



## **Amended Annual Work Plan and Budget for 2021**

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In accordance with Article 17 of the Statutes of the IMI2 JU annexed to Council Regulation (EU) No 557/2014 of 6 May 2014 and with Article 33 of the Financial Rules of the IMI2 JU.

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

**Sole annex to the Decision of the Governing Board of the  
Innovative Medicines Initiative 2 Joint Undertaking  
no. IMI2-GB-DEC-2021-05 adopted on 23.04.2021**

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## **Chronology and list of reviews**

<b>Version</b>	<b>Date of the adoption by the Governing Board</b>	<b>Items</b>
<b>Version 1.0</b>	11.12.2020	Annual Work Plan and Budget for 2021
<b>Version 2.0</b>	23.04.2021	Update of the following sections: <ul style="list-style-type: none"><li>▪ 2.3.5 Administrative budget and finance</li><li>▪ 3. Budget</li></ul>

# 1 Introduction

In 2021, IMI2 JU will evaluate the IMI proposals submitted in 2020 and sign the resulting Grant Agreements. It will then focus on monitoring the large project portfolio of over 116 IMI projects. The IMI portfolio will reach its peak as number of simultaneously running projects and will cover the key challenges highlighted in the IMI2 JU Strategic Research Agenda in areas such as diabetes/metabolic disorders, neurodegeneration, immunology, infection control (including vaccines), translational safety, digital health, and oncology. We will identify areas of cross project collaboration and synergies.

In addition, the Programme Office will continue implementing the recommendations of the experts' panel on the interim evaluation of IMI2 JU. This will include continuing with the strategy to attract more small and medium-sized enterprises (SMEs) to IMI2 JU, as well as putting greater efforts into identifying our projects' most important outputs and communicating on them to a wider audience.

Throughout the year, the Programme Office will strive to deliver work of the highest quality, following strict ethical standards, adhering to the principle of sound financial management and within the context of a robust internal control framework.

Having ensured business continuity throughout 2020 in the face of the COVID-19 pandemic, the Programme office will continue to strive for operational excellence during this year.

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, healthcare systems, patients and European society at large.

As 2021 will be a transition year, preparing for the launch of a new partnership in health, the IMI office will strive to create an environment which will ensure a smooth transition to implementing the new programme.

Pierre Meulien  
Executive Director

## **2 Annual Work Plan Year 2021**

### **2.1 Executive Summary**

In order to continue to bring value to the EU citizen and execute the Strategic Research Agenda of IMI2 JU, the Programme Office will continue to successfully manage and connect a growing portfolio of projects, ensuring sound budget management and close monitoring of project performance. In 2021, this portfolio will reach its peak as number of simultaneously running projects.

The IMI2 programme office will continue to assess risks associated with the current COVID-19 pandemic and potential future public health crises.

The IMI2 JU will continue with its programme of regular project reporting, mid-term reviews and audits of beneficiaries.

The close monitoring of project performance will also allow the IMI2 JU to demonstrate the EU added value of the programme and facilitate continued communication to target audiences. Efforts to engage with key stakeholders such as patients and SMEs will continue as will those related to improving the dissemination of project results.

Given the importance of demonstrating the impact of the programme to the EU citizen and policy decision maker, reporting and dissemination activities will be complemented by socio-economic impact studies.

The IMI programme office will strive to ensure a smooth transition to the new proposed cross-sectorial partnership in health under Horizon Europe by providing lessons learned at operational level and involving key members of IMI2 JU staff in discussions where appropriate.

## 2.2 Operations

### 2.2.1 Objectives & indicators - risks & mitigations

The key objectives for IMI2 JU operations in 2021 are identified by the Governing Board in the Annual Work Plan and by the Management at operational level.

Key operational objectives for 2021 as follows:

1. ensure a smooth transition to the new proposed cross-sectorial partnership in health under Horizon Europe by providing lessons learned at operational level and involving key members of IMI2 JU staff in discussions where appropriate;
2. complete the execution of the Strategic Research Agenda priorities, bringing together the different stakeholders involved in health research (including SMEs, regulators and patient organisations) through the continued monitoring of project implementation and by fostering cross-project collaboration;
3. ensure sound budget implementation through the effective and efficient management of grant award process, close monitoring of projects and error rate;
4. demonstrate the EU added value of IMI2 JU through assertive communication to target audiences with emphasis on the openness, transparency, relevance, and coherence of IMI2 JU activities;
5. involve industry from related sectors other than the pharmaceutical industry (diagnostics, medical technologies industry, imaging, digital industry, food and nutrition, etc.) in IMI2 JU through proactive outreach strategies;
6. ensure IMI2 JU internationalisation and build productive linkages to major international efforts to address Global Challenges (AMR, Alzheimer and other dementias, autism, cancer, diabetes, emerging infectious diseases, etc.);
7. improve and broaden access to IMI project outcomes by embedding dissemination in all stages of the project lifecycle.

## IMI2 KPIs

Reporting on measuring and outcomes on the ten following Key Performance Indicators will be provided yearly as part of the IMI2 JU Annual Activity Reports for year 2020 and beyond.

KPI	Definition	Comment	Relates to	Baseline	Target
1	Number of relevant priority areas in the WHO 'Priority Medicines for Europe and the World 2013 Update' reflected in the IMI2 JU Strategic Research Agenda (SRA) and addressed by IMI2 JU projects.	<p>Based on the SRA and including the WHO priority medicines therapeutic areas:</p> <ul style="list-style-type: none"> <li>▪ expressed as a number of areas reflected in the IMI2 JU portfolio;</li> <li>▪ complemented by the number and budget of grant agreements that delivered them.</li> </ul>	<p>IMI2 JU Regulation<sup>1</sup> objective b1: b1: 'increase the success rate in clinical trials of priority medicines identified by the WHO'</p>	0	12
2	The number of project-developed assets which complete a significant milestone during the course of an IMI2 JU project.	Assets are defined as new drug or diagnostic candidates, targets, biomarkers or other tools that can be shown to have reached a significant milestone or pass a significant stage gate.	<p>IMI2 JU Regulation objective b1, b2, b4, b5 and b6:</p> <p>b1: 'increase the success rate in clinical trials of priority medicines identified by the WHO'</p> <p>b2: 'reduce the time to reach clinical proof of concept in medicine development...'</p> <p>b4: 'develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators'</p> <p>b5: 'reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks'</p> <p>b6: 'improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products'</p>	0	50

<sup>1</sup> Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU), OJ L 169, 7.6.2014, p. 54–76.

KPI	Definition	Comment	Relates to	Baseline	Target
<b>3</b>	<p>New or improved guidelines, methodologies, tools, technologies or solutions accepted by regulatory authorities for use in the context of R&amp;D, specifically for:</p> <ul style="list-style-type: none"> <li>- new tools for preclinical drug development;</li> <li>- biomarkers and tools developed to predict clinical outcomes;</li> <li>- improved protocols to design and process of clinical trials;</li> <li>- new biomarkers developed for the efficacy and safety of vaccine candidates.</li> </ul>	<ul style="list-style-type: none"> <li>- Measured by the number of the formal qualification procedures completed (letters of support, qualification opinions received).</li> <li>- Complemented by number of qualification procedures launched.</li> <li>- Expressed as net figure.</li> <li>- Complemented by the number and budget of grant agreements that delivered them.</li> </ul>	<p>IMI2 JU Regulation objective b1, b2, b4, b5 and b6:</p> <p>b1: 'increase the success rate in clinical trials of priority medicines identified by the WHO'</p> <p>b2: 'reduce the time to reach clinical proof of concept in medicine development...'</p> <p>b4: 'develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators'</p> <p>b5: 'reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks'</p> <p>b6: 'improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products'</p>	0	10 (for completed procedures)

KPI	Definition	Comment	Relates to	Baseline	Target
<b>4</b>	New taxonomies of diseases and new stratifications (such as the definition of patient subpopulations, development, validation and use of new diagnostics) developed.	<ul style="list-style-type: none"> <li>- Expressed as net figure.</li> <li>- As published and/or implemented by industrial partners and evidenced in annual reporting.</li> <li>- Complemented by the number and budget of grant agreements that delivered them.</li> </ul>	<p>IMI2 JU Regulation objective b3 and b4:</p> <p>b3: 'develop new therapies for diseases for which there is a high unmet need...'</p> <p>b4: 'develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators'</p>	0	30
<b>5</b>	Contribution (in-kind or in-cash) from non-pharma actors (e.g. non-pharma industries, foundations, charities, professional organisations).	Expressed as total amount in EUR.	<p>IMI2 JU Regulation objective a:</p> <p>a: 'to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership...';</p> <p>and IMI2 JU Regulation recital 8:</p> <p>'The initiative should consequently seek to involve a broader range of partners, including mid-caps, from different sectors, such as biomedical imaging, medical information technology, diagnostic and animal health industries.'</p>	0	EUR 300 Million

KPI	Definition	Comment	Relates to	Baseline	Target
6	Share of IMI2 JU projects whose resources/outputs are made accessible beyond the consortia partners (with or without fee), such as major databases, bio-banks, <i>in silico</i> tools, training materials, clinical trial networks, guidance etc.	<ul style="list-style-type: none"> <li>- Complemented by the number and budget of grant agreements that delivered them.</li> <li>- Accessibility to be evidenced by online availability (with or without fee), and documented by project reports.</li> </ul>	<p>IMI2 JU Regulation objective a, b2 and b6:</p> <p>a: 'to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership...'</p> <p>b2: 'reduce the time to reach clinical proof of concept in medicine development'</p> <p>b6: 'improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products'</p>	0	50%
7	Co-authorships and cross-sector publications between European researchers on IMI2 JU projects (sectors include academia, small and mid-sized companies, pharma, regulators, patient organisations, etc.).	<ul style="list-style-type: none"> <li>- Expressed as net figure</li> <li>- Complemented by the number and budget of grant agreements that delivered them.</li> </ul>	<p>IMI2 JU Regulation objective a:</p> <p>a: 'to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership...'</p>	0	1500

KPI	Definition	Comment	Relates to	Baseline	Target
<b>8</b>	New tools and processes generated by IMI2 JU projects that have been implemented by the industry participants of IMI projects.	<ul style="list-style-type: none"> <li>- New tools and processes: e.g. animal models, standards, biomarkers, SOPs, use of screening platforms and clinical trial networks.</li> <li>- Expressed as net figure.</li> <li>- Complemented by the number and budget of grant agreements that delivered them.</li> <li>- Assessment based on yearly reporting by industrial partners until the project close-out meetings.</li> </ul>	<p>IMI2 JU Regulation objective a, b2 and b6:</p> <p>a: 'to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership...'</p> <p>b2: 'reduce the time to reach clinical proof of concept in medicine development'</p> <p>b6: 'improve the current drug development process by providing the support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products'</p>	0	50
<b>9</b>	Share of projects involving patient organisations and healthcare professionals' associations (as consortium partners, members of advisory boards, members of stakeholder groups etc.).	<ul style="list-style-type: none"> <li>- Complemented by the number and budget of grant agreements that delivered them.</li> </ul>	<p>IMI2 JU Regulation objective a, and b1:</p> <p>a: 'to support... the development and implementation of pre-competitive research and of innovation activities of strategic importance to the Union's competitiveness and industrial leadership...'</p> <p>b1: 'increase the success rate in clinical trials of priority medicines identified by the WHO'</p>	Share of IMI JU projects involving patient organisations: (participants /advisory boards etc. 40%)	80%

<b>10</b>	Support to SMEs: share of SMEs participating as formal IMI2 JU project beneficiaries.	- To be complemented by the number of SMEs benefitting from IMI project support in other ways.	H2020 priority; IMI2 JU Regulation recital 9  '(...) should seek to foster the capacity of smaller actors such as research organisations, universities and SMEs for participating in open innovation models and to promote the involvement of SMEs in its activities, in line with its objectives'	Share of SMEs participating as formal IMI JU project beneficiaries: 15.96%	20%
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To ensure the monitoring of the above-mentioned 10 Key Performance Indicators, IMI2 JU has established a performance evaluation plan which aims at identifying appropriate sources of information, a suitable framework as well as consistent processes and tools.

## Risks & mitigations

Risks management is a strategic element of planning activities as their identification enables IMI2 JU to effectively customise its objectives and prioritise actions.

Following the risk assessment exercise carried out by the Programme Office in view of this AWP, the following two categories of risks, identified as critical, might challenge the achievement of the objectives planned by IMI2 JU on 2021:

- The on-going and lasting COVID-19 pandemic has already impacted and is likely to further impact all IMI activities as well as working practices, communication methods and individual workloads, putting at risk the implementation of the IMI2 JU activities for 2021, the staff wellbeing and the annual declaration of assurance.
- The transition to the new European Partnership in Health within Horizon Europe and the uncertainty surrounding this transition might significantly affect the IMI2 JU operational activities and the Programme Office in terms of financial (e.g. budget overrunning) and human resources (e.g. missing expertise, staff leaving the organisation).

Moreover, the Programme Office will have to ensure the conclusion of the last grant agreements, the monitoring of the ongoing grant agreements (including from FP7) and the closure of a range of IMI projects. 2021 will represent the peak in the number of simultaneously running projects. With the winding-up of H2020 on 31 December 2020, calls for proposal can no longer be launched.

The Executive Director and the Management team will closely monitor these risks and put in place the corresponding mitigation measures identified in the Risk Assessment Exercise. The staff should be regularly informed on the objectives, activities and new planning.

## **2.2.2 Scientific priorities for 2021**

The IMI2 JU activities for 2021 are fully in line with the objectives as set out in Article 2 of the IMI2 JU Regulation. They aim at successful 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 wellbeing.

These activities are always to be put in context within the general framework of the Scientific Research Agenda (SRA) for IMI2 JU (see <http://www.imi.europa.eu/about-imi/strategic-research-agenda>) and its priorities. The SRA identifies a set of scientific priorities, where IMI2 JU attempts to pilot new ideas in a real life, safe harbour environment. The IMI2 JU model 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 it 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, IMI2 JU will continue to foster the implementation of 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).

In 2021 IMI2 JU will complete the execution of the Strategic Research Agenda priorities, bringing together the different stakeholders involved in health research (including SMEs, regulators and patient organisations) through the continued monitoring of project implementation and by fostering cross-project collaboration. The Programme Office will also monitor the progress of the projects, including important aspects of cross-project collaboration and contribution to the European Commission's wider response to the coronavirus outbreak.

While IMI2 JU will not launch further Calls for proposals in 2021, the Programme Office will continue to manage its portfolio and will carry out the evaluation and kick-off of projects resulting from the last two stage Call for proposals launched in the second half of 2020. In 2021, the portfolio of running projects will reach its peak as number of simultaneously running projects. While this broad and complex portfolio will be progressing and maturing, specific efforts will be dedicated to documenting and monitoring progress, notably through key performance indicators, and best exploit outputs. In parallel, communication activities will be further expanded by conducting outreach campaigns targeting different audiences.

The actions in the portfolio 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 benefits 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.

## Budget

The budget for the financial year 2021 is based on the currently available information.

IMI2 JU launched its last Call for proposals in 2020. Operational commitment appropriations are not foreseen for 2021, as there are no new Calls to be launched on IMI2 JU in 2021. The payment appropriations will be consumed as pre-financing payments, intermediate and final payments for the IMI projects (FP7 and H2020).

A table overview of the operational budget for 2021 is set out below.

	Heading	Financial year 2021		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
3	<b>Operational expenditure</b>			
30	Implementing the research agenda of IMI2 JU		180,000,000 <sup>2</sup>	Payments FP7 and H2020
<b>Total Title 3 (Operational expenditure)</b>		-	<b>180,000,000</b>	

A table overview of the amended Budget 2021 is set out in Chapter 3 to this amended Annual Work Plan<sup>3</sup>.

<sup>2</sup> Amount estimated and put forward in January 2020. Subject to further revision, in line with operational needs, estimated to be in the range of EUR 210 mil.

<sup>3</sup> This revision of the Annual Work Plan for 2021 is independent from, and does not reflect the impact of the Commission proposal for Innovative Health (COM(2021) 87 final of 23.2.2021).

### **2.2.3 Activities to support and monitor ongoing projects**

116 projects will be running at different stages of their life cycle in 2021, of which 92 are expected to report, and additional projects starting when the ongoing IMI2 JU Calls launched in 2020 complete their evaluation cycle (as indicated in the second column on the below table—‘ongoing in 2021’). Most of the 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 projects’ duration, it is expected that IMI2 JU will organise 25 reviews for projects launched under IMI2 JU Calls 10, 12, 13, 14, 15 and 16.

The following table presents a forecast of the reporting expected for 2021.

IMI Calls	Total Projects	Ongoing in 2021	Project periodic report due in 2021						Of which	
			1st RP in 2021	2nd RP in 2021	3rd RP in 2021	4th RP in 2021	5th to 7th RP in 2021	Total reports	Project ending in 2021	Final reports due in 2021
IMI JU C1	15									
IMI JU C2	8									
IMI JU C3	7									
IMI JU C4	7									
IMI JU C5	1									
IMI JU C6	2	1						1	1	
IMI JU C7	2									
IMI JU C8	4	1						1	1	
IMI JU C9	4	2						1	1	2
IMI JU C10	1	1						1	1	1
IMI JU C11	8	6						7	7	3
<b>IMI JU</b>	<b>59</b>	<b>11</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>11</b>	<b>11</b>	<b>6</b>	<b>5</b>
IMI2 C1	1	1						1	1	
IMI2 C2	8	2						2	2	2
IMI2 C3	5	4						4	4	3
IMI2 C4	1									
IMI2 C5	6	4						4	4	3
IMI2 C6	4	3						3	3	
IMI2 C7	7	5						5	3	1
IMI2 C8	4	4						4	1	1
IMI2 C9	6	4						4		
IMI2 C10	8	7						7		
IMI2 C11	3	0						0		3
IMI2 C12	7	7						7		
IMI2 C13	13	13						13		
IMI2 C14	4	4						4		
IMI2 C15	7	7						7		
IMI2 C16	5	5						5	1	1
IMI2 C17	3	3	3							3
IMI2 C18	6	6	5						5	
IMI2 C19	2	2	2							2
IMI2 C20*	6	6							0	
IMI2 Call 21	8	8	1							1
IMI2 Call 22*	4	4							0	
IMI2 Call 23*	6	6								
<b>IMI2 JU</b>	<b>124</b>	<b>105</b>	<b>11</b>	<b>39</b>	<b>20</b>	<b>8</b>	<b>3</b>	<b>81</b>	<b>17</b>	<b>12</b>
<b>Totals</b>	<b>183</b>	<b>116</b>	<b>11</b>	<b>39</b>	<b>20</b>	<b>8</b>	<b>14</b>	<b>92</b>	<b>23</b>	<b>17</b>

\* The estimated number of projects is based on the number of topics included in the ongoing IMI2 JU Call.

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 the 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 Programme Office will work with consortia on helping to communicate on project progress and dissemination of achievements.

## **2.2.4 Monitoring and analysis of projects' results**

92 project periodic reports will be submitted in 2021 (for ongoing projects and those finalised in 2020 see column 9 in the above table – ‘Project periodic report due in 2021 – Total reports’). 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.

In 2021, the analysis of the project scientific outputs in terms of publications and collaboration among 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.

## **2.2.5 Stakeholders' engagement and external collaborations**

In 2021, IMI2 JU will continue to develop its relationships and engagement with key stakeholders such as patients, SMEs, regulators, payers and healthcare professions to ensure that its outputs are aligned with and address the needs of the society.

### **Patient engagement**

Building on the experience of patient engagement so far, the Programme Office will continue to work on developing an open and transparent system of meaningful patient engagement at all levels.

Having already put in place the IMI2 JU pool of patient experts, the Programme Office will continue to undertake significant efforts to facilitate and enhance patient participation in its activities. The systematic involvement of patients/informal carers from the IMI2 JU pool of patient expert will enable IMI2 JU to identify, address and respond to patients' specific needs but also continuously improve, adapt and focus the patient engagement strategy priorities where necessary. Drawing from the IMI2 JU Pool of patient experts, the Programme Office will continue to invite patients/ informal carers to perform a variety of roles and tasks depending on the need and topics discussed. Their input will contribute to shaping the IMI2 JU portfolio and improving the quality of IMI projects from the patient perspective.

In order to deploy the full potential of the IMI2 JU Pool of patient experts, the Programme Office will provide continuous training and support to all members, enabling their meaningful engagement and performance all across the spectrum of its activities. Moreover, IMI2 JU will hold meetings covering specific disease areas/topics which will optimise its approach to patient-centrality and provide guidelines on how to implement patient participation in IMI projects.

Additionally, using examples and best practices, IMI2 JU will lead efforts to collaborate with all stakeholders to explore ways to promote and govern tools for a meaningful patient engagement strategy.

## **SMEs**

IMI2 JU will also continue to disseminate the results of IMI projects to 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 facilitating SMEs to take-up the results of IMI projects.

## **Regulators**

The regulatory environment is key and it is critical to maximise the impact of research on innovative medicines. To ensure that the science generated by IMI projects is translated into patient-centred healthcare, the regulatory environment is key to ensuring that safe and effective medicines reach the market for the benefit of patients. IMI2 JU will continue to engage with all relevant regulatory authorities, in particular, the European Medicines Agency (EMA). When possible and relevant, IMI2 JU will continue to strengthen engagement with other international agencies and competent national authorities, through for instance interactions with the heads of agencies. Similarly, IMI2 JU will continue to strengthen engagement with relevant health technology assessment (HTA) bodies, for instance in order to progress the goal of end-to-end integration in medicine development.

## **Other industries and stakeholders**

As the healthcare challenges faced by society are global, IMI2 JU will continue to interact with charities, foundations, and industries and stakeholders outside of the pharmaceutical sector, especially in consideration of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe. , IMI2 JU will continue exploring interactions and seeking synergies with EU and non-EU organisations (including technology hubs at national or regional level) when appropriate, for example in the areas of antimicrobial resistance, mental health/neuroscience, ATMP vaccines, bio preparedness or oncology.

IMI2 JU and ECSEL JU will facilitate collaboration between the IMI Trials@Home project and the ECSEL project to be selected following the ECSEL JU Call for proposals H2020-ECSEL-2020-3-RIA-IMI-ECSEL-joint-activity-one-stage. Moreover, participation of both JUs in their respective governance bodies will continue in 2021 as needed. The objective is to further support synergies between the JUs' activities and other potential collaborations between projects of the respective JUs, especially in consideration of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe.

In order to share best practices between projects and develop potential synergies, IMI2 JU will encourage its projects to organise cross-projects meetings. This is particularly important in helping disseminate information about IMI2 JU and ensuring harmonisation of approaches at both a European and global level.

## **2.2.6 Dissemination and information about projects results**

Although the responsibility for maximising the impact of their own research and innovation lies primarily with the project consortia, promoting the successes of IMI projects is a core element of both the IMI2 JU communications and dissemination strategies.

The 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. Particular efforts will be invested in scaling up the online catalogue of accessible tools generated by our projects on the IMI2 JU website.

In addition, IMI2 JU will continue to explore how to make better use of EU specific dissemination channels for the promotion of projects and their results by actively participating in the European Commission's Dissemination and Exploitation Network (D&E Net).

In 2021, IMI2 JU expects to receive 17 final project reports. Capturing the outcomes and impacts of these projects presents IMI2 JU with the opportunity of ensuring that project results are disseminated widely and taken up by researchers in the field and potential end user (e.g. healthcare professionals).

For 17 projects, close-out meetings will be organised around the time of submission of the final report. The IMI2 JU will prepare specific communication materials for each project based upon information provided in the respective final report and close out meeting. When necessary the IMI2 office may organise cross-project meetings, or meetings in thematic areas to facilitate the identification of significant impacts and learnings from the projects and ensure that this information is disseminated via the channels previously described.

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.

## **2.2.7 Socio-economic impact assessment**

An important part of evaluating the performance of IMI2 JU consists in assessing the socio-economic impact of the IMI projects.

The efforts to assess the socio-economic impact will be continued using the previously developed methodology that consisted in reviewing the projects final reports as well as conducting surveys and interviews of project coordinators and participants, with the support of an external consultant.

In 2020, IMI2 JU released a new Socio-economic Impact Assessment Report that covered 44 finished projects. In 2021 the Programme Office plans to continue this work for the additional projects that have finished and will release an updated Socio-economic Impact Assessment Report including these findings.

IMI2 JU may also explore the opportunity and the feasibility of developing new methodologies to track the socio-economic impact of its projects. If found feasible IMI2 JU may then embark on a small scale pilot study to assess the potential of any new methodology developed.

## 2.3 Support to Operations

### 2.3.1 Communication and events

#### Communication objectives

As mentioned above, from 2021 onwards no new Call for proposals will be launched. However, 2021 will see the launch of some new IMI projects and the Programme Office will continue to manage ongoing projects.

Consequently, for this last phase of IMI2 JU, the communications strategy will mainly focus on the following three strategic goals:

- raise awareness levels and perception of IMI2 JU among all target groups focusing on results and impact;
- increase the engagement of patients in IMI2 JU's activities;
- maintaining and further developing political support for the Joint Undertaking among key groups of policymakers and opinion leaders by demonstrating the benefits of the instrument and the impact of its results.

At the same time, the Communications team will remain alert to issues that could damage IMI2 JU's reputation and respond accordingly by providing timely feedback on stakeholders' views and reactions.

#### Focus on results and impact

As more IMI projects draw to a close, the 2021 communication work plan will further build on the results obtained and elaborate on the dissemination of the results and impact of both completed and ongoing projects.

In order to amplify the reach of project success stories and results, IMI2 JU will continue to work in close collaboration with the communication unit of the European Commission's Directorate-General for Research and Innovation, responsible for services such as the Horizon Magazine and the webpage for EU research success stories.

#### Strengthening the role of patients as experts

The Communications team will work closely with the patient engagement officer to strengthen communications with the pool of patient experts, and to engage with the wider patient community.

#### Media outreach

In 2021, the Communications team will continue to work to ensure that general and specialist press coverage continues to be primordially neutral or positive in tone by building and maintaining links with journalists, issuing regular press releases, organising press interviews, and inviting journalists to our events.

#### Communication channels

IMI2 JU will continue to develop content for the following channels with the aim of providing all interested stakeholders with access to relevant and specific information on the work of IMI and its projects:

- events;
- website;
- newsletter;
- social media (LinkedIn, Twitter);
- videos;
- multipliers (e.g. European Commission & EFPIA, States Representatives Group, Scientific Committee, National Contact Points, relevant scientific associations, patient organisations, healthcare professional associations, etc.);
- media (general and specialist, mainly in Europe but also elsewhere);
- direct mailings;
- publications;
- direct contacts with opinion leaders.

In 2021, IMI2 JU might need to implement the revision of its corporate identity and update its communication tools accordingly. This will require the support of external contractors.

## Key events in 2021

Events are a tool of central importance for engaging with the scientific community and reaching out to key stakeholders. The following events have been planned for 2021 (list to be updated during the year taking into consideration, among other factors, the impact of a potentially unremitting COVID-19 pandemic):

Events	Timeline
Promote IMI projects	Throughout year
Presence in the European Parliament (including joint JU's events)	Throughout year
Presence at relevant external events	Throughout year
Stakeholder Forum 2021	Q2

### 2.3.2 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.

The IMI2 JU will pursue its plans to acquire corporate identity-related services, for a total maximum value of EUR 200,000.

To make tender and contract management as effective and efficient as possible, IMI2 JU resorts extensively to multi-annual framework contracts and EU inter-institutional tenders. Most essential framework contracts are already in place and will be renewed beyond 2021.

### 2.3.3 IT and logistics

IMI2 JU information technologies (IT) 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 the Programme Office. Operations and administration information systems and infrastructure aim at making all IMI2 JU processes simpler and more efficient.

In order to achieve the afore-mentioned goal, the IT team will focus its 2021 activities on three areas:

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

#### 2.3.3.1 Business operations information systems

IMI2 JU's business operations will make use of the full suite of eGrants IT tools for the management of evaluations and grants. The IT team will continue monitoring satisfactory functioning for all end-users, in close liaison with the European Commission services.

Since some IMI projects go on until at least 2024 and some of the IMI2 JU specific requirements (e.g. EFPIA and Associated Partners annual reporting of in-kind contributions, Overview of Project Outputs) are not available in eGrants, the Programme Office will continue the maintenance and development of the in-house SOFIA.

The Programme Office will also continue further development of IMI data warehouse and QlikSense analytical platform.

### *2.3.3.2 Collaboration, communication and administration management information systems*

The Programme 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.

### *2.3.3.3 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 2021 and are expected to provide efficiency gains in the operation of the organisation: monitoring and maintenance of the common infrastructure and end-user office-automation support covering incidents, service requests and improvements.

The Programme Office will consider Microsoft 365 implementation on the basis on the outcome of EDPS assessment and Joint Undertakings own Data Protection Impact Assessment (DPIA).

To respond to the new ways of working, the IMI will implement Unified communications (UC) - the integration of enterprise communication services such as instant messaging (chat), presence information, voice (including IP telephony), mobility features (including extension mobility and single number reach), audio, web & video conferencing, fixed-mobile convergence (FMC), desktop sharing, data sharing (including web connected electronic interactive whiteboards), call control and speech recognition with non-real-time communication services such as unified messaging (integrated voicemail, e-mail and SMS). UC is a set of products that provides a consistent unified user interface and user experience across multiple devices and media types.

## **2.3.4 Human Resources**

The 2021 objective for Human Resources (HR) will be to ensure an efficient management of staff and an optimal working environment. To this end, the HR team will make sure to recruit, develop, assess, motivate and retain highly qualified staff with a view to ensure effective and efficient operation of the IMI2 JU, as well as equal opportunities. This objective will be implemented through the following four main themes:

### ***Staff management and recruitment***

In 2021 the total number of staff will remain the same 54 temporary and contract agents (of which 39 temporary agents and 15 contract agents), as well as two Seconded National Experts (SNEs).

Nevertheless, with the winding-up of H2020 on 31 December 2020 and the ongoing preparatory work for a possible new European Partnership in Health within Horizon Europe, the Programme Office might be significantly affected in terms of human resources. The Programme Office will explore measures to minimize the potential impacts and to ensure business continuity.

Selection and recruitment processes will remain key areas of the HR team, and due to the COVID-19 pandemic the selection procedures will be run remotely. It is expected that IMI2 JU will reach its complete staff establishment plan in 2021.

IMI2 JU will also foster its traineeship programme to provide young university graduates with the opportunity to gain hands-on professional experience in scientific fields related to IMI2 JU and to develop and strengthen their skills and competences. IMI2 JU might also need to recruit interim staff to address punctual needs to ensure business continuity.

In addition to the above, the human resources will deal with core functions such as: day-to-day management of administrative workflows and processes, salary, compensation and benefits, performance management, career development, reclassification, learning and development, safety and wellbeing at work; employees' motivation and communication. To optimise the daily management of HR activities, in 2021 the HR team will fully implement two new SYSPER II modules (i) digitalisation of the personal files and (ii) evaluation and promotion which will help IMI to streamline these processes. During the year, other SYSPER II modules may be implemented according to the need of the JU.

## **Legal Matters**

IMI2 JU will continue working closely with DG HR and the Standing Working Party (group following the Staff Regulation and its implementing rules) to ensure the adoption of the implementing rules and to strengthen its legal framework also adopting internal guidelines. In 2021 IMI2 JU is expected to adopt among others the following implementing rules amending Decision C(2013) 9051 of 16 December 2013 on leave (Special leave for welcoming a new-born child in the household), amending the Commission Decision C(2011)1278 of 3 March 2011 on the general implementing provisions for Articles 11 and 12 of Annex VIII to the Staff Regulations on the transfer of pension rights and the model decision on the conduct of administrative inquiries and disciplinary proceedings.

## **Organisation development**

To help the development and the personal and professional growth of IMI2 JU staff, the HR team will further develop the Learning and Development framework paying particular attention to the training needs of its staff and the organisation, and organising training activities to maintain staff knowledge up-to-date. The training activities will be mainly organised remotely due the COVID-19 pandemic. The HR team will also continue advising management on means and actions to enhance operational efficiency and effectiveness. Tailor-made training courses and coaching programmes for managers will be organised to support and keep them abreast in their day-to-day management of staff and operational activates. Teambuilding activities will also be organised to strengthen the collaboration among staff members and to enhance the team spirit.

The Programme Office is committed to preserve a physically and psychologically healthy work environment where work is meaningful and people have conditions to contribute to their best. To this end, IMI2 JU is committed to a zero tolerance towards psychological and sexual harassment and disrespectful work environment, and it will further develop its well-being program providing tailor-made lunchtime workshops, conferences and training courses for its staff. Due to COVID-19 pandemic these training actions will most likely be organised on-line.

The HR team will keep overseeing duties and responsibilities assigned to staff in order to achieve the fulfilment of IMI2 JU objectives and tasks.

## **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 2021, the JUs will continue to share the human-resource IT tools where necessary, common Calls for tender, as well as a common approach to implementing rules of the EU staff regulations.

To enhance the selection process, a new selection tool should be in place in 2021 following discussions with the other JUs. Cooperation with the others JUs will be further strengthen in other areas such as Learning and Development (e.g. organisation of standard and common training courses) and the management of the JUs network of confidential counsellors.

### 2.3.5 Administrative budget and finance

The administrative budget for the financial year 2021 is based on the currently available information.

The administrative budget has been reduced by EUR 2,045,674, in line with the figures revised by the European Commission for 2021 in view of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe.

The table below gives an overview of the 2021 budget initially approved, the adjustments and the 2021 budget amended after adjustments, per chapters.

	Heading	Budget initially approved 2021	Adjustments 2021	Budget 2021 amended, after adjustments
Title Chapter		Budget EUR	EUR	Budget EUR
<b>1</b>	<b>Staff expenditure</b>			
<b>11</b>	Staff in active employment	5,956,529	-305,529	5,651,000
<b>12</b>	Staff recruitments - miscellaneous expenditure	20,000	-10,000	10,000
<b>13</b>	Missions and duty travels	190,000	-130,000	60,000
<b>14</b>	Socio-medical structure	202,624	-10,624	192,000
<b>15</b>	External staff services	175,000	-50,000	125,000
<b>17</b>	Representation	20,000	-10,000	10,000
<b>Total Title 1 (Staff expenditure)</b>		<b>6,564,153</b>	<b>-516,153</b>	<b>6,048,000</b>

	Heading	Budget initially approved 2021	Adjustments 2021	Budget 2021 amended, after adjustments
Title Chapter		Budget EUR	EUR	Budget EUR
<b>2</b>	<b>Infrastructure expenditure</b>			
<b>20</b>	Office building and associated costs	776,000	-126,000	650,000
<b>21</b>	Information technology purchases	936,000	143,000	1,079,000
<b>22</b>	Office equipment (movable property and associated costs)	154,000	-149,000	5,000
<b>23</b>	Current administrative expenditure	137,000	-10,000	127,000
<b>24</b>	Telecommunication and postal expenses	78,000	-40,000	38,000
<b>25</b>	Expenditure on formal meetings	156,000	-128,000	28,000
<b>26</b>	Administrative expenditure in connection with operational activities	449,000	-309,000	140,000
<b>27</b>	External communication, information and publicity	766,000	-400,000	366,000
<b>28</b>	Service contracts	523,000	-104,000	419,000
<b>29</b>	Expert contracts and cost of evaluations	606,521	-406,521	200,000 <sup>4</sup>
<b>Total Title 2 (Infrastructure expenditure)</b>		<b>4,581,521</b>	<b>-1,529,521</b>	<b>3,052,000</b>
<b>Total Title 1+2 (Administrative expenditure)</b>		<b>11,145,674</b>	<b>-2,045,674</b>	<b>9,100,000</b>

<sup>4</sup> The expert costs are related to stage 2 evaluations of the Calls launched in 2020. There are no new Calls to be launched on IMI2 JU in 2021.

The operational budget is covered under section 2.2.2. Scientific priorities for 2021.

Amended Budget 2021 – see Chapter 3.

## ***Financial Management***

During 2021, the Programme Office will continue to ensure sound financial management through the implementation of the IMI2 JU Financial Rules<sup>5</sup>.

In this context, 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 Financial Circuits Manual and a set of standard operating procedures and workflows. In addition, knowledge dissemination will be further developed through guidance, checklists and the tenure of several financial workshops, in particular targeting beneficiaries, with the aim to reduce errors in financial reporting.

### **2.3.6 Data protection**

IMI2 JU will continue its efforts undertaken in the wake of the entry into effect of Regulation (EU) 2018/1725.

This will include raising awareness among IMI2 JU staff and stakeholders, liaising with the relevant services of the European Data Protection Supervisor and contributing to the activities of the inter-institutional data protection networks and working groups in which IMI2 JU participates.

### **2.3.7 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 outputs closer to the public in line with the policy developed by the Programme Office. IMI2 JU will continue the implementation of the standard operating procedure (SOP) on Access to documents and the training of the staff on access to documents issues, in case updates are deemed necessary.

Furthermore, 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.

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<sup>5</sup> The new version of the IMI2 Financial Rules has been adopted by the IMI2 JU Governing Board on 27.05.2020 (IMI2-GB-DEC-2020-19) according to the Commission Delegated Regulation (EU) 2019/887 on the model financial regulation for public-private partnership bodies referred to in Article 71 of the Regulation (EU, Euratom) 2018/1046 on the financial rules applicable to the general budget of the Union, repealing Regulation (EU, Euratom) No 966/2012 (2012 Financial Regulation).

## 2.4 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, the SC, the SRG and management.
- Align planning activities (strategy, annual work plans and related budget) and the associated monitoring and reporting activities.
- Improve responsibilities and accountability.
- Enhance communication and transparency.

IMI2 JU will continue to provide support to the Governing Board, the SC, the SRG, and the Stakeholder 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** (SC) will continue in its advisory role to the IMI2 JU and will notably be consulted on the scientific achievements to be described in the Annual Activity Report. One meeting of the SC is planned for 2021. The Chair will participate in the Governing Board meetings as an observer.

The **States Representatives Group** (SRG) will be consulted on the Annual Work Plan (and subsequent amendment(s)) and will receive information on Calls outcomes and evaluation process. Two meetings of the SRG are planned for 2021. The Chair will participate in the Governing Board meetings as an observer.

In addition, a joint meeting between the SC and the SRG might be planned in order to support the activities initiated to strengthen the synergies between the two advisory bodies and exchange on topics of common interest.

The **Strategic Governing Groups** (SGGs) will continue to ensure the coordination of IMI2 JU's work in seven strategic areas. 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 Programme Office and the SC. Currently, the seven established SGGs focus on the following areas: immunology; diabetes / metabolic disorders; neurodegeneration; translational safety; infections control; oncology; and digital health and patient-centric evidence generation.

Given that no more calls will be launched under IMI2, the focus of SGG activity will shift from coordinating the preparation of topic texts in their given areas to tracking outputs of the portfolio of projects generated in that area. Meeting as necessary, they will also explore, where possible, synergies with ongoing projects, both within IMI2 JU and those outside. They will be called upon to advise on how best to exploit IMI2 JU projects' outputs to achieve highest impact, also considering the external landscape. They may include contributions to exchanging good practices, identifying outputs that could be scaled up or built upon, gaps and potential additional activities of the projects, as well as explore synergies with similar or complementary activities at both national and global levels.

## 2.5 Internal Control framework

H2020 Research Framework Programme was designed to expire on 31 December 2020 however, the actions undertaken by the IMI2 JU will continue until 2024 as foreseen by the Council Regulation, to ensure the conclusion of the research projects funded. To that purpose, the IMI2 JU shall maintain an effective internal control framework to provide reasonable assurance that it operates effectively and efficiently, has a reliable financial reporting system and complies with applicable laws and regulations<sup>6</sup>.

Pursuant to the principle of sound financial management, the budget of the IMI2JU shall be implemented in compliance with effective and efficient Internal Control. In this regard 2021 objectives are:

- **Objective 1:** Maintain effective and efficient internal control system to ensure legality and regularity of processes and procedures, reliability of financial reporting;
- **Objective 2:** Maintain an effective risk management process, which allow identifying, assessing, and managing risks, i.e. potential problems (or changes) that could affect the achievement of the IMI2 JU objectives;
- **Objective 3:** Mitigate the risk of fraud by implementing effective anti-fraud measures in line with IMI2 anti-fraud strategy (AFS), in particular, by raising awareness of staff and stakeholders on fraud prevention, strengthening cooperation with anti-fraud services and implementing a revised anti-fraud strategy action plan.

The actions that will be developed at operational level to achieve these objectives will also take into account the specificities and needs linked to the new framework programme Horizon Europe where needed.

### 2.5.1 Ex-ante and ex-post controls

#### Ex-ante controls

Through the ex-ante controls embedded in the administrative and financial processes the Programme Office will ensure that:

- the expenditure is in order and complies with the provisions applicable;
- the principle of sound financial management is applied.

In particular, administration and finance processes will be conducted in a timely and efficient manner. They will be monitored through a defined set of KPIs, such as the time to pay (TTP) and the effective budget and work plan execution.

Full compliance with IMI Financial Rules, H2020 manuals and the Guidance set up by the Programme Office will be ensured to manage financial operations related to grants, expert management and administrative expenditure. As usual, specific attention will be placed on:

- Grant Agreement preparation (GAP) including pre-financing;
- Validation of financial and technical reports;
- Ex ante controls for interim and final payments executing recovery orders where needed;
- Raising the awareness of beneficiaries on financial and administrative aspects of H2020 rules, and how to avoid errors in cost reporting.

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<sup>6</sup> 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).

## **Ex-post controls**

For projects running under IMI JU (which was set up under the Seventh Framework Programme), the Programme Office will carry on with the implementation of its ex-post audit 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 rejection of any costs found to be in breach with the requirements of IMI JU Grant Agreement. Rejection of systematic errors will continue to be extended to unaudited financial statements ('Form C') of the audited participants. Representative ex-post audits of participants will be launched on new cost claims received and validated by the Programme Office since the last audited period to reach the audit coverage ratio set in its ex-post audit strategy and if necessary risk based audits will be launched according to its risk based audit strategy.

Systematic ex-post audits of accepted declarations of in-kind contributions by EFPIA companies will not be carried out in 2021 as the Work plan on ex post audits of EFPIA companies under IMI JU has reached its end in 2020 and the majority of the EFPIA companies' in-kind contributions has been covered by ex-post audits. Controls of in-kind contributions by EFPIA companies will also be based on the review of audit certificates provided by independent auditors for the final reporting period. Risk-based ex-post audits may nevertheless be initiated should a specific need arise.

As regards IMI2 JU, ex-ante and ex-post controls of grants are both aligned with the harmonised strategies adopted for the entire H2020 Programme. The Programme Office will carry out the ex-ante checks as prescribed in the H2020 Control strategy including the rejection of any costs found to be in breach with the requirements of IMI JU Grant Agreement. As for ex-post controls, the Commission Common Audit Service (CAS) will carry out the H2020 ex-post audits in accordance with the common H2020 audit strategy. The Programme Office contributes to the implementation of the H2020 audit strategy in close cooperation with the CAS and ensures that its ex-post audit strategy is complied with, including its audit coverage ratio. If necessary, risk based audits will be launched according to the risk based audit strategy approved by the Programme Office.

The harmonised legal framework will enable the Programme Office to draw an additional element of assurance from the extension of audit results on unaudited financial statements of common 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 the review of audit certificates provided annually by independent auditors and their validation by the Authorising Officer.

### **2.5.2 Internal and External audits**

The audit environment is an assurance and accountability pillar within the IMI2 JU internal control framework. 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.

Throughout the annual audit cycle IMI2 JU will support and coordinate audits carried out by its internal and external auditors, will follow up and assess the implementation of the Internal Audit Service (IAS) of the European Commission and the European Court of Auditors (ECA) audit recommendations and will report the state of implementation.

Internal audits are carried out by the IAS in liaison with the Business Assurance Coordinator.

In 2021, the focus will be put on:

The implementation of the IAS Strategic Internal Audit Plan 2019-2021<sup>7</sup>. IAS will audit performance management of IMI2 JU activities.

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<sup>7</sup> Ares(2019)4058461 - 26/06/2019

The objective of the audit is to assess the adequacy of the design, and the efficiency and effectiveness of the performance management system to support IMI2 JU in planning, monitoring and reporting and ultimately, in achieving its objectives.

External audits are carried out by the ECA. ECA will audit and issue opinions on the legality and regularity of the underlying transactions, revenue, and reliability of accounts. In accordance with the IMI2 JU Financial Rules, IMI2 JU's 2020 annual accounts will be audited by an external audit company while the ECA will draw an opinion on the basis of their work.

In view of the overall corporate objective of receiving an unqualified ('clean') ECA audit opinion and positive statement of assurance, the key activities will focus on:

- liaising and supporting ECA auditors throughout the audit on 2020 and 2021 accounts and following up on preliminary findings and recommendations;
- liaising with an independent financial audit firm and coordinating with ECA throughout the audit of accounts for financial year 2020 and 2021.

### **2.5.3 Anti-Fraud strategy**

In 2021 the Programme Office will continue to ensure the implementation of the IMI2 JU Anti-fraud Strategy (new version adopted in 2020) focusing on the awareness raising of its staff and stakeholders and through the action plan set up in coordination with the Commission Research Services.

### 3 Budget 2021

The budget for the financial year 2021 has been revised in line with the figures revised by the European Commission for 2021 in view of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe.

The administrative budget has been reduced by EUR 2,045,674 (50% EC EUR 1,022,827 - 50% EFPIA EUR 1,022,827), on both commitment and payment appropriations.

An overview of the amended 2021 budget per chapters is set out below.

STATEMENT OF REVENUE								
	Heading Revenue	Budget 2021.0		Budget 2021 Amendment 1		Amended Budget 2021.1		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
10	European Commission contribution (including EFTA contribution)	5,572,837	185,572,837	-1,022,837	-1,022,837	4,550,000	184,550,000	Commitment appropriations include EUR 4,550,000 for administrative costs. Payment appropriations include administrative costs of EUR 4,550,000 and operational costs of EUR 180,000,000.
	<b>European Commission contribution</b>	<b>5,572,837</b>	<b>185,572,837</b>	<b>-1,022,837</b>	<b>-1,022,837</b>	<b>4,550,000</b>	<b>184,550,000</b>	
20	EFPIA contribution	5,572,837	5,572,837	-1,022,837	-1,022,837	4,550,000	4,550,000	EFPIA contribution to administrative costs.
21	Subsidy from other members (other than Union and Associated Partners, constituent or affiliated)							
	<b>EFPIA and other members contributions</b>	<b>5,572,837</b>	<b>5,572,837</b>	<b>-1,022,837</b>	<b>-1,022,837</b>	<b>4,550,000</b>	<b>4,550,000</b>	
30	Associated Partners contributions							
	<b>Associated Partners contributions</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	
	<b>Total revenue</b>	<b>11,145,674</b>	<b>191,145,674</b>	<b>-2,045,674</b>	<b>-2,045,674</b>	<b>9,100,000</b>	<b>189,100,000</b>	

STATEMENT OF EXPENDITURE								
	Heading Title 1	Budget 2021.0		Budget 2021 Amendment 1		Amended Budget 2021.1		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
1	<b>Staff expenditure</b>							
11	Staff in active employment	5,956,529	5,956,529	-305,529	-305,529	5,651,000	5,651,000	Salaries and allowances of current staff (TAs and CAs), SNE, promotion and indexation
12	Staff recruitments - miscellaneous expenditure	20,000	20,000	-10,000	-10,000	10,000	10,000	Miscellaneous expenditure on staff recruitment: publication of vacancy calls, medical visits to take up duties, services provided by the European Personnel Selection Office (EPSO)
13	Missions and duty travels	190,000	190,000	-130,000	-130,000	60,000	60,000	Missions expenditure
14	Socio-medical structure	202,624	202,624	-10,624	-10,624	192,000	192,000	Other staff costs: EU school, medical check-up, trainings
15	External staff services	175,000	175,000	-50,000	-50,000	125,000	125,000	Interim staff expenses
17	Representation	20,000	20,000	-10,000	-10,000	10,000	10,000	Representation expenses
<b>Total Title 1 (Staff expenditure)</b>		<b>6,564,153</b>	<b>6,564,153</b>	<b>-516,153</b>	<b>-516,153</b>	<b>6,048,000</b>	<b>6,048,000</b>	

	<b>Heading Title 2</b>	<b>Budget 2021.0</b>		<b>Budget 2021 Amendment 1</b>		<b>Amended Budget 2021.1</b>		<b>Comments</b>
<b>Title Chapter</b>		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
<b>2</b>	<b>Infrastructure expenditure</b>							
<b>20</b>	Office building and associated costs	776,000	776,000	-126,000	-126,000	650,000	650,000	Building related expenditure: rent, works, charges, maintenance, repairs, security and surveillance
<b>21</b>	Information technology purchases	936,000	936,000	143,000	143,000	1,079,000	1,079,000	IT purchases, software licences, software development
<b>22</b>	Office equipment (movable property and associated costs)	154,000	154,000	-149,000	-149,000	5,000	5,000	Purchases and rental of office equipment, maintenance and repair
<b>23</b>	Current administrative expenditure	137,000	137,000	-10,000	-10,000	127,000	127,000	Office supply, newspaper subscriptions, translation services, bank charges and miscellaneous office expenditure
<b>24</b>	Telecommunication and postal expenses	78,000	78,000	-40,000	-40,000	38,000	38,000	Data communication such as telephone, video, audio conferences, postal services
<b>25</b>	Expenditure on formal meetings	156,000	156,000	-128,000	-128,000	28,000	28,000	Official meetings such as States Representative Group, Scientific committee, Governing Board and working groups created by the Governing Board
<b>26</b>	Administrative expenditure in connection with operational activities	449,000	449,000	-309,000	-309,000	140,000	140,000	Administrative expenditure in connection with research activities and objectives of IMI2 JU (workshops, meetings and events targeting IMI projects)
<b>27</b>	External communication, information and publicity	766,000	766,000	-400,000	-400,000	366,000	366,000	External communication and events such as Info Days,

	Heading Title 2	Budget 2021.0		Budget 2021 Amendment 1		Amended Budget 2021.1		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
								Stakeholder forums
28	Service contracts	523,000	523,000	-104,000	-104,000	419,000	419,000	Ex-post audits, studies, audits, accounting services
29	Expert contracts and cost of evaluations	606,521	606,521	-406,521	-406,521	200,000	200,000	Costs linked to evaluations, expert contracts
<b>Total Title 2 (Infrastructure expenditure)</b>		<b>4,581,521</b>	<b>4,581,521</b>	<b>-1,529,521</b>	<b>-1,529,521</b>	<b>3,052,000</b>	<b>3,052,000</b>	
<b>Total Title 1 + 2 (administrative expenditure)</b>		<b>11,145,674</b>	<b>11,145,674</b>	<b>-2,045,674</b>	<b>-2,045,674</b>	<b>9,100,000</b>	<b>9,100,000</b>	

	Heading Title 3	Budget 2021.0		Budget 2021 Amendment 1		Amended Budget 2021.1		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	Commitment Appropriation (CA)	Payment Appropriation (PA)	
3	<b>Operational expenditure</b>							
30	Implementing the research agenda		180,000,000			0	180,000,000	Payments FP7, H2020
<b>Total Title 3 (Operational expenditure)</b>		<b>0</b>	<b>180,000,000</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>180,000,000</b>	
<b>Total expenditure</b>		<b>11,145,674</b>	<b>191,145,674</b>	<b>-2,045,674</b>	<b>-2,045,674</b>	<b>9,100,000</b>	<b>189,100,000</b>	

An overview of the amended 2021 Budget per budget lines is set out in the table below.

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
1100	Staff in active employment and costs linked to employees	3,297,000	3,297,000
1101	Family Allowances	370,000	370,000
1102	Transfer and expatriation allowances	510,000	510,000
1110	Contract Agents	934,000	934,000
1111	Seconded National Experts	65,000	65,000
1130	Insurance against sickness	120,000	120,000
1131	Insurance against accidents and occupational diseases	15,000	15,000
1132	Unemployment insurance for temporary staff	48,000	48,000
1133	Pension	-	0
1140	Birth and death allowances	1,000	1,000
1141	Annual travel costs from the place of employment to the place of origins	60,000	60,000
1144	Fixed local travel allowances	-	0
1149	Other allowances	-	0
1172	Cost of organising traineeships within IMI2 JU	10,000	10,000
1175	Translation and typing services	-	0
1177	Other services rendered	90,000	90,000
1178	Paymaster Office (PMO) fees	65,000	65,000
1180	Sundry recruitment expenses	5,000	5,000
1181	Travelling expenses (including taking up duty)	1,000	1,000
1182	Installation allowance	30,000	30,000
1183	Moving expenses	10,000	10,000
1184	Temporary daily allowance	15,000	15,000
1190	Weightings (correction coefficient)	5,000	5,000
1191	Salaries adaptation	-	0
<b>11</b>	<b>Staff in active employment</b>	<b>5,651,000</b>	<b>5,651,000</b>
1200	Miscellaneous expenditure on staff recruitment	10,000	10,000
<b>12</b>	<b>Staff recruitments - miscellaneous expenditure</b>	<b>10,000</b>	<b>10,000</b>
1300	Mission expenses	60,000	60,000
<b>13</b>	<b>Missions and duty travels</b>	<b>60,000</b>	<b>60,000</b>
1401	EU school costs	80,000	80,000
1410	Other trainings	50,000	50,000
1430	Medical service	20,000	20,000
1440	Trainings covered by the EC service level agreement	30,000	30,000
1490	Other interventions	12,000	12,000
<b>14</b>	<b>Socio-medical structure</b>	<b>192,000</b>	<b>192,000</b>
1500	External staff expenditure	125,000	125,000
<b>15</b>	<b>External staff services</b>	<b>125,000</b>	<b>125,000</b>
1700	Representation expenses	10,000	10,000
<b>17</b>	<b>Representation</b>	<b>10,000</b>	<b>10,000</b>
<b>Total Title 1 (Staff expenditure)</b>		<b>6,048,000</b>	<b>6,048,000</b>

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2000	Rentals office building	450,000	450,000
2001	Guarantees		
2002	Contributions		
2010	Insurance		
2020	Charges (water, gas, electricity, works)	190,000	190,000
2030	Cleaning and maintenance		
2040	Furnishing of premises	10,000	10,000
2050	Security and surveillance	0	0
2090	Other expenditure on buildings		
<b>20</b>	<b>Office building and associated costs</b>	<b>650,000</b>	<b>650,000</b>
2101	Hardware, infrastructure and related services	325,000	325,000
2102	Software development, licenses and related services	754,000	754,000
2103	Other expenses maintenance and repair		
<b>21</b>	<b>Information technology purchases</b>	<b>1,079,000</b>	<b>1,079,000</b>
2200	Purchase office equipment	0	0
2201	Rentals office equipment	0	0
2202	Maintenance utilisation and repair	5,000	5,000
2203	Other office equipment		
<b>22</b>	<b>Office equipment (movable property and associated costs)</b>	<b>5,000</b>	<b>5,000</b>
2300	Stationery and office supply	50,000	50,000
2320	Bank charges	0	0
2321	Exchange rate losses	0	0
2329	Other financial charges	0	0
2330	Legal expenses	15,000	15,000
2350	Other operating expenditure	3,000	3,000
2351	Petty expenses	0	0
2360	Library stocks purchase of books and subscriptions	50,000	50,000
2370	Translation, interpretation	9,000	9,000
<b>23</b>	<b>Current administrative expenditure</b>	<b>127,000</b>	<b>127,000</b>
2400	Correspondence and communication expenses	38,000	38,000
<b>24</b>	<b>Telecommunication and postal expenses</b>	<b>38,000</b>	<b>38,000</b>
2500	Formal meetings	28,000	28,000
<b>25</b>	<b>Expenditure on formal meetings</b>	<b>28,000</b>	<b>28,000</b>
2600	Administrative costs in connection with operational activities	20,000	20,000
2601	Events targeting IMI projects	0	0
2602	Workshops	120,000	120,000
2603	Knowledge Management	0	0
<b>26</b>	<b>Administrative costs in connection with operational activities</b>	<b>140,000</b>	<b>140,000</b>
2700	External communication	126,000	126,000
2701	Events external communication	200,000	200,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2702	Material	40,000	40,000
<b>27</b>	<b>External communication, information and publicity</b>	<b>366,000</b>	<b>366,000</b>
2800	Ex-post Audits	200,000	200,000
2801	Studies, consultancy	100,000	100,000
2802	Audit services	49,000	49,000
2803	Accounting services	70,000	70,000
<b>28</b>	<b>Service contracts</b>	<b>419,000</b>	<b>419,000</b>
2900	Evaluation Experts meetings	200,000	200,000
2901	Evaluation Facilities		
2902	Evaluations Exploring New Scientific Opportunities (ENSO)		
<b>29</b>	<b>Expert contracts and cost of evaluations</b>	<b>200,000</b>	<b>200,000</b>
<b>Total Title 2 (Infrastructure expenditure)</b>		<b>3,052,000</b>	<b>3,052,000</b>

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3000	Implementing the research agenda of IMI1 JU		
3001	IMI1 JU Call 1		
3002	IMI1 JU Call 2		
3003	IMI1 JU Call 3		
3004	IMI1 JU Call 4		
3005	IMI1 JU Call 5		
3006	IMI1 JU Call 6		9,000,000
3007	IMI1 JU Call 7		
3008	IMI1 JU Call 8		
3009	IMI1 JU Call 9		3,000,000
3010	IMI1 JU Call 10		300,000
3011	IMI1 JU Call 11		11,700,000
3012	Exploring New Scientific Opportunities (ENSO) 2012		
3013	Exploring New Scientific Opportunities (ENSO) 2013		
3020	Implementing the research agenda of IMI2 JU		
3021	IMI2 JU Call 1		500,000
3022	IMI2 JU Call 2		700,000
3023	IMI2 JU Call 3		2,700,000
3024	IMI2 JU Call 4		0
3025	IMI2 JU Call 5		7,500,000
3026	IMI2 JU Call 6		6,000,000
3027	IMI2 JU Call 7		7,200,000
3028	IMI2 JU Call 8		7,300,000
3029	IMI2 JU Call 9		8,500,000
3030	IMI2 JU Call 10		20,000,000

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3031	IMI2 JU Call 11		500,000
3032	IMI2 JU Call 12		10,000,000
3033	IMI2 JU Call 13		22,500,000
3034	IMI2 JU Call 14		9,000,000
3035	IMI2 JU Call 15		15,000,000
3036	IMI2 JU Call 16		3,200,000
3037	IMI2 JU Call 17		2,800,000
3038	IMI2 JU Call 18		10,504,000
3039	IMI2 JU Call 19		
3040	IMI2 JU Call 20		18,000,000
3041	IMI2 JU Call 21		3,600,000
3042	IMI2 JU Call 22		496,000
3043	IMI2 JU Call 23		
3999	Recovery Ex-post audit		
<b>30-C1</b>	<b>Implementing the research agenda of IMI2 JU</b>	<b>0</b>	<b>180,000,000</b>
<b>Total Title 3 (Operational expenditure)</b>		<b>0</b>	<b>180,000,000</b>
<b>Total expenditure</b>		<b>9,100,000</b>	<b>189,100,000</b>

### 3.1 Staff Establishment Plan 2021

Grade	Posts filled on 31/12/2019	Establishment Plan 2020				Year 2021											
						Posts evolution						Organisational evolution			Establishment Plan 2021		
						Promotion / Career advancement			Turn-over (departures/arrivals)			New posts (per grade)			Requested (Budget)		
		TEMP	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	1
AD13																	
AD12	1			2	2											2	2
AD11	2			2	2											2	2
AD10				1	1											1	1
AD9	5			7	7											7	7
AD8	4			6	6											6	6
AD7	6			2	2											2	2
AD6	4			8	8	+3										11	11
AD5	9			4	4	-3										1	1
Total AD	32			33	33											33	33
AST11																	
AST10																	
AST9																	
AST8	1			1	1											1	1
AST7																	
AST6																	
AST5																	
AST4	2			4	4											4	4
AST3	2																
AST2				1	1											1	1
AST 1	1																
Total AST	6			6	6											6	6
SC6																	
SC5																	
SC4																	
SC3																	
SC2																	
SC1																	
Total SC	0			0	0											0	0
Overall Total	38			39	39											39	39

Contract Agents Grade	Posts filled on 31/12/2019	Establishment plan 2020	Establishment plan 2021
<b>FG IV</b>	2	3	3
<b>FG III</b>	11	11	11
<b>FG II</b>	1	1	1
<b>FG I</b>	0	0	0
<b>Total CA</b>	<b>14</b>	<b>15</b>	<b>15</b>

Seconded National Experts	Posts filled on 31/12/2019	Establishment plan 2020	Establishment plan 2021
	1	2	2

## List of acronyms

Acronym	Meaning
<b>AD (HR)</b>	Administrator
<b>AMR</b>	Antimicrobial Resistance
<b>APs</b>	IMI2 JU Associated Partners
<b>AST</b>	Assistant
<b>CA (Budget)</b>	Commitment Appropriation
<b>CA (HR)</b>	Contractual Agent
<b>COVID-19</b>	Infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The WHO recognised the spread of COVID-19 as a pandemic on 11 March 2020.
<b>DG HR</b>	Directorate-General Human Resources and Security (European Commission)
<b>DG RTD</b>	Directorate-General for Research and Innovation (European Commission)
<b>EC</b>	European Commission
<b>ECA</b>	European Court of Auditors
<b>EDPS</b>	European Data Protection Supervisor
<b>EFPIA</b>	European Federation of Pharmaceutical Industries and Associations
<b>EMA</b>	European Medicines Agency
<b>EU</b>	European Union
<b>EUR</b>	Euros
<b>FG</b>	Function Group
<b>GA</b>	Grant Agreement
<b>GB</b>	IMI2 JU Governing Board
<b>GDPR</b>	General Data Protection Regulation
<b>H2020</b>	Horizon 2020, the Framework Programme for Research and Technological Development of the European Union for 2014–2020
<b>HR</b>	Human resources
<b>IAS</b>	Internal Audit Service of the European Commission
<b>ICC</b>	Internal Control Coordinator
<b>ICS</b>	Internal Control Standards
<b>ICT</b>	Information Communications Technology
<b>IMI JU</b>	Innovative Medicines Initiative Joint Undertaking
<b>IMI2 JU</b>	Innovative Medicines Initiative 2 Joint Undertaking
<b>IT</b>	Information Technology
<b>JUs</b>	Joint Undertakings
<b>KPI</b>	Key performance indicator
<b>MEP</b>	Member of the European Parliament
<b>PA</b>	Payment Appropriation
<b>PM</b>	Person/month
<b>PPP</b>	Public-private partnership
<b>R&amp;D</b>	Research and development
<b>RAE</b>	Risk assessment exercise
<b>RI</b>	Research Infrastructure
<b>RIA</b>	Research and Innovation Action
<b>RP</b>	Reporting Period
<b>SC</b>	IMI2 JU Scientific Committee
<b>SGGs</b>	Strategic Governing Groups
<b>SMEs</b>	Small and medium-sized enterprises
<b>SOP</b>	Standard operating procedure
<b>SRA</b>	Strategic Research Agenda
<b>SRG</b>	IMI2 JU States Representatives Group
<b>TA</b>	Temporary Agent
<b>TPP</b>	Time to Pay
<b>WHO</b>	World Health Organisation



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