Annual Work Plan and Budget for 2018

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-2017-26 adopted on 15.12.2017

IMI reference: IMI2/INT/2017-00001

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1 Introduction

The year 2018 will mark the 10th anniversary of the launch of the very first Innovative Medicines Initiative (IMI) Call for proposals. As such, it is an excellent opportunity for IMI2 JU to assess and communicate on how far it has come and stimulate a discussion on IMI2 JU's current activities and future direction.

IMI2 JU will continue to focus on its core activity of launching Calls for proposals for projects that address key challenges highlighted in the IMI Strategic Research Agenda in areas such as diabetes/metabolic disorders, neurodegeneration, immunology, infection control (including vaccines), translational safety, data and knowledge management, and oncology.

In addition, as the results of the interim review of the IMI2 programme have been made public in October 2017, in 2018 IMI2 JU will focus on reviewing and implementing the recommendations made by the reviewers.

We have already started putting in place systems to address these recommendations. For example, a new set of relevant, accepted, credible, easy and robust key performance indicators is being defined. We have also developed a strategy to attract more small and medium-sized enterprises (SMEs) to IMI2 JU. We are also putting greater efforts into identifying our projects' most important outputs and communicating on them to a wider audience.

To ensure that IMI2 JU projects include a broad range of stakeholders, IMI2 JU will continue to reach out to priority groups like SMEs, patients, and regulators. IMI2 JU will also engage proactively with potential Associated Partners from the philanthropic and public sectors as well as companies from other industry sectors (e.g. ICT, imaging, medical technology, animal health, nutrition, etc.).

Throughout the year, the IMI2 JU Programme Office will strive to deliver work of the highest quality, following strict ethical standards, adhering to the principle of sound financial management and using appropriate checks and balances.

In the long term, these activities will help IMI2 JU to achieve its goals of accelerating and improving medicines development and ensuring that new discoveries are rapidly transformed into benefits for both the wider medical research community, and healthcare systems and patients.

Pierre Meulien

Executive Director

2 Annual Work Plan Year 2018

2.1 Executive Summary

The main goals of IMI2 JU in 2018 are set out as follows:

- Launching two new Calls for proposals based on scientific priorities set out in section 2.2.2.
- Successfully manage and connect 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.
- Implement the recommendations of the interim evaluation of IMI2 JU (completed on 30 June 2017, with conclusions and observations published on 9 October 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 IMI2 JU Programme Office towards enhanced efficiency and cost effectiveness.
- Carry out and implement audits and controls over beneficiaries that receive of IMI2 JU funding and companies' in-kind contributions.

2.2 Operations

2.2.1 Objectives & indicators - risks & mitigations

The key objectives for IMI2 JU operations in 2018 are identified by the Governing Board in the Annual Work Plan and by the Management at operational level.

Key operational objectives for 2018 are as follows:

- Initiate competitive calls for proposals within the Strategic Research Agenda priorities bringing together the different stakeholders involved in drug development (including SMEs, regulators and patient organisations) and foster cross-project collaboration through proactive outreach strategies and conducive call design;
- Ensure sound budget implementation through the efficient management of calls for proposals, grant award process and close monitoring of ongoing projects, ensuring the completion and close-out;
- Demonstrate the EU added value of IMI2 JU through assertive communication to target audiences of the openness, transparency, relevance, effectiveness, efficiency and coherence of IMI2 JU activities;
- Involve industry from related sectors other than the pharmaceutical industry (diagnostics, medical technologies industry, imaging, digital industry, etc.) in IMI2 JU projects through proactive outreach strategies;
- Ensure IMI2 JU internationalisation and build productive linkages to major international efforts to address Global Challenges (AMR, Alzheimer's, autism, cancer, emerging infectious diseases, etc.).

Key performance indicators (KPIs) of IMI 1[1] and 2[2] as set out by EU Council regulations and based on the current Scientific Research Agenda[3]

The KPI framework is under revision by IMI2 JU Governing Board, and will be incorporated in this Annual Work Plan early 2018.

Key Strategic Focus	Annual Objectives 2018	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2018 Target
		73/2008 of 20.12.2007[4]	557/2014 of 6.05.2014[5]			
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 IMI2 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 2018 that are addressed by IMI's calls for proposals launched in 2018	Extent of coverage of priority areas for 2018 as defined in Section 2.2.2	**KPI 1:** ≥4 priority areas from IMI2 JU's Annual Scientific Priorities for 2018
Scientific Output	IMI2 JU 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 IMI2 JU 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 IMI2 JU publications[6] per EUR10 million of total IMI2 JU funding requested by the projects	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.	**KPI 3:** ≥20 publications
				KPI 4: Target to measure	Latest available information from IT systems will be used for the calculation of	**KPI 4:** ≥10% higher

[1] COUNCIL REGULATION (EC) No 73/2008 of 20 December 2007 setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

[2] COUNCIL REGULATION (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking. *Official Journal of the European Union*. L 169/54. 7.6.2014

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

[4] OJ L 30 of 4.2.2008

[5] OJ L159 of 7.6.2014

[6] Covering all publications resulting from IMI2 JU projects from the start of IMI2 JU up the end of the year under review.

Key Strategic Focus	Annual Objectives 2018	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2018 Target
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				extent to which IMI2 JU's average impact factor of journals in which IMI2 JU publications[5] have been published is higher than the EU average **KPI 5:** Target to measure extent to which the citation impact of IMI2 JU publications[5] is higher than the EU average **KPI 6**: Target to measure the extent to which IMI2 JU's bibliometric indicators compare with those of other international funding bodies. Target to compare the citation impact of IMI2 JU 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[7] (**KPI 6.2**)	the estimated requested IMI2 JU funding by the end of the year under review. The benchmarking analysis with other international funding bodies to be performed by external contractor, applying internationally recognised standards and criteria	than EU average **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 standardisation	IMI2 JU projects translate key scientific discoveries into clinical practice and regulatory framework	▪ Article 2 ▪ Article 1(e) in Statutes of IMI2 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	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	**KPI 7:** ≥ 5 **KPI 8:** Baseline data will be collected in

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

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				guidelines derived from IMI2 JU projects **KPI 9:** Target to measure new standards and best practices derived from IMI2 JU projects	Activity Report. If necessary, additional complementary information may also be collected as part of an annual survey of the consortia. For KPI 8 and KPI 9, the methodology for capturing information and the baseline data for establishing the targets will be determined and compiled in 2018.	2018 **KPI 9:** Baseline data will be collected in 2018
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 IMI2 JU projects which have been reimbursed at least for the third year of implementation[8] **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 IMI2 JU projects **KPI 13:** Target to measure the estimated number of reported Full-Time Equivalents (FTEs) based in	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 2018. 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 IMI2 JU. [9] **KPI 11:** Baseline data will be collected in 2018 **KPI 12:** 25% of finalised projects **KPI 13: ≥ 1500**

[8] During 2018, initial baseline data will continue to be collected and analysed on the number of patents resulting from IMI2 JU projects, particularly on the first finalised projects.

[9] The calculation will be based on the total value of interim and final payments made by IMI2 JU 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.

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				the EU that can be considered as directly related to the IMI2 JU programme		
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 IMI2 JU IT applications. Participations in IM2 JUI 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 IMI2 JU 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 IMI2 JU IT applications for the project partners. Participations in IMI2 JU 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 2018.	**KPI 16:** 100% **KPI 17:** Baseline data will be collected in Q1 2018
Impact on society	IMI2 JU projects address the unmet healthcare needs,	▪ 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	**KPI 18:** Baseline data will be collected in 2018

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	e.g. chronic, emerging or diseases lacking effective treatment				baseline data for establishing the target will be determined in 2018.	
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 2018.	**KPI 19:** ≥10 000 **KPI 20:** Baseline data will be collected in 2018 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(l) in	▪ Article 1(f) in Statutes of IMI2 JU ▪ Article 1(f)	**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 IMI2 JU report on the budgetary and financial management	**KPI 22:** ≥95% **KPI 23:** ≥95% **KPI 24:** ≥95%

Key Strategic Focus	Annual Objectives 2018	Link to the Council Regulations setting up IMI JU & IMI2 JU		Selected Key Performance Indicator (KPI)	Method	2018 Target
		73/2008 of 20.12.2007[4]	557/2014 of 6.05.2014[5]			
	The Programme Office meets the maximum time limits for expenditure operations established by the EU	Statutes of IMI2 JU	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 IMI2 JU 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. That further enables the prioritisation of actions to reduce the risks to an acceptable level. This section gives an overview of the risks and corresponding mitigating actions identified by the IMI2 JU Programme Office to support the achievement of the strategic goals and objectives set out above.

The risk assessment on the objectives and actions planned for 2018 shows in particular that some strategic risks identified are associated with IMI2 JU mission and have therefore to be accepted as such thus the IMI2 JU has planned appropriate mitigating measures to control any possible adverse effects This is typically the case of:

- Insufficient participation of non-pharma industry and SMEs as well as limited leverage effect of private contributions.
    - Control measures planned aim at developing new partnerships and promoting IMI2 JU visibility at international level through targeted actions by area and in collaboration with projects. This will ensure that the IMI2 JU brand is enhanced by the international strategy and relationship. In addition, joint IMI-EFPIA events are planned at regional and national level involving industry and policymakers. Furthermore, the IMI website is promoting different ways of contributing to IMI projects as Associated Partners and Partners in Research. Finally, on the specific issue of SME participation IMI2 JU and EFPIA are exploring new initiatives (such as incubator models) and potential call topics targeting SMEs (focusing on areas of new technology where standardisation and interaction between SMEs and large pharma companies could accelerate the development of innovative solutions such as sensors or organ-on-a-chip platforms).
- In addition, the IMI2 JU rogramme may be affected adversely by factors such as delay in defining the annual scientific priorities and call topics, insufficient comprehensibility of the participation process, low budget execution and postponement of project conclusion. The risk is that IMI2 JU may be perceived as unable to meet the needs of patients and the scientific community losing scientific attractiveness and stakeholders' (especially SME) involvement, resulting in low participation to calls and unsatisfactory programme implementation.
    - In view of ensuring efficient management of the grant award process and optimal budget implementation on ongoing projects, the IMI2 JU Programme Office is reinforcing its monitoring activities in liaison with all project coordinators in order to:
        - reassess the project needs and the work plan;
        - thoroughly review the overall need for payments appropriations in 2018 as the basis for a revised forecast;
        - enhance interactions between science and finance operations;
        - closer monitoring of the high-risk projects.
    - Furthermore, IMI2 JU will continue i) to implement the reengineered Call topic definition process reinforcing the Strategic Governing Groups (SGG) as thematic platforms addressing defined areas under the umbrella of the IMI2 JU SRA and ii) to search the advice of patients through the Patient Advisory Committee (PAC).
- Unbalance – at the end of the programme – between the EU financial contribution and the in-kind contribution provided by industry.
    - Measures to control and mitigate this risk are the systematic monitoring of projects' financial management made by the IMI2 JU Programme Office on the periodic report received from coordinators associated with ex-post control of costs incurred in indirect actions by industry and associated partners planned according to a risk-based plan.

- Finally, the risks of negative external perception at political level due to inaccurate comments about IMI in the press and other public fora have been identified.

    - IMI is promoting an ambitious communication strategy to demonstrate, in a spirit of openness and transparency, the results achieved by the partnership. To that end, the IMI2 JU will be proactive in identifying and promoting stories that highlight IMI's successes. The Programme Office shall also maintain close relationships with key decision-makers to ensure they have an informed view of how IMI works and its successes.

Concerning risks related to the performance of the Programme Office and operations, particular attention will be given to the organisational structure and staff allocation, especially as regards project management activities, the efficiency of which is dependent upon a sound interaction between science and finance. This is considered crucial by the 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 are 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, as UK stakeholders have largely contributed to the IMI success and the consequences of Brexit remain unpredictable, the IMI2 Governing Board will continue to monitor within the EU's broader political agenda the potential impact of Brexit on its strategy and programme implementation.

2.2.2 Scientific priorities for 2018

The IMI2 JU activities for 2018 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 improving 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/about-imi/strategic-research-agenda). The SRA identifies a set of scientific priorities where IMI attempts to pilot new ideas in a real life, 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.

In order to achieve its objectives, the IMI 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 resulting from the 2018 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.

Small- and medium-sized enterprises (SMEs) have an important role in strengthening the competitiveness and industrial leadership in the European Union. In addition SMEs involvement might offer a complementary perspective to industry and the academia, and help deliver the long-term impact of IMI2 JU. Thus IMI2 in 2018 will increase its efforts for engaging SMEs in all its activities and encourages their involvement in applicant consortia.

IMI has identified eight scientific priorities, broken down into several topics, for 2018, 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 2018 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 2018 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 2018 would then be updated accordingly.

To implement the 2018 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 foreseen for Q1 and Q3 in 2018.[10]

Topics launched on the basis of this Annual Work Plan 2018 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.

[10] 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 being involved 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 health system sustainability of treatment intervention.

Activities in 2018 will address the following topics:

1. **A clinical reference baseline database in support of flexible clinical trial designs in the area of metabolic diseases.** A clear and unequivocal assessment of the benefits and advantages of novel drug candidates to treat type 2 diabetes (T2D) in clinical trials is very challenging. This is caused by, among other factors, the heterogeneity of the T2D population, and the lack of understanding of the impact of the multidrug treatment of diabetic patients on clinical outcomes, and of the incidence of safety outcomes which are not-treatment-related and potentially inherent to the disease.
   In this context, the objective is to create a pooled database of safety data collected from the placebo/standard-of-care arms of clinical drug trials performed in T2D patients by industry and clinical institutions. This should include 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 anonymised patient information to build a reference baseline database of individuals with diabetes and metabolic disorders to enable flexible and stratified clinical trial designs.

2. **The role of the gut Microbiome as modulator of type 1 Diabetes: Need for a systematic and integrated approach.** In the past years, major scientific interest has grown to elucidate the possible role of the microbiome in health and disease. The relevance for understanding the role of the microbiome in complex diseases like cancer, Parkinson´s disease or T2D is high but strongly hampered by the heterogeneity of these disease populations and the complexity of their disease mechanisms. Therefore, a systematic approach to study the microbiome in a homogeneous disease like type 1 diabetes (T1D) with careful clinical phenotyping and deep-dive analysis of immune, genetic, ß-cell and 'omics`-biomarker could be the first step in elucidating the role of the gut microbiome in maintenance of health. A better understanding of the complex interactions between the intestinal microbiota and several functional systems of the body like the immune system, intestinal integrity and function, intermediary metabolism, ß-cell function and others may provide new and scientifically rational approaches for diagnosis, prediction and therapeutic options to prevent the decline of pancreatic ß-cells and the development of type 1 diabetes. The objective of this topic is the systematic elucidation of the gut microbiome in T1D individuals, already recruited and deep phenotyped, with integration of functional and taxonomic microbiome results with clinical phenotyping and immune, genetic, ß-cell and broad 'omic`-analysis. The IMI2 INNODIA project has created a unique European clinical infrastructure recruiting, deep-dive phenotyping and biosampling newly diagnosed T1D subjects and at-risk relatives (around 5000 individuals) which represents an extremely valuable resource to build on to tackle this challenge in a timely way.

3. **Future of Diabetes/Metabolic Disorder healthcare Coordination and Support Action.** On 5-6 April 2017 senior research executives from the leading diabetes pharma companies together with leading experts of existing and upcoming players in diabetes healthcare (e.g. payers, regulators, patient organisations, physicians, medical device and Big Data / m-health companies) came together for the 1st " Diabetes / Metabolic Disorder Forum" and reflected on how to connect the dots to develop a holistic view on how the Diabetes/Metabolic Disorders space may look in 10 to 15 years from now. They discussed future challenges and opportunities for identifying the "unknown unknowns", novel trends and needs of patients considering the following aspects: 1) Being holistic in the context of Precision Medicine; 2) Covering the entire spectrum of the Cardio-metabolic Continuum; 3) Full integration of basic research with clinical research and 4) deployment into medical practice in line with IMI2 goals. Building on this blue print this topic covers collaborative and support activities needed to address the identified critical challenges in this area and to explore the "unknown unknowns" some of which will present disruptive game changers in the field of diabetes/metabolic disorders care. This will include activities to enable a wide engagement of key stakeholders (workshops), to understand what has been achieved in other initiatives and to consolidate all these aspects. This will be supported by proactive communication activities to engage key stakeholders and opinion leaders.

Along these lines the “Diabetes Forum” should be established as an annual event bringing together key stakeholders in diabetes/metabolic disorders to develop improved healthcare concepts for this pandemic of the 21st century.

Expected impact:

- 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.
- Pave the way for integrated healthcare solutions for Diabetes / Metabolic Disorders in different geographical regions

Type of actions:

Research and Innovation Actions and Coordination and Support Actions

B. Neurodegeneration and other Neuroscience Priorities

The priority area neurodegeneration aims to address the high unmet medical need for effective disease-modifying and improved symptomatic interventions, as well as relevant companion diagnostics, for neurodegenerative disorders in general and Alzheimer's disease (AD) in particular. The priority area addresses the following themes: 1) increasing disease aetiology understanding for new drug target identification & validation as well as predictive animal models; 2) development of translational model systems and identification/validation of biomarkers;; 4) improving clinical trial capabilities and methodologies 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) strengthen our understanding of the effect of pain in rare diseases and improve its treatment; 3) clinical trial methodologies in migraine and headache.

Activities in 2018 will address the following topics:

4. **Tau imaging**. The topic supports activities for accelerating development of tau radioligands. The final aim is to enhance exploitation of tau Positron Emission Tomography (PET) imaging as a target engagement biomarker for emerging tau therapies, and to enable its use in Alzheimer's disease clinical trials (e.g. for patient selection and outcome measures) and clinical practice.

5. **New genes as Alzheimer's disease modifiers:** The topic supports activities enabling the identification of novel, validated targets. A platform should be developed that covers new biological and phenotypic approaches for improved disease understanding based on systems biology.

6. **Immune system and Alzheimer's disease.** This topic supports activities to further explore the role of the innate immune system n neurodegeneration, complementing the TREM2/CD33 activities launched in 2016.

7. **Progress in experimental modelling of Alzheimer's disease.** The topic supports activities aimed to develop new experimental model systems that mimic Alzheimer's disease.

8. **Premotor Parkinson's disease.** The topic objective is to develop new approaches towards pre-motor status definition and validation of Parkinson's disease including interaction with regulators.

9. **Synaptic plasticity**. The topic supports activities for the development of predictable animal models and predictive early translational clinical models or biomarkers, such as a physiological marker of synaptic dysfunction, which is altered in early AD (at very least in prodromal subjects, preferably in pre-symptomatic subjects). These should be sensitive enough to detect both abnormalities versus healthy controls and pharmacological intervention.

10. **Early markers of progression in Alzheimer's disease**. The topic supports activities for the identification of early markers of progression of AD to facilitate recruitment into - and read out of - clinical trials, including biomarkers of synaptic dysfunction.

11. **Personalised treatment for Parkinson's disease patients.** The topic supports activities to enable the development of innovative personalised treatments for Parkinson's disease using a biomarker approach.

12. **Identification and validation of novel pain targets / pathways with disease-modifying potential:** The topic supports activities for the analysis of tissue samples from pain patients using omics-scale technologies to increase disease understanding, and for the development of new platforms to facilitate future drug screening.

13. **Pain in rare diseases.** The topic objective is to strengthen the understanding of the effect of pain in rare diseases, and to identify and facilitate activities to improve the treatment of individuals where pain constitutes a major component of their symptoms and disability (e.g. to understand the association between a rare disease's pathophysiology and its manifested pain symptoms to identify novel targets and treatment approaches, to establish registries that provide patient-oriented or professional-oriented information about the time course or intensity of pain or pain-related disabilities in rare diseases).

14. **Clinical endpoints in headache medicine**. The objective of the topic is the exploration and validation of clinical endpoints in abortive and preventive migraine and headache trials in adult and paediatric populations. This may include the following abortive migraine trial endpoints: pain freedom, associated migraine symptoms, migraine-associated disability, quality of life, real-world evidence for functional outcome or treatment preference in different geographical regions. Preventive migraine trial endpoints for chronic and episodic migraine are: 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 should also be addressed.

Expected impact of the topics:

- Assignment of new functional roles to rare genetic variants implicated in disease causation.
- Accelerating tau tracers' development and better integration of novel imaging techniques into pharma development.
- 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.
- More efficient, cost-effective and successful use of Parkinson's and Alzheimer's disease model systems in support of the development of novel therapies and biomarkers.
- Improved understanding of pain mechanisms and increasing feasibility for drug development paving the way to new disease-modifying treatment options.
- Identification of novel pain treatment options positively impacting the quality of life of rare disease patients with significant pain.
- Better definition of clinical endpoints in acute migraine episodes and in chronic migraine and in headache.

Type of actions:

Research and Innovation 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. In addition there is an increased awareness that immune-mediated mechanisms play a key role in several, if not all, chronic diseases from cancer to metabolic disorders and therefore new immunology based approaches may be game changers for treatment of millions of patients affected by these conditions. Respiratory diseases in particular are relevant here. Within this remit, activities should seek progress towards novel diagnostic, monitoring and treatment paradigms for the mechanisms being involved in triggering the early onset, remission and progression of early lung diseases in particular, bronchiectasis, asthma, Chronic Obstructive Pulmonary Disease (COPD) and Idiopathic Pulmonary Fibrosis (IPF).

The proposed work will focus on a key set of immune mediated diseases or on disease mechanisms where working in partnership will benefit the knowledge base and accelerate delivery of drug treatments to patients. The proposed work will build on the knowledge base and infrastructure present within the European Union and the H2020 Associated Countries from ongoing research-based initiatives 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. This should aim to enable identification of potential targets for therapeutic intervention and early diagnosis of disease with predictive biomarkers, eHealth, digital or telemedicine tools, to allow the development of experimental medicine approaches to safe and efficacious treatments, considering also health system sustainability of treatment intervention.

Last but not least understanding the role of the microbiome on immune disease and immune components of disease in general is an important challenge to be addressed.

Activities in 2018 will address the following topics:

15. **Targeted immune intervention for treatment of non-response and remission.** A high percentage of patients suffering from immune-mediated disease do not respond well or at all to currently available treatments and many relapse on treatment or show exacerbations. There is a lack of mechanistic understanding of non-response combined with an absence of biomarkers to predict clinical response. The topic objective is to identify molecular mechanisms that can be targeted to control immune-mediated exacerbation and relapse. This will be achieved by studying patients that respond and do not respond to treatment, as well as placebo patients. The aim is to identify new approaches to 1) characterise human immune-mediated diseases, 2) trace and analyse immune cells, 3) perform early clinical trials (e.g. in patient populations pre-enriched for certain molecular pathways; adaptive and basket trial designs etc.) and 4) identification of potential novel patient-centric treatment approaches. The topic will focus on patients from well-characterised immune-mediated diseases (e.g. Rheumatoid Arthritis (RA), Multiple Sclerosis (MS), Asthma, Chronic Obstructive Pulmonary Disease (COPD), Inflammatory Bowel Disease (IBD), Lupus).

16. **Characterisation of human immunology mechanisms.** The topic focusses on the role of the interplay and crosstalk of tissue and immune system for progression/remission of immune diseases. This includes identification of new epigenetic and non-epigenetic therapeutic targets, biomarkers and diagnostics involved in immune mediated diseases. Activities covered by the topic are those aimed to the discovery/validation/benchmarking of disease-relevant actionable parameters in blood (i.e. liquid biopsies) to improve and enable human target validation, model system selection, patient stratification, informative Proof of Concept endpoints and overall more effective, safer therapies.

17. **Non-invasive molecular imaging of immune cells.** Current pharmacodynamic assessments of immune cells are based on peripheral blood biomarkers, or on biopsies acquired by invasive procedures, while current imaging tracers provide limited information on disease-relevant immune cell subtypes, or measures of direct engagement of immune targets. The topic objective is to study how immunotracers designed to bind specific immune cell biomarkers may enable the clinical imaging of immune cell subtypes and immune markers of disease. Activities supported are those that will provide in vivo insights into effects of immunomodulatory therapies at disease sites (organs/tissues), improve knowledge about the pathophysiology of various immune-mediated diseases, and enable patient stratification based on immune signatures.

The topic also addresses how molecular imaging agents, (hybrid) imaging modalities, and image processing algorithms to image immune cells in vivo can provide an immediate, non-invasive read-out of target expression over time. Furthermore novel imaging agents and technologies will need to be developed, in order to extend the applicability of immune cell imaging to additional disease areas, additional tissue sites, and/or immune cell subpopulations. The final objective is to extend the current markers and validate them extensively for clinical use.

18. **Early disease interception of immune dependent disease.** The topic supports activities to enable earlier diagnosis of an immune disease and enable early disease interception and more effective patient treatment to improve quality of life. Activities should aim among others 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 focusses 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 objective is also to develop ways to prosecute newly identified targets via the use of tool molecules, or drug repositioning with clinical trial cohorts.

19. **Emerging technologies and tools for interrogating human immunobiology.** The overall objective is to enable the development of novel classes of immuno-modulatory medicines of high safety. To this end the topic supports activities for 1) the development of a predictive safety assessment for immuno-modulatory drugs; 2) the establishing and validating non-clinical tools i.e. technologies for in-situ molecular profiling of immune cells and ex-vivo technologies for recapitulating in vivo human immuno-biology.

20. **Fibrosis.** 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 objective is to study common underlying mechanisms of fibrotic diseases that offer the opportunity to explore cross disease approaches. The final aim is to identify, among others, immune-fibrotic pathways and cross talk. This should lead to new biomarkers, better patient stratification and in particular the identification of rapid progressors, empowering experimental medicine approaches across different disease settings.

21. **Immunology and the microbiome.** The topic objective is the understanding of the impact of the microbiome on immune disease development, and of how learnings can be applied across therapeutic areas. This could be part of an IMI2 microbiome research programme.

22. **Enhanced understanding of early respiratory disease.** This topic, building on the successful IMI collaborative effort and results within U-BIOPRED, has the objective of developing disease understanding in early respiratory disease cohorts to help define the progression to bronchiectasis, asthma, Chronic Obstructive Pulmonary Disease (COPD) and Idiopathic Pulmonary Fibrosis (IPF). The activities should also focus around beginning to understand the progression and the remission of asthma in the early cohort to enable switching off the drivers of the disease. Novel ways of monitoring progression and remission with predictive biomarkers, eHealth, digital or telemedicine tools should be explored.

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 in different geographical regions..
- Advance the understanding of disease mechanisms including epigenetics of immune and inflammatory disease for disease interception at the earliest stage, for progression, relapse, 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.

- Expanding our current knowledge will give rise to more precise, targeted treatments that can yield long-lived reductions in disease and improved patient quality of life, fulfilling unmet medical needs in patient care.
- Options for improved treatment of respiratory patients to decrease their risk for morbidity and mortality, via a better understanding of disease progression, remission and the identification of reliable markers for its diagnosis and risk.
- Facilitating the design and interpretation of rationally designed stratified clinical trials via the better understanding and scientific base of the early respiratory disease population.
- Potential high impact on future guidelines to treat patients with respiratory diseases.

Type of actions:

Research and Innovation Actions

D. Infection control including vaccines

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

Antimicrobial resistance (AMR) continues to be a major global public health threat. 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 will focus on overcoming the barriers to the discovery, development and delivery of effective antibiotics; furthermore work on novel, resistance-breaking antibiotics should be supported.

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. Personalised 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 appropriate and most effective antibiotic.

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 utilisation of available immunisation measures.

Activities in 2018 will address the following topics:

23. **Sustainable European antibacterial clinical trial network.** This topic addresses the key challenges faced by antibacterial drug development such as: 1) lack of a vibrant antibacterial clinical development pipeline to address current and anticipated unmet medical needs in the treatment of serious drug resistant bacterial infections; 2) the time and cost involved in generating clinical data to both support the registration of new antibacterial agents and to provide the evidence to reliably diagnose and optimally treat drug resistant bacterial infections in general and in specific patient sub-populations are unstainable; 3) there are significant barriers to the integration of diagnostics into standardised care settings to optimise the use of antibacterial interventions and reduce drug resistant infections. The topic aims to deliver a sustainable clinical trial network that will build on existing capabilities within the European Union and the H2020 Associated Countries and connect internationally to deliver a global solution to the sparse antibacterial pipeline. The network should build off experiences in other diagnostic, preventative and therapeutic areas to serve as a platform to accelerate study start-up and overall recruitment timelines, improve quality and efficiency and reduce overall costs associated with clinical development programs for anti-bacterial medicines. The scope is to develop and implement in the European Union and the H2020 Associated Countries a globally leading and aligned sustainable Clinical Trials Network. The Clinical trial network should consist of 4 key segments that are discrete but also link expertise, resources and infrastructure where possible to establish a platform for the study of: 1) bacterial indications; 2) drug resistant infections; 3) paediatric studies; 4) validation of new diagnostics.

24. **Progress in tuberculosis research.** This topic supports preclinical and early clinical research activities on tuberculosis including activities aimed to shorten therapy and address AMR strains, as such this last aspect might become a component of topic number 23.

25. **AMR Accelerator.** The discovery and development of new antimicrobials to address AMR is an undisputed European and global challenge that is compounded by a low return on investment (RoI). This has subsequently led to a reduction in resources applied across the pharmaceutical industry and decline in scientific discoveries. Overall this situation has compromised the delivery of new options to treat and prevent resistant infections. This topic addresses these challenges by: 1) creation of a Capability Building

Network (CB Network) that will accelerate scientific discoveries to enable the AMR community to deliver new ways to treat and prevent Multiple Drug Resistance (MDR) infections. The CB Network should focus on precompetitive research in areas that are of specific interest and benefit to the AMR community as a whole. 2) Creation of multiple Portfolio Building Networks (PB Networks) that are vibrant and nimble collaborations between EFPIA companies and SMEs/academics that will advance the R&D pipeline of new and innovative agents to address AMR. 3) Increasing the overall investment in AMR research, via the CB and PB Networks, with minimal complexity for the groups involved. Reducing the complexity compared to normal IMI constructs will make funding from the AMR Accelerator one of the most attractive options for SMEs/academics in the AMR space globally.

26. **Novel immunisation technologies for next generation vaccines**. Innovative solutions to understand and measure the maturation of the immune system and to tackle emerging/unmet medical needs are needed. Approaches supported by the topic should 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.

27. **Coordination and Support Action for future vaccines R&D.** 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. This coordination and support action supports activities to address the key challenges and gaps identified in relation to e.g. vaccines R&D, awareness, education and training, and regulatory pathways.

28. **Hepatitis B therapeutics and improved preparedness** (pilot initiative)**.** 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 objective is to explore activities to support the development of new platforms that facilitate rapid delivery of novel and improved diagnostics, vaccines and treatments for these infections. This will include activities to advance and facilitate clinical development of Hepatitis B virus therapeutics (including therapeutic vaccines and immunotherapies).

Expected impact of the topics:

- A pipeline of promising new agents for tackling antibiotic-resistant bacterial infections, including AMR tuberculosis.
- 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.
- 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.
- Facilitated clinical development of hepatitis B therapeutics.

Type of actions:

Research and Innovation Actions and Coordination and Support Actions

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 (i.e. from the European Union and the H2020 Associated Countries) 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 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.

Activities in 2018 will address the following topics:

29. **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, improved in vitro models are needed that can prospectively help predict human toxicities using physiologically relevant human models, and retrospectively to aid in understanding preclinical to clinical translation of findings observed in in vivo animal studies, as well as understanding the relevance of mechanisms of action. 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 objective of the topic is to establish a Microphysiological system (MPS) biological unit, with organ compartments (such as Gastrointestinal system, liver, exocrine pancreas, circulating white blood cells…). All these compartments should be biologically functional and connected together in a physiological manner. At least three different species should be established, rat, dog (and/or monkey) and human, using either primary cells or preferably iPS-derived differentiated cells. The format, without being a high throughput set up, should be amenable to testing several compounds at different doses and durations. As some therapeutics may induce different toxicities or increase toxicity potential when applied to diseased tissues, animals, or higher risk patient populations (elderly, neonates) compared to healthy models that are typically used in preclinical assessments, a second phase would be the development and characterisation of diseased tissues or cells from genetically susceptible populations.

30. **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 impaired patients, children, the elderly and pregnant women. 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, this topic objective is 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.

31. **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. This topic supports activities 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

- Better prediction and understanding of toxicities of drugs.
- Reduce use of animals in toxicology studies.
- Accelerate clinical development programs.
- Deliver more efficient and effective treatments in elderly populations.

Types of action:

Research and Innovation Actions

F. Big data, digital health, clinical trials and regulatory research

This area of priority will address key areas that have the potential to be game changers for delivering access to innovative treatments for large patients populations: 1) the challenge and opportunities of the increasing digitalisation in health research and technology, including the need for developing and implementing regulatory strategies and policies for digital health technologies; 2) the challenge to fully leverage the opportunity offered by new technologies, digitisation, telehealth, the current concept of running clinical trials, how patients are recruited, how they are followed, how data are monitored and reported must be fully revisited. In this context pioneering multi-company platform trials such as I-SPY2 (breast cancer), IMI EPAD (prevention of Alzheimer's Disease), and GBM AGILE (glioblastoma multiforme) are already demonstrating the potential benefits of this approach; 3) finally, new capabilities to utilise real world data (RWD) offer powerful opportunities to complement the evidence obtained from clinical trials and this concept needs further development.

Activities in 2018 will address the following topics:

32. **Centre of excellence - decentralised, remote clinical trials.** Recruitment and retention of patients are known to be one of the most challenging aspects in completion of clinical trials. One of the three main barriers commonly reported that refrains patients from participating in a clinical trial is the geography and the distance to the clinical site. Telemedicine is viewed as the central capability needed for distributing meaningful parts of clinical trial activities out to community settings. The topic aims on disaggregating the current model of running clinical trials, defining building blocks and mapping new technologies (telemedicine, mobile health, blockchain approach to some of the processes e.g. e-consent) to support the new decentralised clinical trial (DCT) approach. Activities might include among others: 1) review of experience to date to define and share challenges, obstacles, minimal requirements and solutions in DCT/home monitoring; 2) definition of the decentralised ecosystem and stakeholders; 3) recommendations on the creation of a Centre of Excellence on decentralised clinical trials; 4) define an intermediary model: hybrid studies mixing DCT approach with classical models, alleviating the burden for patients (e.g. rare diseases); 5) setting up of initial pilot studies.

33. **Digital Transformation of Clinical Trials Endpoints.** The overall objective of this topic is to gain regulatory and payer acceptance of clinical endpoints and Quality of Life (QOL) metrics derived from remote, passive and pervasive measurement of heart rate (HR), heart rate variability (HRV), body movements and sleep. To start with, activities will address analytical validity wherein algorithmically derived sensor based measures of HR, HRV, sleep and body movement will be validated for accuracy against their respective 'gold standards': These are electrocardiograms (ECG) for HR/HRV, polysomnography for sleep, video monitoring for body movements. If this is successful, these analytically validated digital measures will be then incorporated into relevant longitudinal patient cohorts to establish relationships with selected clinical scales, hard clinical outcomes and QOL metrics.

34. **Data Lakes.** Advances in machine learning, present opportunities to interrogate large pools or lakes of data in both structured and unstructured ways. This may allow for the discovery of new drug targets, previously unknown response profiles and predictors of toxicity. The topic supports activities necessary to identify one indication/disease area to serve as a test case and "training dataset" to be used for defining algorithm validation criteria acceptable to regulators. New insights could provide value to society, particularly in difficult to treat conditions like Alzheimer's disease, obesity, metabolic syndrome/multi-morbidity populations, and certain oncology indications.

35. **Integrated research platform for patient-centric drug development.** The topic objective is to deliver a patient-centric" and highly efficient approach for medical research, through the combined approach of co-operation across companies and an Integration of Real World Data (RWD) with clinical platform trials. Activities include the establishment of "readiness cohorts" and "longitudinal natural history studies", and the creation of a patient-centric precision medicine enabling clinical trial platform that has the potential of allocating each patient to whatever treatment or combination of treatments is best for that patient, given the data. Synergies should be created from sharing inferences across all treatment arms, including common controls. Activities include the establishment of Integrated Research Platforms (IRPs) for five (5) disease areas (Crohn's Disease, major depressive disorder, non-alcoholic steatohepatitis, smouldering multiple myeloma and tuberculosis); the creation of a hospital network to support these IRPs and multi-stakeholder alignment on Common Elements for IRPs (i.e. best practices and guidance).

Expected impact of the topics:

- Expand and democratise clinical trial participation globally and expand use of telemedicine in areas of current low uptake, potentially improving health outcomes.
- Accelerate patient access to innovative medical treatments.
- Reduce patient burden while participating in clinical trials.
- Provide benefit to society by expanding access to healthcare via telemedicine.
- Enable more efficient and cost-effective clinical trials and real world studies.
- Create business opportunities and economic growth by bringing technology companies and sensor developers into medically regulated space and drive new developments in data standards and privacy safeguards.

Type of actions:

Research and Innovation Actions

G. Oncology

IMI2 via its strategic area of oncology aims to foster a significant progress towards the extension and quality improvement of the treatment for 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 personalised medicines; 3) speed of drug development; 4) treatment tolerability, and 5) cost effectiveness in cancer drug development.

In 2018 a major focus will be to harness progress in next generation sequencing (NGS) to seamlessly monitor the multitude of dynamic genetic determinants of an individual cancer phenotype and integrate this data with patient profiling to advance precision oncology using a pharmacogenomics based approach. This will include a better understanding of cross talk of signal transduction pathways and of the context specificity of tumours as well as the development of better tools and methods (i.e. liquid biopsies) to monitor the molecular cancer dynamics in time and space. Another area will be to further advance, using a multipronged approach, the field of immune-oncology in order to boost the patient population that can benefit from such therapies. Finally the development of data and knowledge management solutions to enable data quality, standardisation, interoperability and full re-usability of all data generated, including also patient reported outcomes, health economic and real world evidence /data will be necessary to ensure full exploitation of results to guide future advances to better treat cancer patients. It expected that some of the topics below may be launched as part of the large platform initiatives of the priority F: Big data, digital health, clinical trials and regulatory research, when this will be considered as adding to the impact.

Activities in 2018 will address the following topics:

36. **Beyond patient stratification.** The topic supports gathering of 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.

37. **Increasing context specificity.** This topic supports activities for developing 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.

38. **Immune oncology.** This topic supports activities to develop patient selection tools to identify responder populations for immune oncology (IO), IO-IO treatment combinations and / or IO targeted therapy.

39. **Cell free DNA – liquid biopsy.** The topic supports activities to explore the potential of cell free tumour DNA (cfDNA) assessment, as an alternative to classic biopsies.

40. **Big data in oncology.** The topic supports activities for the creation of a centralised 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 visualisation 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 in different geographical regions.

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 with continuous evidence generation to empower policy makers and clinicians to optimise care for patients with solid tumours in different geographical regions.

Type of actions:

Research and Innovation Actions

H. 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.

Topics will tackle some of numerous factors and challenges that complicate the translation from research into patient access of ATMPs. These include lack of fit for purpose preclinical models, need for novel approaches for clinical study of ATMPs, challenges in ATMPs manufacturing, need to establish a common platform for vector technology, the challenge of immunogenicity of ATMPs, the need for a single central processing facility for inducible pluripotent stem (iPS) cell technology, and last but not least several challenges have to be addressed for enabling patient access to ATMPs.

Activities in 2018 will address the following topics:

41. **Novel approaches for clinical study of ATMPs.** This topic addresses 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 the European Union and the H2020 Associated Countries.

42. **ATMPs manufacturing.** This topic addresses 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.

43. **Patient access to ATMPs.** The topic objective is to 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 in different geographical regions, 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 the European Union and the H2020 Associated Countries as a fully-fledged industrial activity to make the EU more competitive and make advanced therapy products available to all patients in need.
- A more consistent and reproducible manufacturing of ATMPs.
- 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 topics	Indicative Call launch timing	Indicative IMI2 JU funding (in EUR)[11],[12]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners
IMI2 Call 14 *Diabetes/Metabolic disorders* ▪ The role of the gut Microbiome as modulator of type 1 Diabetes (RIA) *Neurodegeneration and other Neuroscience Priorities* ▪ Immune system and Alzheimer's disease (RIA) ▪ Synaptic plasticity (RIA) *Immunology* ▪ Targeted immune intervention for treatment of non-response and remission (RIA) ▪ Non-invasive molecular imaging of immune cells (RIA) *Infection control including vaccines* ▪ Sustainable European antibacterial clinical trial network (RIA) ▪ AMR Accelerator (RIA) *Translational safety* ▪ Translational microphysiological systems (RIA) *Big data, digital health, clinical trials and regulatory research* ▪ Centre of excellence - decentralised, remote clinical trials. (RIA) ▪ Digital Transformation of Clinical Trials Endpoints (RIA) *Oncology* ▪ Big data in oncology (RIA)	15 March 2018	132,665,729	132,808,338
IMI2 Call 14 process			
Two-stage call with predefined submission deadline. Indicative Call deadline for **Short proposals**: **14 June 2018** Indicative Call deadline for **Full Proposals**:**11 December 2018** Research and Innovation Actions (RIA)			

[11] Based on estimate of total operational commitment appropriations available in 2018. This is without prejudice to commitment appropriations to be carried over from 2017 to 2018 (to be determined early 2018).
[12] The maximum possible rate of co-financing is 100 %.

Call number and indicative topics	Indicative Call launch timing	Indicative IMI2 JU funding (in EUR)[13],[14]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners
IMI2 Call 15 *Diabetes/Metabolic disorders* ▪ A clinical reference baseline database in support of flexible clinical trial designs in the area of metabolic diseases (RIA) ▪ Future of Diabetes/Metabolic Disorder healthcare CSA (CSA) *Neurodegeneration and other Neuroscience Priorities* ▪ Tau imaging (RIA) ▪ New genes as Alzheimer's disease modifiers (RIA) ▪ Progress in experimental modelling of Alzheimer's disease (RIA) ▪ Premotor Parkinson's disease (RIA) ▪ Early markers of progression in Alzheimer's disease (RIA) ▪ Personalised treatment for Parkinson's disease patients (RIA) ▪ Identification and validation of novel pain targets / pathways with disease-modifying potential (RIA) ▪ Pain in rare diseases (RIA) ▪ Clinical endpoints in headache medicine (RIA) *Immunology* ▪ Characterisation of human immunology mechanisms (RIA) ▪ Early disease interception of immune dependent disease (RIA) ▪ Emerging technologies and tools for interrogating human immunobiology (RIA) ▪ Fibrosis (RIA) ▪ Immunology and the microbiome (RIA) ▪ Enhance understanding of early respiratory disease (RIA) *Infection control including vaccines* ▪ Progress in tuberculosis research (RIA) ▪ Novel immunisation technologies for next generation vaccines (RIA) ▪ Coordination and Support Action for future vaccines R&D (CSA) ▪ Hepatitis B therapeutics and improved preparedness (pilot initiative) (RIA) *Translational safety* ▪ Dosing in specific populations (RIA) ▪ Human metabolism, disposition and pharmacokinetics (RIA)	18 July 2018	132,665,728	132,808,338

[13] Based on estimate of total operational commitment appropriations available in 2018. This is without prejudice to commitment appropriations to be carried over from 2017 to 2018 (to be determined early 2018).
[14] The maximum possible rate of co-financing is 100 %.

Call number and indicative topics	Indicative Call launch timing	Indicative IMI2 JU funding (in EUR)[13],[14]	Indicative in-kind contribution (in EUR) from EFPIA entities and Associated Partners
Big data, digital health, clinical trials and regulatory research ▪ Data Lakes (RIA) ▪ Integrated research platform for patient-centric drug development (RIA) *Oncology* ▪ Beyond patient stratification (RIA) ▪ Increasing context specificity (RIA) ▪ Immune oncology (RIA) ▪ Cell free DNA – liquid biopsy (RIA) *Facilitating the translation of advanced therapies to patients in Europe* ▪ Novel approaches for clinical study of ATMPs (RIA) ▪ ATMPs manufacturing (RIA) ▪ Patient access to ATMPs (RIA)			
IMI2 Call 15 process			
Two-stage call with predefined submission deadline. Indicative Call deadline for **Short proposals**: **24 October 2018** Indicative Call deadline for **Full Proposals**: **15 May 2019** Research and Innovation Actions (RIA) & Coordination and Support Actions (CSA)			

Overall total IMI2 Call 14 and IMI2 Call 15	**265,331,457**	**265,616,676**

Draft Budget

Subject to the adoption of the draft budget 2018 as proposed, the draft budget for the financial year 2018 is based on the currently available information.

A table overview of the operational budget for 2018 is set out below.

	Heading Title 3	Financial year 2018		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
30	Implementing the research agenda of IMI JU	265,331,457	203,242,167	EC contribution to grant agreements - Payments
30	Implementing the research agenda of IMI JU		2,354,000	EFPIA companies and Associated Partners contributions to grant agreements - Payments
30	Implementing the research agenda of IMI JU - carry over from 2017			To be determined at the end of 2017 based on final year budget execution
	Total operational costs Title 3	***265,331,457***	***205,596,167***	

A table overview of the 2018 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 2018 will comprise the launch of two competitive Calls for proposals implementing the 2018 scientific priorities with indicative launch dates on 15 March 2018 and 18 July 2018. 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. IMI2 JU will utilise the H2020 Participant Portal and Horizon 2020 IT infrastructure.

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 2018 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.[15]

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

58 ongoing projects will be running at different stages of their life cycle in 2018 with additional projects coming online during the year when Call 8 Ebola+ (4th and 5th cut-off), Call 10 (launched in 2016) and two calls launched in 2017 (Calls 11 and 12) complete their evaluation cycles (as indicated in the second column on the below table– “ongoing in 2018”). 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.

Given the current planning and project durations, it is expected that IMI2 JU will organise 14 reviews for projects launched under IMI1 JU (Calls 6, 9 and 11) and IMI2 JU (Calls 1, 2, 3, 5, 6 and 7).

[15] 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”

The following table presents a forecast of the reporting expected for 2018.

		Project periodic report due in 2018						Of which	
IMI Calls	**ongoing in 2018**	**1st RP**	**2nd RP**	**3rd RP**	**4th RP**	**5th to 7th RP**	**Total**	**finishing in 2018**	**Final report due 2018**
1	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	1	1	0	1
3	3	0	0	0	0	4	4	2	3
4	3	0	0	0	0	3	3	3	2
5	1	0	0	0	0	1	1	1	1
6	1	0	0	0	0	2	2	0	1
7	1	0	0	0	0	1	1	1	1
8	3	0	0	0	4	0	4	1	2
9	2	0	0	3	1	0	4	0	2
10	1	0	0	1	0	0	1	0	0
11	8	0	1	7	0	0	8	1	1
IMI2 C1	1	0	0	1	0	0	1	0	0
IMI2 C2	4	0	1	6	0	0	7	2	5
IMI2 C3	5	0	5	0	0	0	5	0	0
IMI2 C4	0	0	1	0	0	0	1	0	1
IMI2 C5	6	1	5	0	0	0	6	0	0
IMI2 C6	4	3	1	0	0	0	4	1	1
IMI2 C7	7	7	0	0	0	0	7	0	0
IMI2 C8	3	1	1	0	0	0	2	0	0
IMI2 C9	6	6	0	0	0	0	6	0	0
IMI2 C10	8	0	0	0	0	0	0	0	0
IMI2 C11	7*	0	0	0	0	0	0	0	0
IMI2 C12	7	0	0	0	0	0	0	0	0
Total	**81**	**18**	**15**	**18**	**5**	**12**	**68**	**12**	**21**

* The estimated number is based on the number of key project results identified in the call text (7 projects)

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 IMI2 JU beneficiaries. In addition, the IMI Programme Office will work with consortia on helping to communicate on project progress and dissemination of achievements.

2.2.5 Monitoring and analysis of projects' results

68 project periodic reports will be submitted in 2018 (for ongoing and finalised in 2017 IMI projects – see column 8 in the above table– "Project periodic report due in 2018 – Total"). These reports will be used to track progress against their stated objectives and deliverables as laid out in the relevant description of the action.

This reporting will also allow an assessment of project achievements and the impact of results. In addition to the usual 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. For projects resulting from IMI2 JU calls launched from December 2016 onwards, this monitoring will be done using the functionalities of the Horizon 2020 IT infrastructures.

In 2018 the analysis of the IMI2 JU 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 2018 IMI2 JU will continue to develop its relationships and engagement with key stakeholders such as patients, small and medium-sized enterprises, regulators, payers and healthcare professions to ensure that its outputs are aligned with and address the needs of society.

IMI2 JU's goal is to champion a patient centric-approach at all levels and encourage all the projects that it funds to work in partnership with patients wherever possible. IMI2 JU has listened to the needs expressed by patients and will create an IMI2 JU Patient Community which will give the patient voice a more prominent position in IMI both strategically and operationally. In addition, IMI2 JU aims to recruit a Seconded National Expert (SNE) to help drive the creation of the IMI2 JU Patient Community (IMI PC) as well as, coordinate and implement the patient engagement strategy of IMI2 JU.

Given their importance in driving employment and innovation in the European Union and the H2020 Associated Countries, the IMI2 JU will increase its engagement with SMEs and encourage their participation in IMI2 JU projects. In 2018, the IMI2 JU will continue to highlight SME opportunities in all topic texts and also embed SME participation at the earliest stages of topic development through collaboration with the Strategic Governance Groups and through exploring call designs more appealing to SMEs.

The IMI2 JU will also continue to develop and disseminate targeted materials for SMEs and continue the SME outreach programme outlined in the IMI2 JU SME strategy. This includes partnering with other European, national and regional clusters to participate in events aimed at encouraging SMEs to apply and participate in IMI2 JU projects.

The regulatory environment is key to ensuring that safe and effective medicines reach the market for the benefit of patients. To date, IMI2 JU has been able to use its unique platform to create an interface between science and regulation. IMI2 JU will continue to develop this framework to engage with all relevant regulatory agencies. In particular, IMI2 JU will support optimising the scientific engagement of the European Medicines Agency (EMA) in IMI2 JU, expected to operate at three levels: strategic science-based recommendation, topics of interest definition within a specific research area, and engagement with research projects.
IMI2 JU will also continue to foster engagement with competent national authorities as well as relevant HTA bodies in order to progress the goal of end-to-end integration in medicine development.

One important strategic objective for IMI2 JU is the involvement of other than the pharmaceutical sectors. For example, IMI2 JU has successfully brought together the major European diagnostics companies in 2017, an effort that will continue to be strengthened and supported throughout 2018. Likewise, important steps to engage the major players in the food and nutrition sector in discussions around a potential programme dedicated to the microbiome, started in 2017, and will be further facilitated in 2018.

IMI2 JU and ECSEL JU (www.ecsel.eu) initiated in 2017 the first discussions to explore possibilities for cooperation between both JU's in the domain of smart health along three thematic areas: sensors and diagnostics, imaging, and patient monitoring platforms. For 2018, dedicated workshops between sensor and diagnostics projects of the respective JU's are planned to explore synergies and potential collaborations, as well as follow-up discussions to identify gaps and a roadmap of common strategic priorities.
As the healthcare challenges faced by society are global, IMI2 JU will explore interactions and seek synergies with non-EU organisations when appropriate, for example in the area of antimicrobial resistance and biopreparedness. In an effort to align strategies and ensure complementarities, IMI2 JU and the Coalition for Epidemic Preparedness Innovations (CEPI) have agreed in 2017 to refer to each other's activities on their websites. In 2018, IMI2 JU will continue to exchange with CEPI and explore potential collaboration.

IMI2 JU and the Critical Path Institute (C-Path) are aligned in many of their scientific priorities, formalised by a Memorandum of Understanding (MoU) signed in 2011. IMI2 JU will continue to interact with C-PATH in 2018 and adapt the relationship as needed. IMI2 JU will also continue to sit on the Scientific Advisory Committee of C-FAST, an initiative formed in June 2012 by CDISC (Clinical Data Interchange Standards Consortium) and C-Path to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health.

In order to share best practice between projects and develop potential synergies, IMI2 JU will encourage its projects to organise cross-project meetings for both IMI2-JU-funded and other initiatives. This is particularly important in helping disseminate information about IMI2 JU and ensuring harmonisation of approaches at both a European and global level. For example, for Q4 2018, a cross project meeting in the area of Mental Health involving IMI2-JU- funded projects as well as projects currently funded under H2020 and collaborating/synergistic initiatives funded by NIMH/NIH (examples are https://www.nimh.nih.gov/about/organization/dtr/index.shtml; https://www.nimh.nih.gov/research-priorities/research-initiatives/fast-fast-fail-trials.shtml; https://www.nimh.nih.gov/research-priorities/rdoc/index.shtml) and SFARI (https://www.sfari.org/) is envisaged. The meeting will allow cross-fertilisation between the projects with a focus on the aspects of digital technology applications in this research area.

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 IMI2 JU projects is a core element of both the IMI2 JU 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.). IMI2 JU will continue to support and supplement the dissemination of projects' public deliverables via a variety of channels, including the IMI2 JU and projects' websites, newsletter, social media (Twitter and LinkedIn), the press and events. In addition, IMI will continue to explore how to make better use of EU specific dissemination channels for the promotion of projects and their results. In addition, following on from a pilot study performed in 2016 on the impact of IMI2 JU projects on the 3Rs (i.e. the replacement, reduction and refinement of animal use in research), IMI2 JU will undertake a more detailed analysis in 2018 on the contribution of project results to this specific area.

In 2018, the IMI2 JU expects to receive 21 final project reports. These reports will come from projects finishing in 2017 but reporting in 2018 (11 projects) and those finishing and reporting in 2018 (10 projects). In addition, 2 projects reaching their end date in 2018 will report in 2019. Capturing the outcomes and impacts of these projects presents IMI with a continuing challenge of ensuring that project results are disseminated widely and taken up by researchers in the field.

It is expected that at least 20 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 IMI2 JU 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. Members of EFPIA, the EC, IMI2 JU 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. The IMI2 JU will prepare specific communication materials for each project based upon information provided in the respective final report and close out meeting.

Lastly, IMI2 JU 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.

2.2.8 Socio-economic impact study

The second phase of the socio-economic impact study begun in 2017 will continue in 2018. The study utilises the previously developed methodology and applies it to the next wave of IMI1 projects that have completed or are drawing to a close. As with the original study this new evaluation looks at short-term outcomes (2-3 years) such as improved scientific quality, enhanced knowledge production, network-based R&D capacity building, and human resources development. It also considers mid-term impacts (4-5 years) and longer term outcomes, known as 'wealth and health' benefits. Mid-term impacts indicators include concrete results on biomarker validation/toxicology test, big data and shared IT infrastructures, improved knowledge transfer and communication. This study is necessary in order to enhance our performance evaluation framework which is currently under review.

The final report will be ready for publication by the end of 2018 and will be disseminated to all stakeholders, including policy makers at the European level. It is expected that this study will cost approximatively 20.000 EUR.

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. They are based on the General Annexes to the Horizon 2020 Work Programme 2018-2020[16].

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

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

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

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

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

(ii) secondary and higher education establishments;

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

(c) the Joint Research Centre;

(d) international European interest organisations.

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[18].

STANDARD ADMISSIBILITY CONDITIONS, PAGES LIMITS AND SUPPORTING DOCUMENTS

Part B of the General Annexes to the Horizon 2020 -Work Programme 2018– 2020 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 RIA/IA short proposals is 30 pages and for CSA short proposals is 20 pages.
For a single stage call, as well as at stage 2 of a two-stage call, the limit for RIA/IA full proposals is 70 pages and for CSA full proposals is 50 pages.

STANDARD ELIGIBILITY CONDITIONS

Part C of the General Annexes to the Horizon 2020 - Work Programme 2018– 2020 shall apply mutatis mutandis for the actions covered by this Work Plan.

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[16] http://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2018-2020/annexes/h2020-wp1820-annex-ga_en.pdf

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

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

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 the stage 1 of the call. The applicant consortium selected from the stage 1 of the Call for Proposals is merged at the stage 2 with the EFPIA constituent entities or their affiliated entities and other Associated Partners.[19]

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

Part D of the General Annexes to the Horizon 2020 - Work Programme 2018– 2020 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 2018–2020 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 2018– 2020 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;	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;	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;

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

Type of action	Excellence	Impact	Quality and efficiency of the implementation
	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	Improving European citizens' health and wellbeing and contribute to the IMI2 objectives[20].	Appropriateness of the proposed management 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;[20] Any other environmental and socially important impacts; Effectiveness of the proposed measures to exploit and disseminate the project results (including management of IPR), to communicate the project, and to manage research data where relevant.	The following aspects will be taken into account: Coherence and effectiveness of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and budget; Complementarity of the participants within the consortium (where relevant); Clearly defined contribution to the project plan of the industrial partners (where relevant); Appropriateness of the management structures and procedures, including manageability of the consortium, risk and innovation management and sustainability plan.

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

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

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

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

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

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

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

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

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

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

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

[23] http://www.imi.europa.eu/sites/default/files/uploads/documents/apply-for-funding/call-documents/imi2/IMI2_ManualForSubmission_v1.6_October2017.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[24] 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 2018–2020 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 2018–2020 shall apply mutatis mutandis for the actions selected under topics covered by this Work Plan.

[24] 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 2018–2020 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 IMI2 JU 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/apply-funding/call-documents/imi2-call-documents#imi2-call-documents-collapsible-1.

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. [25]

In order to ensure excellence in data and knowledge management consortia will be requested to Disseminate scientific publications on the basis of open access[26] (see "Guidelines on Open Access to Scientific Publications and Research Data in Horizon 2020").

To ensure actions are implemented properly, at the time of the signature of the grant agreement, each selected consortia must have agreed upon a consortium agreement, i.e. the internal arrangements regarding their operation and co-ordination.

Single-stage proposals and two-stage full proposals must contain a draft plan for the exploitation and dissemination of the results.

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

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

[26] 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

[27] http://www.imi.europa.eu/apply-funding/call-documents/imi2-call-documents

2.4 Support to Operations

2.4.1 Communication and events

Communication objectives

The overarching objectives of IMI2 JU's communications efforts are:
- to raise awareness and perception of IMI2 JU among all target groups;
- to encourage experts from all relevant groups to apply for funding under IMI2 JU Calls for proposals (with a particular focus on groups such as patients and SMEs).

The year 2018 marks the 10th anniversary of the very first IMI Call for proposals and this will represent an excellent opportunity to both showcase what IMI has achieved and discuss its future direction. In addition, IMI2 JU is now gathering growing numbers of success stories from both ongoing and closed projects, and this will help to support the message that IMI is a successful initiative, delivering scientifically excellent results and offering value for money to taxpayers.

IMI's 10th anniversary

In 2018, IMI will celebrate its 10th anniversary, and this is an excellent hook for communications. IMI2 JU will therefore plan a year-long programme of events and activities across its communications channels to promote IMI's successes and encourage discussion on its future plans. Highlights of the year will include:
- a scientific symposium featuring IMI2 JU-funded research;
- a book of IMI projects;
- a series of short video interviews.

Development of the IMI2 JU website

The IMI2 JU website is undergoing a redesign that will be completed in late 2017. In 2018, IMI2 JU will focus on refining the content, and on building on the dedicated sections for core stakeholder groups, namely universities, patients, SMEs, regulatory bodies, HTA, payers, and industry.

Further develop success stories

IMI2 JU now holds meetings with the representatives of projects that have finished, learning about what the projects have achieved and their legacy. With a large number of projects scheduled to finish in 2017 and 2018, these meetings will provide IMI2 JU with a wealth of success stories that can be adapted for different audiences and channels and back up IMI2 JU's key messages. IMI2 JU will also continue to maintain close contacts with ongoing projects to gather and promote their latest news and results.

Media outreach

The coverage of IMI2 JU in both the general and specialist press tends to be either neutral or positive in tone. In 2018, IMI2 JU will work to ensure that this trend continues by building and maintaining links with journalists, issuing regular press releases, organising press interviews, and inviting journalists to IMI2 JU events.

At the same time, IMI2 JU will remain alert to issues that could damage IMI2 JU's reputation and respond accordingly, for example by preparing briefings or sets of questions and answers.

Communication channels

IMI2 JU will continue to develop the following channels:
- events (both IMI2 JU and external)
- website
- newsletter
- social media (LinkedIn, Twitter)
- multipliers (e.g. European Commission & EFPIA, States Representatives Group, Scientific Committee, National Contact Points, relevant scientific associations, patient organisations, etc.)
- media (general and specialist, mainly in Europe but also elsewhere)
- direct mailings
- publications
- videos
- direct contacts with opinion leaders.

Key events in 2018

Event	Timeline
Promote IMI2 JU projects	Ongoing
IMI2 JU presence in the European Parliament	Ongoing
IMI2 JU presence at relevant external events, e.g. BIO, BIO-Europe, ESOF, BioFIT	Throughout year
Event with and for patients	Q2
Promote IMI2 JU Calls for proposals (webinars, info days, website, etc.)	Q2, Q4
IMI2 JU scientific symposium (10 years)	Q4
IMI2 JU Stakeholder Forum 2018	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 as much use as possible of multi-annual framework contracts, several of which are inter-institutional in nature.

In 2018, IMI2 JU intends to implement one such framework contract by concluding a specific contract for the provision of external audit services for its 2018 and 2019 accounts. Most essential framework contracts are already in place or and will be running beyond 2018. The framework contract for the provision of IT services (for all Joint Undertakings occupying the White Atrium building) will come to an end in 2018. An open procedure will have to be launched in Q1 2018 to ensure seamless service continuity. The estimated budget for this tender is approximately 4,500,000 EUR, covering the needs of all contracting Joint Undertakings over a four-year period.

Furthermore, the IMI2 JU will launch an open call for tender for the conclusion of a communication services contract, for which the estimated value is 250,000 EUR, designed to cover the tenth anniversary events and activities mentioned in Section 2.4.1.

Finally, the framework contract for the provision of Ex-Post Audits for the Framework Programme 7 (for all EC services, DG RTD being the lead contractor) came to an end in 2017. An open call for tender will be launched in Q1 2018 for a cascade type framework contract with other Joint Undertakings (FCH JU and Clean Sky JU), with IMI2 JU as lead contractor, to ensure seamless service continuity. The estimated budget is 1,600,000 EUR, covering the needs of all contracting Joint Undertakings over a four-year period.

2.4.3 IT and logistics

IMI2 JU 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.

In order to achieve the afore-mentioned goal IMI2 JU IT will focus its 2018 activities on three areas:

- business operations information systems,
- collaboration, communication and administration management information systems and
- infrastructure, security and office automation support.

2.4.3.1 Business operations information systems

In 2017, IMI2 JU's business operations started utilising the full suite of H2020 IT tools for the management of IMI2 calls, applications, evaluations and grants.

With the full transition expected to be completed by the end of 2017, IT will monitor satisfactory functioning for all end-users, in close liaison with EC services.

IMI1 projects remain in IMI's in-house developed application SOFIA.

The reporting needs of various IMI's stakeholders are supported by 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 projects.

Since IMI1 projects continue running until at least 2020 the following developments are foreseen for SOFIA application:

- Maintenance (continuous) of the application with helpdesk support, bug fixes and implementation of service requests (Q1 – Q4 2018)

Moreover, the following developments are foreseen for Qlikview:

- Addition of reports based on the needs of external, for example EFPIA Office, SRG, and internal stakeholders, and improvement of currently available dashboards (Q1 – Q4 2018)

2.4.3.2 Collaboration, communication and administration management information systems

IMI Office 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, a number of web-based applications, related to human resources management, time management, mission management, document management, incident management and internal communications are available to IMI2 JU staff.

Last but not least, a new website was implemented in 2017, replacing the look and feel but also the back-end web content management system.

The following developments are foreseen in 2018 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 IMI2 JU staff work (Q1 – Q4 2018)
- Maintenance (continuous) of the applications with helpdesk support, bug fixes and implementation of service requests (Q1 – Q4 2018)
- Implementation of the paperless office concepts based on the assessment of the practicality of current document repository application to support the automation of IMI2 JU's administrative processes compared to commercial off-the-shelf products with applied workflows, which is taking place in 2017 (Q2-Q4 2018).

Furthermore, in 2017 IMI2 JU considered the possibility of using the EC application SYSPER II for personnel time management. In 2018, IMI2 JU should move to SYSPER II, therefore all the necessary IT changes will have to take place in order to support this transition (Q3-Q4 2018).

2.4.3.3 Infrastructure, security and office automation support

IMI2 JU 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 2018, which are expected to provide with efficiency gains in the operation of the organisation:

- Maintenance (continuous) of the common infrastructure and networks and end-user office-automation support covering incidents, service requests and improvements (Q1 – Q4 2018)

- A new call for tenders for the provision of IT services (office support, IT infrastructure maintenance, etc.) that will lead to the signature of a new framework contract. (Q3- Q4 2018)

Moreover, IMI2 JU 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 2018 in the context of the dedicated infrastructure:

- Maintenance (continuous) of the online infrastructure (Q1 – Q4 2018).

2.4.4 Human Resources

The 2018 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 the following four main themes:

Staffing

The staffing needs of IMI2 JU will be the same as in 2017. The total number of staff remains to 54 temporary and contract agents as well as 2 additional seconded national experts.
In accordance with the Staff Regulations, technical adaptations have been made to the Staff Establishment Plan in order to create margin for reclassification (promotions) of staff. Those adaptations do not affect the total number of staff, 54 (39 temporary agents and 15 contract agents).

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. The main action shall be the oversight of duties and responsibilities that has been assigned to best achieve fulfilment of objectives and tasks.

HR management

Human Resources 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 addition, during the second semester of 2018, IMI2 JU is expected to move to SYSPER II, which will help in the personnel administration.

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 2018, the JUs will continue to share human resources IT tools where necessary, 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 2018

Subject to finalisation of the 2018 procedure by the EU Budgetary Authority, the forecast put forward in the draft annual budget plan for 2018 has been re-evaluated based on the available information. The budget of administrative expenditure has increased by 4.92% in 2018 compared to 2017, mainly due to increase in staff related expenditures as well as IT costs related to licences and one-time cost of the paperless project. A comparison table of the financial years 2017 and 2018 is set out below.

Heading Title 1		Financial year 2017	Financial year 2018	Evolution	Comments
Chapter		Budget EUR	Budget EUR	%	
11	Staff in active employment	5,242,000	5,425,000	3.49%	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	360,000	56.52%	New treatment of European school' costs of EUR 80.000. It is foreseen by EC to be implemented starting with 2018, representing a shift from EC directly supporting the costs to Agencies budgets. One time cost trainings regarding transition to the new H2020 tools EUR 50.000
17	Representation	20,000	20,000	0.00%	
	Title 1 - Total	**5,702,000**	**6,015,000**	**5.49%**	

Heading Title 2		Financial year 2017	Financial year 2018	Evolution	Comments
Chapter		Budget EUR	Budget EUR	%	
20	Office building and associated costs	679,000	729,000	7.36%	Additional costs with newly rented space in the building in order to accommodate new staff. Streamline of office spaces to accommodate new staff.
21	Information technology purchases	592,000	712,000	20.27%	Additional recurring costs related to licenses (Microsoft, Qlikview, Sysper, licenses related to the new web site). One time cost for the project paperless.
22	Office equipment (movable property and associated costs)	153,000	153,000	-	
23	Current administrative expenditure	123,000	123,000	-	
24	Telecommunication and postal expenses	68,000	68,000	-	
25	Expenditure on formal meetings	158,000	158,000	-	
26	Running costs in connection with operational activities	300,000	300,000	-	
27	External communication, information and publicity	625,000	625,000	-	
28	Service contracts	729,000	730,000	0.14%	
29	Expert contracts and cost of evaluations	700,000	700,000	-	
	Title 2 - Total	**4,127,000**	**4,298,000**	**4.14%**	
	Total Running Costs	**9,829,000**	**10,313,000**	**4.92%**	

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

Draft Budget Plan 2018 – see Chapter 3.

Financial Management

During 2018, 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.

2.4.6 Data protection

Objectives	To implement the Data Protection reform following the adoption of the General Data Protection Regulation [Regulation (EU) 2016/679 of 27 April 2016] which enters into application on 25 May 2018 after a two-year transition period. To continue to promote a culture of data protection at IMI2 JU. To support processes and projects in establishing common minimum requirements for protecting and sharing personal data.
Planned Activities	To implement the data protection reform following the adoption of the General Data Protection Regulation and in particular: ▪ increased accountability: advise and support controller and data processors on their responsibility and liability for further processing; ▪ higher data handling standards: reinforce 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: implement changes in consent and take into account the shifting of the burden of proof for compliance. To continue to promote a culture of data protection at IMI2 JU: ▪ training and advising; ▪ implement the revised procedure for handling notifications; ▪ participate in the EU network for Data Protection Officers and implement best practices; ▪ follow-up progress on implementation and potential impact of the new EU framework for data protection. To support processes and projects in establishing common minimum requirements for protecting and sharing data: ▪ advising; ▪ follow-up on recommendations addressed to IMI2 JU by the European Data Protection Supervisor.
Expected results	To ensure that personal data is protected, that the General Data Protection Regulation is complied with and that the implementation of the related legal requirements for EU agencies and bodies is handled smoothly. Actions: ▪ train newcomers; ▪ inform IMI2 JU staff on data protection matters during internal meetings; ▪ provide advice 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

IMI2 JU will continue to address requests for access to IMI2 JU 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. In this context, the programme office will further develop a transparency policy on activities of its governance bodies in accordance with the Council Regulation setting up IMI2 JU.

The objectives of actions in this field will continue, as a means to keep a 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 IMI2 JU activities and processes;
- Stimulating the interaction on key issues.

2.5 Governance

Key objectives

- Further develop an IMI2 JU strategic orientation and related objectives.
- Ensure that activities are in line with and support IMI2 JU strategic orientation.
- Further improve the efficiency and effectiveness of the IMI2 JU'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.

IMI2 JU 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** will continue in its advisory role to the Governing Board of the IMI2 JU and will notably be consulted on the scientific priorities to be addressed in Annual Work Plans and on the scientific achievements to be described in the Annual Activity Report.

At least two meetings of the Scientific Committee are planned for 2018.

The term of the current Scientific Committee members will come to end in 2018, and a new Committee will be appointed in 2nd half of 2018.

The Chair will participate in Governing Board meetings as observer. Information can be found at: http://www.imi.europa.eu/about-imi/governance/scientific-committee

The **States Representatives Group** will be consulted on the Annual Work Plans and will receive information on Calls outcomes and evaluation process. At least two meetings of the States Representatives Group are planned for 2018. With the end of the current mandate of the SRG Chair and Vice-Chair, an election process will be held. The Chair will participate in Governing Board meetings as observer. Information can be found at: http://www.imi.europa.eu/about-imi/governance/states-representatives-group

In addition, a joint meeting between the IMI2 Scientific Committee and the States Representatives Group is planned in order to strengthen the synergies between the two advisory bodies and exchange on topics of common interest.

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 promoting the possibility to become **Associated Partners** at programme or topic level. Practical information can be found at: http://www.imi.europa.eu/get-involved,

The **Strategic Governing Groups** (SGGs) continue to ensure the coordination of IMI2 JU's work in seven strategic areas and work to make the development of new topics more transparent and effective. The SGGs are made up of representatives from 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 IMI2 JU Scientific Committee. Currently, the seven established SGGs focus on the following areas: immunology; diabetes / metabolic disorders; neurodegeneration; translational safety; data and knowledge management (DKM); infections control, and oncology. In 2018, the DKM SGG will evolve with a new mandate into an SGG focused on digital health and evidence generation which will build on the achievements and the initial mandate of the SGG DKM.

In 2018 the SGGs will continue to develop comprehensive strategies for future projects for their specific areas.

Each SGG will meet at least 2 to 3 times a year to discuss their portfolio of projects and ensure synergies with ongoing projects, both projects within IMI2 JU and those outside. 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 feedback on any significant IMI activities and developments.

An objective in 2018 will also be to facilitate better cross SGG coordination and interactions by putting in place an updated IT platform and organising dedicated cross-SGG meetings. These improved efficiency mechanisms will facilitate the increased flow of information not only within a given SGG, but also with IMI2 governance bodies (GB, SC, SRG). Therefore, the SGG meeting agendas, publishable minutes and attendance lists will be more readily available. In addition, they will be called upon to advise on how best to exploit IMI2 JU 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.[28]

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.

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

2.6 Internal Control framework

Internal control

The IMI2 JU is aligning its Internal Control Framework (ICF) to the revised control framework adopted by the European Commission on 19 April 2017[29]. The new ICF moves away from a compliance-based to a principle-based system and provides the necessary flexibility to adapt to specific characteristics and circumstances while ensuring a robust internal control with a consistent assessment throughout the IMI2 JU. This approach aims at helping the organisation to achieve its objectives and sustain operational and financial performance[30]. In that context, the activities foreseen for 2018 will essentially aim at maintaining throughout the JU Office the achieved level of effectiveness and efficiency of the internal control framework while in parallel setting up the tools, functions and methodologies needed for the implementation of the new approach.

Financial procedures

Financial procedures guide IMI2 JU operations and lay out how the JU uses and manages its funds and resources.

In 2018 focus will be put on the following:

- periodic revision of the operating financial procedures and in particular of the Manual of Procedure for financial Operations (MoP);
- follow up and implementation of the results of the validation performed during 2017 by DG BUDG on the accounting management system of the IMI2 JU.

Ex-ante and ex-post controls

Ex-ante controls

In accordance with Article 18 of IMI 2 JU Financial Rules “each operation shall be subject at least to an ex ante control based on a desk review of documents and on the available results of controls already carried out relating to the operational and financial aspects of the operation”. In that view, ex-ante controls are essential to prevent errors and avoid the need for ex-post corrective actions. Those controls are performed by the IMI2 JU in the form of a desk and mid-term review and definitely assure the implementation of the principle of sound financial management throughout the IMI2 JU operations.

In 2018 the IMI2 JU will continue to assess and update the procedures defining the controls to be performed by project and finance officers for every cost claim, invoice, commitment and payment taking into account risk based and cost-effectiveness considerations. Specific attention will be placed on the:

- continued implementation of the joint guidance on H2020 ex-ante controls for interim and final payments adopted by the Commission Common Support Centre;
- financial checks during the Grant Agreement Preparation (GAP) phase;
- information and communication campaigns for IMI2 JU beneficiaries on H2020 rules and how to avoid errors in cost reporting.

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.

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[29] Communication on the revision of the Internal Control Framework (ICF) – C(2017)2373.

[30] Effectiveness, efficiency and economy of operations; reliability of reporting; safeguarding of assets and information; prevention, detection, correction and follow-up of fraud and irregularities; and adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments (IMI2 JU Financial Rules, Art 12.2).

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, 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, IMI's ex-ante and ex-post controls of grants are both aligned with the harmonised strategies adopted for the entire H2020 Programme. The IMI programme office will carry out the ex-ante checks as prescribed in the H2020 Control strategy. As for ex-post controls, the Commission Common Audit Service (CAS) will carry out the H2020 audits in accordance with the common H2020 audit strategy. IMI2 JU contributes to the implementation of the audit strategy in close cooperation with the 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.

Internal and external audits

The audit environment is an assurance and accountability pillar within 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 Court of Auditors (ECA) audit recommendations with the objective to confirm the effective implementation.

The IAS will continue performing the internal audit function. IAS will perform an in-depth risk assessment in IMI2 JU in the course of 2018, which will result in a new Strategic Internal Audit Plan for the period 2019-2021.

In 2018, the Audit manager will contribute to the overall corporate objective of receiving an unqualified ('clean') ECA audit opinion and positive statement of assurance.

ECA will audit and issue opinions on the legality and regularity of the underlying transactions. In accordance with the IMI2 Financial rules, IMI2 JU's 2017 annual accounts will be audited by an external audit company while the Court will draw an 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 JU to provide independent assessment and consulting aimed at adding value and improving IMI2 JU's operations.

Anti-fraud strategy

Anti-fraud measures are an essential part of sound financial management required under the EU Financial Regulation, safeguards to financial interests of the Joint Undertaking and contribute to its reputation.
In 2018 IMI2 JU will make an assessment of the first three years of implementation of its anti-fraud Action Plan.
Additional actions will focus on:

- awareness about fraud risk across the JU as well as among partners and beneficiaries;
- fraud risk analysis and reviews especially in areas considered vulnerable;
- training of staff disseminating relevant reports within the JU as appropriate and maintaining operational contacts with the European Anti-fraud Office (OLAF).

3 Draft Budget 2018

Subject to the adoption of the draft budget 2018 as proposed, an overview of the 2018 draft budget per chapters is set out below.

STATEMENT OF REVENUE

	Heading Revenue	Financial year 2018		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
10	European Commission contribution (including EFTA contribution)	270,487,957	208,398,667	Commitment appropriations include EUR 5,156,000 for running costs and EUR 265,326,420 for operational costs. Payment appropriations include running costs of EUR 5,156,500 and operational costs of EUR 203,242,167.
	Title 1 - Total	**270,487,957**	**208,398,667**	
20	EFPIA contribution	5,156,500	5,156,500	EFPIA contribution to IMI2 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 contribution to operational payment appropriations
	Title 2 - Total	**5,156,500**	**6,156,500**	
30	Associated Partners contributions	-	1,354,000	Bill and Melinda Gates Foundation contribution to operational payment appropriations
	Title 3 - Total		**1,354,000**	
	Total contributions	**275,644,457**	**215,909,167**	

STATEMENT OF EXPENDITURE

	Heading Title 1	Financial year 2018		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
11	Staff in active employment	5,425,000	5,425,000	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	360,000	360,000	Other staff costs: training, language classes, medical service, interim staff
17	Representation	20,000	20,000	Representation, receptions and internal meetings
	Title 1 - Total	**6,015,000**	**6,015,000**	
	Heading Title 2	**Financial year 2018**		**Comments**
Chapter		Commitment Appropriations (CA)	Payment Appropriations (PA)	
20	Office building and associated costs	729,000	729,000	Rent, works, common/IMI2 JU charges and parking. Additional costs: indexation, insurance, water/gas, electricity, heating, maintenance + repairs, security and surveillance.
21	Information technology purchases	712,000	712,000	IT purchases, software licences, software development, IMI2 JU website.
22	Office equipment (movable property and associated costs)	153,000	153,000	Purchases and rental of office equipment, maintenance and repair.

	Heading Title 2	Financial year 2018		Comments
Chapter		Commitment Appropriations (CA)	Payment Appropriations (PA)	
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 IMI2 JU (workshops, meetings and events targeting IMI2 JU projects).
27	External communication, information and publicity	625,000	625,000	External communication and events such as Info Days, stakeholder forums.
28	Service contracts	730,000	730,000	Studies, audits.
29	Expert contracts and cost of evaluations	700,000	700,000	Costs linked to evaluations, expert contracts.
	Title 2 - Total	**4,298,000**	**4,298,000**	
	Total running costs Title 1 + Title 2	***10,313,000***	***10,313,000***	

	Heading Title 3	Financial year 2018		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
30	Implementing the research agenda of IMI2 JU	265,331,457	205,596,167	Grant agreements - Payments
	Total operational costs Title 3	***265,331,457***	***205,596,167***	
	Total contributions	**275,644,457**	**215,909,167**	

An overview of the 2018 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	3,644,000	3,644,000
A01101	Family Allowances	374,000	374,000
A01102	Transfer and expatriation allowance	405,000	405,000
A01110	Contract Agents	636,000	636,000
A01111	Seconded National Experts	0	0
A01130	Insurance against sickness	98,000	98,000
A01131	Insurance against accidents and occupational diseases	15,000	15,000
A01132	Unemployment insurance for temporary staff	39,000	39,000
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	59,000	59,000
A01144	Fixed local travel allowances	3,000	3,000
A01149	Other allowances	0	0
A01172	Cost of organising traineeships within IMI2 JU	32,000	32,000
A01175	Translation and typing services and work to be contracted	0	0
A01177	Other services rendered	5,000	5,000
A01178	PMO fees	45,000	45,000
A01180	Sundry recruitment expenses	0	0
A01181	Travelling expenses (taking up duty)	5,000	5,000
A01182	Installation allowance	43,000	43,000
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**	**5,425,000**	**5,425,000**
A01200	Miscellaneous expenditure on staff recruitment	20,000	20,000
12	**Staff recruitments - miscellaneous expenditure**	**20,000**	**20,000**
A01300	Mission expenses	190,000	190,000

Expense budget line	Description	Commitment appropriations	Payment appropriations
13	**Missions and duty travels**	**190,000**	**190,000**
A01401	Socio-medical structure, EU school	80,000	80,000
A01410	Other trainings	110,000	110,000
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**	**360,000**	**360,000**
A01700	Representation expenses	20,000	20,000
17	**Representation**	**20,000**	**20,000**
	Title 1 - Total	**6,015,000**	**6,015,000**
A02000	Rentals	569,000	569,000
A02001	Guarantees	0	0
A02002	Contributions	0	0
A02010	Insurance	0	0
A02020	Water gas electricity and charges	131,000	131,000
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**	**729,000**	**729,000**
A02101	Hardware, infrastructure and related services	218,000	218,000
A02102	Software development, licenses and related services	494,000	494,000
A02103	Other expenses maintenance and repair	0	0
21	**Information technology purchases**	**712,000**	**712,000**
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	536,000	536,000
A02801	Studies, consultancy	114,000	114,000
A02802	Audit services	80,000	80,000
28	**Service contracts**	**730,000**	**730,000**
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	**4,298,000**	**4,298,000**
B03000	Implementing the research agenda of IMI1 JU	0	0
B03001	Call 1	0	57,000
B03002	Call 2	0	700,000
B03003	Call 3	0	6,086,573
B03004	Call 4	0	2,630,148
B03005	Call 5	0	0
B03006	Call 6	0	7,500,000
B03007	Call 7	0	54,426

Expense budget line	Description	Commitment appropriations	Payment appropriations
B03008	Call 8	0	9,206,582
B03009	Call 9	0	6,927,000
B03010	Call 10	0	1,200,000
B03011	Call 11	0	21,523,399
B03012	ENSO 2012	0	0
B03013	ENSO 2013	0	0
B03020	Implementing the research agenda of IMI2 JU	265,331,457	0
B03021	IMI2 Call 1	0	2,900,000
B03022	IMI2 Call 2	0	16,784,857
B03023	IMI2 Call 3	0	7,679,759
B03024	IMI2 Call 4	0	113,000
B03025	IMI2 Call 5	0	7,001,500
B03026	IMI2 Call 6	0	8,060,000
B03027	IMI2 Call 7	0	4,147,984
B03028	IMI2 Call 8	0	19,592,850
B03029	IMI2 Call 9	0	1,000,000
B03030	IMI2 Call 10	0	58,008,218
B03031	IMI2 Call 11	0	2,627,194
B03032	IMI2 Call 12	0	21,795,677
B03033	IMI2 Call 13	0	0
B03034	IMI2 Call 14	0	0
B03035	IMI2 Call 15	0	0
B03036	IMI2 Call 16	0	0
B03037	IMI2 Call 17	0	0
B03999	Recovery Ex-post audit	0	0
30	**Implementing the research agenda of IMI2 JU**	**265,331,457**	**205,596,167**
	Total expenditures	**275,644,457**	**215,909,167**

3.1 Staff Establishment Plan 2018

Grade	Establishment Plan 2017			Year 2018									Establishment Plan 2018		
				Posts evolution						Organisational evolution					
				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		+ 2									5	5
AD8		7	7		- 2 + 2									7	7
AD7		6	6		- 2									4	4
AD6					+2									2	2
AD5		12	12		- 2									10	10
Total AD		**33**	**33**											**33**	**33**
AST11															
AST10															
AST9															
AST8		1	1											1	1
AST7															
AST6															
AST5															
AST4					+ 2									2	2
AST3		4	4		- 2									2	2
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		**39**	**39**											**39**	**39**

Contract Agents Grade	2017	2018
FG IV	2	2
FG III	12	12
FG II	1	1
FG I	0	0
Total CA	**15**	**15**

Seconded National Experts	2017	2018
	2	**2**

LIST OF ACRONYMS

Acronym	Meaning
ABAC	Accrual Based Accounting System
AD	Alzheimer's disease
AD (HR)	Administrator
AER	Average error rate
AMR	Antimicrobial Resistance
AST	Assistant
AWP2018	Annual Work Plan 2018
CA (Budget)	Commitment Appropriation
CA (HR)	Contractual Agent
CDISC	Clinical Data Interchange Standards Consortium
CEOi	Global CEO Initiative
CFAST	Coalition for Accelerating Standards and Therapies
CFS	Certificates on Financial Statements
C-Path	Critical Path Institute
CPD	Continuing professional development
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)
DPO	Data protection officer
E&T	Education & Training
EBiSC	European induced pluripotent stem cell
EC	European Commission
ECA	European Court of Auditors
EDPS	European Data Protection Supervisor
EEG	Electroencephalograph
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHR	Electronic Health Record
EMA	European Medicines Agency
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
FDA	Food and Drug Administration
FG	Function Group
FTE	Full-Time Equivalent
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
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
ICC	Internal Control Coordinator
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
MAPPs	Medicines adaptive pathways to patients
MEP	Member of the European Parliament
MRI	Magnetic resonance imaging
MS	Multiple sclerosis
MTA	Material transfer agreement
ND4BB	New Drugs for Bad Bugs
NIMH	National Institute of Mental Health
OECD	Organisation for Economic Co-operation and Development
OLAF	European Anti-Fraud Office
PA	Payment Appropriation
PET	Positron emission tomography
PM	Person/month
PMDA	Pharmaceuticals and Medical Devices Agency
PPP	Public-private partnership
PRO	Patient reported outcomes
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
T1D	Type 1 diabetes
T2D	Type 2 diabetes
TA	Temporary Agent

TTG	Time to Grant
TTP	Time to Pay
US	United States
WHO	World Health Organisation
WP(s)	Work Package(s)

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