out by SMEs in the topic description. Another important step will be the overhaul of the IMI website with better and clearer information targeted to SMEs, particularly relating to the management of IPR and the benefits of participating in IMI projects via testimonies from SMEs already participating. Begun in 2016, it is foreseen that the overhaul of the website and updating of information targeted at SMEs will be concluded in 2017.

Whenever possible IMI will look to partner with other EU, national and regional clusters to host events aimed at encouraging SMEs to apply and participate in IMI projects. The IMI will also explore the avenues available for SMEs from other non-pharmaceutical sectors such as IT, medical devices and nutrition to become more involved in IMI activities and projects.

The impact of these activities can be measured through dedicated SME key performance indicators (KPIs).

External collaborations

Clinical Data Interchange Standards Consortium (CDISC)

In 2016 the memorandum of understanding between IMI and CDISC and IMI's membership of CDISC were renewed, so the collaboration focused on providing information on the implementation of data standards and training in this area will be continued. In particular webinars and when necessary face-to-face trainings will be provided by CDISC staff to IMI projects. It is expected that further activities will be explored to ensure that all IMI projects have access to the benefits of IMI membership. In addition, IMI will continue to participate in the Scientific Advisory Committee of the Coalition For Accelerating Standards and Therapies (CFAST).

C-PATH Institute

IMI will continue to collaborate with C-Path Institute to explore synergies and seek alignment of respective activities with the aim of avoiding duplication of efforts in 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
Interaction in the coming year will be on enabling a collaborative relationship in paediatrics particularly between the C-Path Global Paediatric Clinical Trials Consortium and the IMI 2 project resulting from a topic launched as part of IMI2 JU Call 10. Furthermore, collaboration in the area of neuroscience and tuberculosis and Type 1 diabetes will continue in 2017. It is envisaged that a Joint IMI and C-PATH face-to-face meeting will be organised in Q3 or Q4 of the coming year.

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 continued 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).

Key to facilitating this collaboration will be the organisation of a joint meeting at a major international Alzheimer's conference (AAIC, CTAD or AD/PD) to align planned activities and monitor the implementation of aligned activities in GAP and the IMI project EPAD as well as related actions generated under IMI2 JU.

IMI2 JU will continue to contribute to activities developed as part of the Global Action against Dementia (https://worlddementiacouncil.wordpress.com/) of the World Dementia Council.

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 JU C3, C5 and C6) including a session with other related EU and national projects (HBP, JPND, DZNE, DPUK) where patients and regulators are invited

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

A cross project meeting is planned for projects in the Ebola programmes aiming to foster collaboration and promote the sharing of information and knowledge in a joint repository. The meeting will also be an opportunity to introduce the new projects launched under IMI2 JU Call 8 and facilitate their integration with the existing Ebola programme projects.

New sectors and priority areas

Several new priority disease areas have emerged since the start of IMI2 and efforts are required to ensure that topics brought forward under IMI are aligned with ongoing international initiatives in these areas and societal needs. Therefore, it is planned that at least two workshops will be organised in the coming year to further develop topic ideas and other activities. It is planned to have at least one workshop dedicated to new sectors such as nutrition/ ICT/ imaging and another in oncology/advanced therapies where discussions have already started but the strategy refined.

2.2.7 Dissemination and information about projects results

Although the first and foremost responsibility of maximising the impact of their own research and innovation lies with the project consortium, promoting the successes of IMI projects is a core element of both the IMI Communications and Dissemination Strategies.

The IMI Programme Office identifies results and successes in a variety of ways, including through formal routes (project periodic reports, interim reviews) and informal routes (direct contacts with project participants, monitoring of project websites and social media, etc.). IMI will continue to support and supplement the dissemination of projects' public deliverables via a variety of channels, including the IMI website, newsletter, social media (Twitter and LinkedIn), the press, and events. In addition, IMI will investigate how to make better use of EU specific dissemination channels (e.g. CORDIS, Futuris, Horizon Magazine, and the Enterprise Europe Network (EEN)) and will promote projects through them.

As mentioned above, 24 projects from the first IMI1 Calls will reach their project end date with 17 of these submitting their final reports in 2017. In addition, 5 projects that reached their project end date in 2016 are also expected to submit their reports in 2017 Capturing the outcomes and impacts of these projects presents IMI with a new challenge. To address it, two new actions will be pursued:

- It is expected that up to 21 close-out meetings will be organised around the time of the final report submission. The close out meeting provides an opportunity for the consortium to present to the IMI office how the project has reached its objectives, to highlight tangible results and to put the achievements of the project into context and to discuss the potential impact and legacy management. Part of this objective is to provide the IMI communications unit with the main achievements and impacts of the project in order to facilitate further IMI dissemination via the channels described above. In addition, members of EFPIA, the EC, IMI Scientific Committee and relevant SGG will be invited to attend the close out meetings to share not only in the results but also in the learnings and experiences of the project consortia.
- IMI will actively participate in the R&I Family tender for tracking research outcomes, which will have the aim of monitoring projects' outcomes for up to five years after their completion, as several studies have demonstrated that at least 40% of projects outcome are generated during this period.

Lastly, IMI will continue to fulfil its role/obligation to look after policy conformity, effectiveness and efficiency of the dissemination and exploitation at the level of each project.

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 JU Calls for Proposals:

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

By way of derogation[15] 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.

Participating legal entities listed in (b) above established in a third country may receive funding from the IMI 2 JU provided their participation is deemed essential for carrying out the action by the IMI 2 JU or when such funding is provided for under a bilateral scientific and technological agreement or any other arrangement between the Union and the country in which the legal entity is established[16].

STANDARD ADMISSIBILITY CONDITIONS AND RELATED REQUIREMENTS

Part B of the General Annexes[17] to the Horizon 2020 -Work Programme 2016– 2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

In addition, 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.

ELIGIBILITY CONDITIONS

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.

In addition, 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

[15] 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

[16] In accordance with Article 10(2) of the Regulation (EU) No 1290/2013 and Article 1 of Commission Delegated Regulation (EU) No 622/2014

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

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.[18]

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

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

EVALUATION RULES

Part H of the General Annexes to the Horizon 2020 - 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 and scores:

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	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	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

[18] 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"

Type of action	Excellence	Impact	Quality and efficiency of the implementation
	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	contribute to the IMI2 objectives[19].	structures and procedures, including manageability of the consortium.
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;[19] 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.

[19] 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
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[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.
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);

[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
	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[21]. 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 JU Manual for submission, evaluation and grant award in line with the H2020 Rules for Participation.[22]

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. The best-ranked proposals, in the framework of the available budget, will be invited to prepare a Grant Agreement.

[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)

[22] 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[23] 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 a 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 Horizon 2020 - Work Programme 2016–2017 shall apply mutatis mutandis for the actions covered by this Work Plan.

ACTIONS INVOLVING FINANCIAL SUPPORT TO THIRD PARTIES

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

[23] In cases clearly identified in the relevant call for proposals where a given topic is composed of two or more sub-topics, one short proposal per sub-topic will be invited

CONDITIONS RELATED TO OPEN ACCESS TO RESEARCH DATA

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

However, should a project "opt-out" of these provisions, a Data Management Plan must still be prepared. A template for the Data Management Plan is available on the IMI website.

SUBMISSION TOOL

Proposals in response to a topic of the IMI2 JU Call for proposals must be submitted on-line, before the call deadline, by the coordinator via the Electronic Submission Service of the Participant Portal:

http://ec.europa.eu/research/participants/portal/desktop/en/home.html

No other means of submission will be accepted.

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 proposal 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 JU Call for proposals shall not be selected. [24]

In order to ensure excellence in data and knowledge management consortia will be requested to Disseminate scientific publications on the basis of open access[25] (see "Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020").

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[26] (e.g. IMI2 JU 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] 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 objectives

The Communication team will continue to focus on attracting the best researchers from relevant target groups to apply for funding under IMI 2 Calls for proposals and to promote networking between the different target groups. It will do so by outreaching directly to potential applicants (mainly through webinars, the IMI website, the IMI newsletter and social media, workshops and events) and by mobilising multipliers and ambassadors (e.g. providing support and participate in info days in Member States, provide training, info and material to SRG, SC and other multipliers).

After 8 years of the first IMI call launch, the first projects are drawing to a close providing unique results that will allow IMI to demonstrate how IMI projects are delivering excellent science that is already having a real impact on the way medicines are developed. Therefore, in the context of IMI's mid-term evaluation, the IMI Communication and External Relations Strategy for 2017 will concentrate on raising the awareness levels and perception of IMI's added value among all target groups, with a particular focus on policymakers and opinion leaders, patients, SMEs, and other industries.

Communication support to IMI stakeholder strategies: patients and SMEs

As the IMI patient strategy keeps evolving with patients and carers reaching new ways of meaningful involvement in IMI projects, the Communications team will continue to support awareness-raising activities and to encourage patients to get involved in both IMI's projects and its broader activities.

Under IMI2, in line with Horizon 2020, IMI2 JU will be expected to ensure 20% of its budget goes to SMEs. Yet IMI is competing with other funding programmes to attract SME participation, some of them SME tailored. The Communications team will focus on a comprehensive outreach and support strategy by (i) improving communication on IMI through SRGs/regional contact points/clusters, (ii) by participating in partnering events and investor conferences and (iii) by designing specific tools for SMEs, such as a comprehensive dedicated webpage in the revamped IMI webpage or a toolkit on IPR specifically developed for SMEs.

Redesign the IMI website

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, IMI has evolved and outgrown the motivations behind the current website.

Following suggestions from a survey among our main stakeholders and IMI's 2017 communication objectives, the revamped website will be designed following three main drivers: (i) it will be tailored to IMI's different stakeholders, (ii) it will give a stronger voice to our projects, and (iii) it will be more visual.

Further develop IMI success stories

The incorporation of a writer to the communications team in 2016 will allow IMI to reinforce contacts with its projects to ensure a steady flow of success stories that will be used to illustrate IMI's key messages through the different communication channels.

Increase synergies with regional research and innovation activities

Even though IMI funds are granted on the sole criterion of scientific excellence, IMI can contribute to regional strategies by providing a rich collaborative environment where open innovation can flourish. During 2017, regional events will be fostered in order to raise awareness on IMI among potential participants, but also to strengthen national and regional support to excellent scientist and SMEs, in particular among those countries with a lower participation in IMI.

Media outreach

In recent years, IMI has enjoyed increased positive visibility in key general and specialist media. In 2017, IMI will work to ensure this trend continues by maintaining links with key journalists, issuing regular press releases, organising press interviews, and inviting media to IMI events.

As described above, one of the four critical risks identified at corporate level is the generation of a negative external perception of IMI2 JU's added value and the publication of inaccurate comments in the press and other public fora. As a consequence, the Programme Office will remain alert to issues that could damage IMI's reputation, and respond accordingly by proactively reaching out to opinion leaders, for example by preparing briefings or sets of questions and answers.

Communication channels

IMI will continue to develop the following channels in support of its communication goals:

- Events (both IMI and external);
- Website;
- Newsletter;
- Social media (LinkedIn, Twitter);
- Multipliers: IMI founding members / Governing Board, members of advisory bodies (States Representatives Group, Scientific Committee), National Contact Points, relevant scientific, patient, business umbrella groups / associations, IMI projects, organisations partnered by IMI, e.g. through a Memorandum of Understanding;
- Media (general and specialist, mainly in Europe but also international);
- Direct mailings;
- Publications;
- Videos;
- Direct contacts with opinion leaders.

Preparation of IMI 10th anniversary

In 2018, IMI will celebrate its 10th birthday, and this will represent an excellent opportunity to showcase what IMI has achieved in that time (and its plans for the future) through a year-long programme of events and activities. Due to the timelines involved the communications team will have to start planning and organising these activities in 2017.

Events planned in 2017

Activity	Timeline
Promote Calls for proposals (webinars, info-days, website, etc.)	Q2, Q4
Create IMI new website	Q2, Q3
Promote projects	Ongoing activity
IMI presence at relevant large conferences: BIO, PSWC2017, BioVision, BIOEurope	Q2 and Q4
IMI presence in the European Parliament	Ongoing activity
Regional events	Ongoing activity
Event with and for patients	tbc
IMI Stakeholder Forum 2017	Q4

2.4.2 Procurement and contracts

In order to reach its objectives and adequately support its operations and infrastructures, IMI2 JU will allocate funds to procure the necessary services and supplies. To make tender and contract management as effective and cost-efficient as possible, IMI2 JU makes use as much as possible of multi-annual framework contracts and EU inter-institutional tenders. Most essential framework contracts IMI is currently using will be running beyond 2017.

As the framework contract for the provision of meeting and event facilities expired by the end of 2016, a new tender procedure will be launched then.

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.

IMI2 JU will earmark a total budgetary envelope of EUR 1 120 000 for procurement needs in 2017.The table below provides a summary of the tenders planned for 2017 and related procurement procedure expected to be used, the estimated budget and expected timing for publication.

Subject	Expected procedure	Max estimated multiannual amount (EUR)	Indicative timing of publication
Meeting and event facilities	Multiannual Framework Contract (FWC)	800 000	Q1
Promotional materials	Multiannual Framework Contract (FWC)	60 000	Q3/4
Event organisation support	Multiannual Framework Contract (FWC)	130 000	Q3/4
Professional printing services	Multiannual Framework Contract (FWC)	130 000	Q1/2
Total		**1 120 000**	

2.4.3 IT and logistics

The 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 use of the full suite of Horizon 2020 IT tools (SEP, EMI, SyGMa/COMPASS) for the management of IMI2 JU operations, from the launch of calls for proposals and selection of evaluation experts, to the follow-up of the grants. The transition to H2020 IT tools started in December 2016 with the launch of the IMI2 JU Call 10 in SEP (Submission & Evaluation of Proposals) and will continue with the gradual transfer of existing IMI2 JU grants from Calls 1 to 9 to SyGMa (Q1-Q3 2017). It will be completed with the transfer to SyGMa of the winning proposals of Call 10 in Q3/4 2017. In addition, all IMI2 data that currently exist in SOFIA will be transferred automatically to CORDA.

In order to achieve the aforementioned goal, IMI IT will focus its 2017 activities on three main areas:

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 started using European Commission's IT tools related to Horizon 2020, such as SEP, EMI, COMPASS and SyGMA. Although the maintenance and new developments of the IT tools related to H2020 fall under the responsibility of European Commission, since IMI1 projects will continue running until at least 2021, the following developments are foreseen for the SOFIA application:

- Enhancement of the application regarding performance, usability and user interface in order to improve the end-user experience and facilitate IMI staff work (Q1 – Q4 2017)
- Maintenance (continuous) of the application with helpdesk support, bug fixes and implementation of service requests (Q1 – Q4 2017)

Moreover, in order for IMI to be fully operational regarding IMI2 JU projects, the following developments are necessary:

- Extraction of IMI2 JU data from SEP and CORDA and other potentially sources and import to Qlikview, which is expected to take place in Q1-Q2 2017
- With the migration to H2020 IT Tools, the EFPIA Operations reporting views in SOFIA will no longer contain accurate data. Therefore, the particular views will be implemented in QlikView. Although this development already started in Q4 2016, it is expected to be completed in Q1 2017 with the migration of QlikView application to a dedicated server and the purchase of additional QlikView licenses to cover the needs of EFPIA operations
- Addition of QlikView reports based on the needs of external groups, for example SRG, and internal stakeholders, and improvement of currently available dashboards (Q1 – Q4 2017)

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 Strategic Governing Groups. These platforms will be maintained and updated both from a content and operations point of view.

Furthermore, IMI uses a number of web-based applications related to human resources management, time management, mission management, document management, incident management and internal communications. Alongside other Joint Undertakings, IMI2 JU will investigate the possibility to access and use European Commission related applications, in case those provide enhanced functionalities compared to those in place.

The following developments are foreseen in 2017 in order to safeguard the continuous improvement and increase of scope of the afore-mentioned systems:

- Enhancement of the applications regarding performance, usability and user interface in order to improve the end-user experience and facilitate IMI staff work (Q1 – Q4 2017)
- Maintenance (continuous) of the applications with helpdesk support, bug fixes and implementation of service requests (Q1 – Q4 2017)
- 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, with the close collaboration of IMI's Communication team, started in 2016 with the gathering and analysis of the business requirements and it is expected to be completed in 2017 (Q3/4 2017)
- Assessment of the practicality of the 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 a paperless office, towards which IMI would like to move in 2018 (Q4 2017).

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 2017, which are expected to provide with efficiency gains in the operation of the organisation:

- Replacement of the end of life of currently used hardware of common data centre, based on the strategy and architecture related to common IT infrastructure study that was concluded in 2016 (Q2 – Q3 2017)
- Maintenance (continuous) of the common infrastructure and networks and end-user office-automation support covering incidents, service requests and improvements (Q1 – Q4 2017)
- Migration of IMI's laptops to Windows 10 and Office 2016 (Q2/3 2017)

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 2017 in the context of the dedicated infrastructure:

- A cyber-capability security assessment took place in Q4 2016. The proposed actions necessary for the improvement of IMI's cloud cyber-security will be implemented in 2017 (Q1-Q2 2017)
- Maintenance (continuous) of the online infrastructure (Q1 – Q4 2017).

2.4.4 Human Ressources

The 2017 objective for HR shall be: recruit, train, assess, motivate and retain highly qualified staff with a view to ensure effective and efficient operation of the JU as well as ensuring equal opportunities. This objective will be implemented through four main themes:

Staffing

The staffing needs of IMI2 JU will be addressed in line with the growth projection set out in IMI2 JU Legislative Financial Statement, as well as the Governing Board decision amending the Staff Establishment Plan (of 10 November 2016, reference IMI2-GB-DEC-2016-27), which altogether foresee a total staff level of 54 people (temporary and contract agents) by the end of 2017. The additional two posts already foreseen in IMI multiannual staff plan will be assigned to reinforce project management tasks, given the sharp increase in volume of work, with IMI2 JU project portfolio to grow from 75 to more than 100 projects by early 2018.

In addition, two seconded national experts will be recruited to provide expertise to the IMI2 JU. This is aimed at bringing specific expertise where there may be a gap and to help with a strategy around regional clusters in health innovation in Europe where IMI2 JU may play an important role in future.

The Human Resources team will implement the selection and recruitment actions.

Organisation development

Human resources will advise management on means and actions to enhance operational efficiency and effectiveness. Main actions planned shall be:

- Assignment of duties and responsibilities to best achieve fulfilment of objectives and tasks, in the particular context of the corporate reorganisation
- Establishment of clear and efficient reporting lines and set up necessary delegations of authority.
- Enhancement of co-ordination between the different activity cluster areas.

HR management

HR will deal with core functions such as day-to-day management of administrative workflows and process, performance management and assessment, safety and wellbeing at work, salary, compensation and benefits, employee motivation, communication, and training. In 2017, the first staff reclassification (promotion) exercise will take place.

Inter-JU cooperation

The efficiency and cost effective management of IMI2 JU resources is also based on a close collaboration with other Joint Undertakings through arrangements and mechanisms of pooling expertise for specific time-bound tasks. In 2017, the JUs will continue to share human resources IT tools, common calls for tender as well as a common approach to implementing rules of the EU Staff regulation.

2.4.5 Administrative budget and finance

Draft Budget Plan 2017

Subject to finalisation of the 2017 procedure by the EU Budgetary Authority, the forecast put forward in the draft annual budget plan for 2017 has been re-evaluated based on the available information. The budget of administrative expenditure has increased by 3.68% in 2017 compared to 2016, mainly due to increase in staff expenditures. A comparison table of the financial years 2016 and 2017 is set out below.

Heading Title 1		Financial year 2016	Financial year 2017	Evolution	Comments
Chapter		Budget EUR	Budget EUR	%	
11	Staff in active employment	4,893,000	5,242,000	7.13	1 new position of Temporary Agent in 2017 1 new position of Contract Agent in 2017 3.5% promotion and indexation
12	Staff recruitments - miscellaneous expenditure	20,000	20,000	-	
13	Missions and duty travels	190,000	190,000	-	
14	Socio-medical structure	230,000	230,000	-	
17	Representation	20,000	20,000	-	
	Title 1 - Total	**5,353,000**	**5,702,000**	**6.52**	

Heading Title 2		Financial year 2016	Financial year 2017	Evolution	Comments
Chapter		Budget EUR	Budget EUR	%	
20	Office building and associated costs	660,000	679,000	2.88	Building security and surveillance liability starting with 2016, total costs shared with the other JUs
21	Information technology purchases	560,000	592,000	5.71	Additional recurrent licenses

Heading Title 2		Financial year 2016	Financial year 2017	Evolution	Comments
Chapter		Budget EUR	Budget EUR	%	
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	68,000	68,000	0.00	
25	Expenditure on formal meetings	158,000	158,000	0.00	
26	Running costs in connection with operational activities	300,000	300,000	0.00	
27	External communication, information and publicity	625,000	625,000	0.00	
28	Service contracts	780,000	729,000	-6.54	Transfer to chapters 20 and 21
29	Expert contracts and cost of evaluations	700,000	700,000	0.00	
	Title 2 - Total	**4,127,000**	**4,127,000**	**0.00**	
	Total Running Costs	**9,480,000**	**9,829,000**	**3.68**	

The operational budget is covered under section 2.2.2. Calls for proposals.

A table overview of the 2017 draft budget is set out in Chapter 3 of this Annual Work Plan.

Financial Management

During 2017, 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. 2016 Financial Year accounts will be for the first time audited by an external audit firm (see also Section 2.6.3).

2.4.6 Data protection

Objectives	To prepare the implementation of the General Data Protection Regulation 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 prepare the implementation of the General Data Protection Regulation and in particular: ▪ increased accountability: advise controller and data processors on their upcoming responsibility and liability for further processing ▪ higher data handling standards: re-define the Data Protection Officer role (e.g. performance of data protection impact assessments, further recording of processing activities and collection of evidence for obtaining consent); ▪ data security: establish internal procedures in relation to the use of technologies ▪ transparency: analyse the implications of changes in consent and the shifting of the burden of proof for compliance. 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, that Regulation (EC) 45/2001 is complied with and that the transition to the application of the General Data Protection Regulation is handled smoothly. Actions: ▪ train newcomers ▪ inform IMI staff on data protection matters during internal meetings ▪ provide advise upon request ▪ support the preparation of internal notifications ▪ prepare prior-checking notifications and/or their updates ▪ attend EDPS and Data Protection Officers meetings ▪ prepare standard operating procedures

Access to documents

IMI will continue to address requests for access to IMI documents according to Regulation (EC) No 1049/2001, in a spirit of openness and transparency in order to bring its activities and output closer to the public.

The objectives of actions in this field will continue, as a means to keep high level of public confidence in IMI2 JU by giving the opportunity to the public to monitor its work. In addition, this will bring additional benefits such as:

- Improving public awareness of IMI activities and processes;
- Stimulating the interaction on key issues.

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 of the IMI2 JU providing its advice in written form. The specific tasks of the Scientific Committee are outlined in Article 10 of the Statutes of the IMI2 JU and include advising on the scientific priorities to be included in the SRA taking into account related activities in Horizon 2020; advising on the scientific priorities to be addressed in the annual work plans and advising on the scientific achievements described in the annual activity report. The Chair will participate in Governing Board meetings as observer.

It is planned that the Scientific Committee shall meet at least twice in 2017 at dates to be proposed by the Chair of the committee. Additional meetings in 2017 may be convened at the request of the Chair or Vice-Chair of the Scientific Committee, the Governing Board or the Executive Director.

The **States Representatives Group** will be consulted on the Annual Work Plans and will receive information on Calls and proposals, evaluation process. At least two meetings of the States Representatives Group are planned for 2017. The Chair will participate in Governing Board meetings as observer.

In order to cover all areas of life science research and innovation of public health interest and to further develop the IMI2 JU objectives, IMI2 JU will pursue its action to attract a wide range of legal entities, notably offering the possibility to become **Associated Partners** at programme or topic level.

The **Strategic Governing Groups** (SGGs) ensure the coordination of IMI 2 JU's work in certain strategic areas and work to make the development of new topics more transparent and effective. As such, the SGGs are made up of representatives of companies active or interested in the area covered by the scope of the SGG as well as representatives from the European Commission, the IMI Programme Office and the IMI Scientific Committee. Currently, the seven established SGGs focus on the following areas: Immunology; Diabetes / metabolic disorders; Neurodegeneration; Translational safety; Data and knowledge management; Infections control, and Oncology.

In 2017 the SGGs will continue to develop comprehensive strategies for future projects for their specific areas. Each SGG will meet on a regular basis to discuss their portfolio of projects and ensure synergy with ongoing projects, both IMI 2 JU and non-IMI2 JU. They may engage with external parties to consult on topic development or key challenges in specific areas as required. Efforts will be made to enhance communication with these bodies as well as seek and feedback on any significant IMI activities and developments. In addition, they will be called upon to advise on how best to exploit IMI projects outputs, enhance cross-projects' collaboration as well as explore synergies with similar or complementary activities at national and global level.

In line with article 13.3 (b) of IMI2 JU Regulation, costs of activities related to allowing the SGGs perform these tasks and achieve their objectives are considered as eligible in-kind contributions under the conditions set out in the SGG charter[27].

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.

[27] http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_GB_DEC_2016_21_Decision_on_new_SGGs_Charter_SIGNED_30SEP2016.pdf

2.6 Internal Control framework

Internal control

The overarching objective of the IMI2 JU internal control system is to ensure the adequate management of the risks relating to the legality and regularity of the underlying transactions. In this view, the 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 through a combination of processes, procedures and supervision, notably including ex ante and ex post controls and 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 (IAS) 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 2017 will also be to assess the Internal Control Standards (ICSs) capability to better meet the expectations of IMI2 JU's Members and stakeholders in terms of efficiency, effectiveness and flexibility. In this context, a revision of the standards may be considered and planned on a multiannual basis, in order to develop for IMI2 JU a quality management system.

2.6.1 Financial procedures

The IMI2 JU 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 2017 will be the optimisation 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) reduce cost of operations ensuring enhanced sound financial management. Actions taken and further planned will then contribute to:

- Continue the adoption and implementation of revised internal control strategies, procedures and workflows;
- Improve efficiency of ex-ante controls, especially of operational expenditure,to reduce the risk of undue payments and administrative errors;
- complete the implementation of harmonized reporting and payment workflows which incorporate the automated financial circuits and are supported by the common grant management IT system (SyGMa-Compass with full integration with ABAC).

2.6.2 Ex-ante and ex-post controls

For projects running under the IMI1 programme, the Programme Office will carry on with the implementation of its ex-post audits strategy as a means to ensure the legality and regularity of operational expenditure. This strategy complements ex-ante controls embedded in IMI's management processes and includes the correction of any amounts found to have been paid in excess. Errors of a systematic nature will also continue to be extended to cover unaudited financial statements ('Form C') of the same participants.

Representative and, if necessary, risk-based audits of beneficiaries will be launched during the year to cover new cost claims received and validated by IMI since the last audited period. In parallel, independent reviews of submitted certificates of in-kind methodology as well as risk-based audits of accepted declarations of in-kind contributions by EFPIA companies will also be continued and followed-up.

As regards the IMI2 JU programme, the Commission Common Audit Service (CAS) will carry out the H2020 audits in accordance with its common audit strategy, as part of the harmonisation effort of the Horizon 2020 Framework. IMI2 JU contributes to the development and implementation of the audit programme in close cooperation with CAS. The harmonised legal framework will enable IMI2 JU to draw an additional element of assurance from extension of audit results on shared beneficiaries across the H2020 programme.

In line with the IMI2 JU Regulation, controls of in-kind contributions by EFPIA companies will be based essentially on review of audit certificates provided annually by independent auditors.

2.6.3 Internal and External audits

The audit environment is an assurance and accountability pillar within the IMI2 JU 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 JU'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 European 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.

In 2017, the Audit manager will contribute to the overall corporate objective of receiving an unqualified ('clean') ECA audit opinion and positive statement of assurance.

The ECA will audit and issue opinion on the legality and regularity of the underlying transactions. In accordance with the revised IMI2 JU Financial rules, IMI2 JU's 2016 annual accounts will be audited by external audit company while the Court will draw opinion on the basis of their work.

The Audit Manager will continue to examine and evaluate risk management, control and governance processes of the IMI2 Joint Undertaking to provide independent assessment and consulting aimed at adding value and improving IMI2 JU's operations.

2.6.4 Anti-Fraud strategy

Anti-fraud measures are an essential part of sound financial management required under the EU Financial Regulation. They also safeguard the financial interests of the Joint Undertaking and contribute to its reputation. Based on its Anti-Fraud Strategy (AFS) - adopted in 2016 in line with the Research Anti-Fraud Strategy (RAFS) - the IMI2 JU activities will implement throughout 2017 its Action Plan focusing 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;
- Training the staff (especially agents involved in direct grant management) and 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;
- Coordination with the research family members in the field of anti-fraud maintaining operational contacts with the Fraud and Irregularity Committee for Research (FAIR) ant the European Anti-fraud Office (OLAF). All cases of suspected fraud are reported to OLAF, there is no target. Official cases shall be regularly monitored and reported in the annual activity report, as well as the number of cases relevant to IMI initiated directly by OLAF.

3 Draft Budget 2017

An overview of the 2017 draft budget per chapters is set out below.

	Heading Revenue	Financial year 2017		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
10	European Commission contribution (including EFTA contribution)	182,953,171	201,697,134	Commitment appropriations include EUR 4,914,500 for running costs and EUR 178,038,671 for operational costs. Payment appropriations include running costs of EUR 4,914,500 and operational costs of EUR 196,782,634.
	Title 1 - Total	**182,953,171**	**201,697,134**	
20	EFPIA contribution	4,914,500	4,914,500	EFPIA contribution to IMI JU running costs.
21	Subsidy from other Members other than the Union and the Associated Partners, or their constituent entities or their affiliated entities	-	1,000,000	Four EFPIA companies (Sanofi Pasteur SA, Abbott Biologicals BV, Seqirus UK Limited, GlaxoSmithKline Biologicals S) contribution to operational payment appropriations
	Title 2 - Total	**4,914,500**	**5,914,500**	
30	Associated Partners contributions	-	1,831,000	Bill and Melinda Gates Foundation contribution to operational payment appropriations
	Title 2 - Total	**-**	**1,831,000**	
	Total contributions	**187,867,671**	**209,442,634**	

Statement of Expenditure				
Heading Title 1		**Financial year 2017**		**Comments**
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
11	Staff in active employment	5,242,000	5,242,000	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	Socio-medical 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	**5,702,000**	**5,702,000**	

Heading Title 2		Financial year 2017		Comments
Chapter		Commitment Appropriations (CA)	Payment Appropriations (PA)	
20	Office building and associated costs	679,000	679,000	Rent, works, common/IMI charges and parking. Additional costs: indexation, insurance, water/gas, electricity, heating, maintenance + repairs, security and surveillance.
21	Information technology purchases	592,000	592,000	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	729,000	729,000	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	**9,829,000**	**9,829,000**	

Heading Title 3		Financial year 2017		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
30	Implementing the research agenda of IMI JU	178,038,671	199,613,634	Grant agreements - Payments
Title 3 - Total		**178,038,671**	**199,613,634**	
Total contributions		**187,867,671**	**209,442,634**	

An overview of the 2017 draft budget and structure per budget lines is set out in the table below.

Expense budget line	Description	Commitment appropriations	Payment appropriations
A01100	Staff in active employment and costs linked to employment	3,576,000	3,576,000
A01101	Family Allowances	361,000	361,000
A01102	Transfer and expatriation allowance	391,000	391,000
A01110	Contract Agents	576,000	576,000
A01111	Seconded National Experts	0	0
A01130	Insurance against sickness	95,000	95,000
A01131	Insurance against accidents and occupational diseases	14,000	14,000
A01132	Unemployment insurance for temporary staff	38,000	38,000
A01133	Pension	0	0
A01140	Birth and death allowance	10,000	10,000
A01141	Annual travel costs from the place of employment to place of origins	57,000	57,000
A01144	Fixed local travel allowances	3,000	3,000
A01149	Other allowances	0	0
A01172	Cost of organizing traineeships within IMI	16,000	16,000
A01175	Translation and typing services and work to be contracted	0	0
A01177	Other services rendered	5,000	5,000
A01178	PMO fees	41,000	41,000
A01180	Sundry recruitment expenses	0	0
A01181	Travelling expenses (taking up duty)	5,000	5,000
A01182	Installation allowance	42,000	42,000
A01183	Moving expenses	0	0
A01184	Temporary daily allowance	10,000	10,000
A01190	Weightings (correction coefficient)	2,000	2,000
A01191	Salaries adaptation	0	0
11	**Staff in active employment**	**5,242,000**	**5,242,000**
A01200	Miscellaneous expenditure on staff recruitment	20,000	20,000

Expense budget line	Description	Commitment appropriations	Payment appropriations
12	**Staff recruitments - miscellaneous expenditure**	**20,000**	**20,000**
A01300	Mission expenses	190,000	190,000
13	**Missions and duty travels**	**190,000**	**190,000**
A01401	Socio-medical structure	0	0
A01410	Other trainings	60,000	60,000
A01430	Medical service	5,000	5,000
A01440	Trainings covered by the SLA	6,000	6,000
A01490	Other interventions	159,000	159,000
14	**Socio-medical structure**	**230,000**	**230,000**
A01700	Representation expenses	20,000	20,000
17	**Representation**	**20,000**	**20,000**
	Title 1 - Total	**5,702,000**	**5,702,000**
A02000	Rentals	570,000	570,000
A02001	Guarantees	0	0
A02002	Contributions	0	0
A02010	Insurance	0	0
A02020	Water gas electricity and heating charges	80,000	80,000
A02030	Cleaning and maintenance	0	0
A02040	Furnishing of premises (works)	10,000	10,000
A02050	Security and surveillance	19,000	19,000
A02090	Other expenditure on buildings	0	0
20	**Office building and associated costs**	**679,000**	**679,000**
A02101	Hardware, infrastructure and related services	168,000	168,000
A02102	Software development, licenses and related services	424,000	424,000
A02103	Other expenses maintenance and repair	0	0
21	**Information technology purchases**	**592,000**	**592,000**
A02200	Purchase	123,000	123,000
A02201	Rentals	10,000	10,000
A02202	Maintenance utilisation and repair	20,000	20,000
A02203	Other office equipment	0	0
22	**Office equipment (movable property and associated costs)**	**153,000**	**153,000**
A02300	Stationery and office supply	40,000	40,000
A02320	Bank charges	0	0
A02321	Exchange rate losses	0	0
A02329	Other financial charges	0	0
A02330	Legal expenses	0	0
A02350	Other operating expenditure	13,000	13,000
A02351	Petty expenses	0	0

Expense budget line	Description	Commitment appropriations	Payment appropriations
A02360	Library stocks purchase of books and subscriptions	44,000	44,000
A02370	Translation interpretation	26,000	26,000
23	**Current administrative expenditure**	**123,000**	**123,000**
A02400	Correspondence and communication expenses	68,000	68,000
24	**Telecommunication and postal expenses**	**68,000**	**68,000**
A02500	Formal meetings	158,000	158,000
25	**Expenditure on formal meetings**	**158,000**	**158,000**
A02600	Running costs in connection with operational activities	24,000	24,000
A02601	Events	0	0
A02602	Workshops	270,000	270,000
A02603	Knowledge Management	6,000	6,000
26	**Running costs in connection with operational activities**	**300,000**	**300,000**
A02700	External communication	225,000	225,000
A02701	Events	300,000	300,000
A02702	Material	100,000	100,000
27	**External communication, information and publicity**	**625,000**	**625,000**
A02800	Ex-post Audits	615,000	615,000
A02801	Studies, consultancy	114,000	114,000
A02802	Audit services	0	0
28	**Service contracts**	**729,000**	**729,000**
A02900	Evaluation Experts meetings	600,000	600,000
A02901	Evaluation Facilities	100,000	100,000
A02902	Evaluations ENSO	0	0
29	**Expert contracts and cost of evaluations**	**700,000**	**700,000**
	Title 2 - Total	**4,127,000**	**4,127,000**
B03000	Implementing the research agenda of IMI1 JU	0	120,000,000
B03001	IMI 1 Call 1	0	0
B03002	IMI 1 Call 2	0	0
B03003	IMI 1 Call 3	0	0
B03004	IMI 1 Call 4	0	0
B03005	IMI 1 Call 5	0	0
B03006	IMI 1 Call 6	0	0
B03007	IMI 1 Call 7	0	0
B03008	IMI 1 Call 8	0	0
B03009	IMI 1 Call 9	0	0
B03010	IMI 1 Call 10	0	0
B03011	IMI 1 Call 11	0	0

Expense budget line	Description	Commitment appropriations	Payment appropriations
B03012	ENSO 2012	0	0
B03013	ENSO 2013	0	0
B03020	Implementing the research agenda of IMI2 JU	178,038,671	79,613,634
B03021	IMI 2 Call 1	0	0
B03022	IMI 2 Call 2	0	0
B03023	IMI 2 Call 3	0	0
B03024	IMI 2 Call 4	0	0
B03025	IMI 2 Call 5	0	0
B03026	IMI 2 Call 6	0	0
B03027	IMI 2 Call 7	0	0
B03028	IMI 2 Call 8	0	0
B03028	IMI 2 Call 9	0	0
B03030	IMI 2 Call 10	0	0
B03031	IMI 2 Call 11	0	0
B03032	IMI 2 Call 12	0	0
B03033	IMI 2 Call 13	0	0
B03034	IMI 2 Call 14	0	0
B03035	IMI 2 Call 15	0	0
B03999	Recovery Ex post audit	0	0
30	**Implementing the research agenda of IMI JU**	**178,038,671**	**199,613,634**
	Total expenditures	**187,867,671**	**209,442,634**

3.1 Staff Establishment Plan

Grade	Establishment Plan 2016			Year 2017											
				Posts evolution						Organisational evolution			Establishment Plan 2017		
				Promotion / Career advancement			Turn-over (departures/arrivals)			New posts (per grade)			Requested (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		2	2											2	2
AD10															
AD9		3	3											3	3
AD8		7	7											7	7
AD7		6	6											6	6
AD6															
AD5		11	11											12	12
Total AD		**32**	**32**											**33**	**33**
AST11															
AST10															
AST9															
AST8		1	1											1	1
AST7															

Grade	Establishment Plan 2016			Year 2017											
				Posts evolution						Organisational evolution			Establishment Plan 2017		
				Promotion / Career advancement			Turn-over (departures/arrivals)			New posts (per grade)			Requested (Budget)		
	PERM	TEMP	TOTAL	Officials	TA - LT	TA - ST	Officials	TA - LT	TA - ST	Perm	TA - LT	TA - ST	Perm	TA	Total
AST6															
AST5															
AST4															
AST3		4	4											4	4
AST2															
AST1		1	1											1	1
Total AST		**6**	**6**											**6**	**6**
SC6															
SC5															
SC4															
SC3															
SC2															
SC1															
Total SC		**0**	**0**											**0**	**0**
Overall Total		**38**	**38**											**39**	**39**

Contract Agents Grade	2016	2017
FG IV	2	2
FG III	11	12
FG II	1	1
FG I	0	0
Total CA	**14**	**15**

Seconded National Experts	2016	2017
	0	**2**

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)

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