

# Annual Work Plan and Budget for 2022

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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 Annual Work Plan and Budget 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-2021-16 adopted on 16.11.2021**

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# 1 Introduction

In 2022 the Programme Office will have two major areas of focus of equal importance. The first is the managing of the significant legacy portfolio of well over 100 running projects of IMI (the projects cover the key challenges highlighted in the IMI2 JU Strategic Research Agenda such as diabetes/metabolic disorders, neurodegeneration, immunology, infection control (including vaccines), translational safety, digital health, and oncology). We will ensure that the results coming from these large scale projects will be disseminated, communicated upon and valorised to maximise the value to the European citizen. This work is particularly important in 2022 as this is the year when the IMI2 programme should undergo its final evaluation by a group of independent experts.

The second area of activity comprises the completion of a range of activities to ensure a smooth transition to the Innovative Health Initiative Joint Undertaking, the cross-sectorial European partnership in health under Horizon Europe. This will encompass the solidification of a brand new governance structure involving a new set of industry partners, a new process of topic definition engaging with a broader stakeholder group in order to define the research priorities in a given year, and preparatory work for launching the first Calls and evaluating proposals.

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 2021 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.

Pierre Meulien  
Executive Director

## 2 Annual Work Plan Year 2022

### 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 its' portfolio of projects, ensuring sound budget management and close monitoring of project performance.

Although the vaccination campaigns against SARS-Cov-2 have been successfully rolled out in the EU the emergence of the delta variant and persistently high infection rates pose a significant risk to getting the pandemic under control. Therefore, the Programme Office will continue to monitor closely risks associated with the COVID-19 pandemic and potential future public health crises. One consequence of the pandemic is that many projects have requested no-cost project extensions due to the impact of COVID on the research community and their work. As a consequence, IMI will maintain a larger than originally foreseen number of running projects in 2022.

Having completed its programme of calls and concluded the signature of its last grant agreements 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 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, efforts focused on reporting and dissemination will be increased complemented by studies assessing the impact of the results of closed projects.

It is foreseen that a future partnership in health will be in place in 2022, therefore the Programme Office will strive to ensure a smooth transition to this new cross-sectorial partnership under Horizon Europe. The Programme Office will balance the required oversight of IMI projects and their outputs while managing the activities associated with the new programme. Whenever possible the experience and know-how of the IMI2 JU will be leveraged to ensure the smooth functioning of the future programme while ensuring the obligations and responsibilities of the IMI projects are monitored and maintained.

## 2.2 Operations

### 2.2.1 Objectives & indicators - risks & mitigations

The key objectives for IMI2 JU operations in 2022 are identified by the Governing Board in the Annual Work Plan and by the Management at operational level.

Key operational objectives for 2022 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 Key Performance Indicators (KPIs)

Reporting on measuring and outcomes on the ten following KPIs will be provided yearly as part of the IMI2 JU Annual Activity Reports for year 2021 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 Strategic Research Agenda (SRA) and addressed by IMI2 projects.	Based on the SRA and including the WHO priority medicines therapeutic areas: - expressed as a number of areas reflected in the IMI2 portfolio; - complemented by the number and budget of grant agreements that delivered them.	IMI2 Regulation objective b1:  b1: 'increase the success rate in clinical trials of priority medicines identified by the WHO'	0	12
2	The number of project-developed assets which complete a significant milestone during the course of an IMI2 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.	IMI2 Regulation objective b1, b2, b4, b5 and b6:  b1: 'increase the success rate in clinical trials of priority medicines identified by the WHO'  b2: 'reduce the time to reach clinical proof of concept in medicine development...'  b4: 'develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators'  b5: 'reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks'  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'	0	50

KPI	Definition	Comment	Relates to	Baseline	Target
3	<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 Regulation objective b1, b2, b4, b5 and b6:</p> <ul style="list-style-type: none"> <li>b1: 'increase the success rate in clinical trials of priority medicines identified by the WHO'</li> <li>b2: 'reduce the time to reach clinical proof of concept in medicine development...'</li> <li>b4: 'develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators'</li> <li>b5: 'reduce the failure rate of vaccine candidates in phase III of clinical trials through new biomarkers for initial efficacy and safety checks'</li> <li>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'</li> </ul>	0	10 (for completed procedures)

KPI	Definition	Comment	Relates to	Baseline	Target
4	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 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
5	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 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 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 IMI 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 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 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 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
8	New tools and processes generated by IMI2 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 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
9	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 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 IMI1 projects involving patient organisations: (participants /advisory boards etc. 40%)	80%

10	Support to SMEs: share of SMEs participating as formal IMI project beneficiaries.	- To be complemented by the number of SMEs benefitting from IMI project support in other ways.	H2020 priority; IMI2 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 IMI1 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 the IMI2 JU to effectively customise its objectives and prioritise actions.

At this stage of the planning lifecycle, the identification and assessment of the risks that might challenge the achievement of the IMI2 JU objectives for 2022 cannot be exhaustive, particularly for mitigation measures.

However, some specific risks factor can be already foreseen while the corresponding mitigating measures may be defined within the final annual work programme. These risks relate to:

- The on-going preparatory work to set-up the new cross-sectorial partnership in health under Horizon Europe is accompanied by uncertainties surrounding the transition, and notably a late start date Call launch that would delay the implementation of a part of Horizon Europe, and by lack of clarity around key concepts on how the future programme will be governed and administered. The Programme Office might be significantly affected in terms of financial (e.g. delay in budget execution and budget overrunning) and human resources (e.g. missing expertise, staff leaving the organisation);
- With the expected termination of the Service Level Agreement concluded with the EC providing the JUs with the accounting expertise and services and the EC proposal to integrate the position of accounting officer as part of the back office arrangements between the JUs set-up under Horizon Europe, there is a risk of not being able to ensure proper business continuity within the expected imposed timeframe, of not getting a clean audit opinion and favourable Governing Board opinion, and of facing subsequent issues during the discharge process.

In order to control this risk, IMI2 JU financial needs and budget for 2022 have to be appropriately estimated while the staff should be regularly informed on the objectives, activities and new planning.

## 2.2.2 Scientific priorities for 2022

The IMI2 JU activities for 2022 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 monitor, and support as necessary the engagement and successful collaboration across a broader range of partners from different sectors during the lifetime of the projects (e.g. biomedical imaging, medical information technology, diagnostics and/or animal health industries among others).

While IMI2 JU will not launch further Calls for proposals in 2022, the Programme Office will continue to manage its portfolio and monitor its impact. In 2022, the portfolio of running projects will be consolidating with a large 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 exploitation of outputs via effective dissemination. 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

Subject to finalisation of the 2022 procedure by the EU Budgetary Authority, the forecast put forward in the budget plan for 2022 has been evaluated based on the available information. This budget refers only to IMI2 JU activities.

The payment appropriations will be consumed as intermediate and final payments for FP7 and H2020 projects.

IMI2 JU launched its last Call for proposals in 2020. Operational commitment appropriations are not foreseen in 2022 for IMI2 JU, as there are no new Calls to be launched under IMI2 JU in 2022.

A table overview of the operational budget for 2022 is set out below.

Chapter	Heading Title 3	Financial year 2022		Comments
		Commitment Appropriation (CA)	Payment Appropriation (PA)	
30	Implementing the research agenda of IMI2 JU		167,000,000	Payment appropriations – payments FP7 and H2020
<b>Total Title 3 (Operational expenditure)</b>			<b>167,000,000</b>	

A table overview of the budget plan for 2022 is set out in Chapter 3 to this Annual Work Plan<sup>1</sup>.

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<sup>1</sup> This Annual Work Plan for 2022 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**

96 projects will be running at different stages of their life cycle in 2022. Taking into consideration those projects under Grant Agreement Preparation in 2021 as well as those projects ending in late 2021, a total number of 104 projects are expected to submit reports in 2022.

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 17 reviews for projects launched under IMI2 JU Calls 12, 13, 14, 15, 16, 17, 19, 21 and 22.

The following table presents a forecast of the reporting expected for 2022.

IMI Calls	Total Projects	Ongoing in 2022	Project periodic report due in 2022							Of which		
			1 <sup>st</sup> RP in 2022	2 <sup>nd</sup> RP in 2022	3 <sup>rd</sup> RP in 2022	4 <sup>th</sup> RP in 2022	5 <sup>th</sup> to 7 <sup>th</sup> RP in 2022	8 <sup>th</sup> to 9 <sup>th</sup> RP in 2022	Total reports	Project ending in 2022	Final report due in 2022	
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											
IMI JU C9	4	1						1	1	1		
IMI JU C10	1	1						1	1	1	1	
IMI JU C11	8							3	3		3	
<b>IMI JU</b>	<b>59</b>	<b>3</b>						<b>5</b>	<b>1</b>	<b>6</b>	<b>2</b>	<b>4</b>
IMI2 C1	1	1						1	1	1	1	
IMI2 C2	8							1	1		1	
IMI2 C3	5	3						3	3	3	3	
IMI2 C4	1											
IMI2 C5	6	3						3	3	2	2	
IMI2 C6	4							3	3		3	
IMI2 C7	7	4						5	5	3	3	
IMI2 C8	4	3			1	1	1		3	2	2	
IMI2 C9	6	4						4	4	4	4	
IMI2 C10	8	7				7			7	2	2	
IMI2 C11	3											
IMI2 C12	7	7			6	1			7	2	2	
IMI2 C13	13	13			13				13	6	6	
IMI2 C14	4	4		2	2				4	1	1	
IMI2 C15	7	7		5	1				6	1		
IMI2 C16	5	5		1	4				5	1	1	
IMI2 C17	3	3		3					3			
IMI2 C18	6	6	3	3					6			
IMI2 C19	2	2		1					1			
IMI2 C20	6	6	6						6			
IMI2 C21	8	6	2	6					8	2	2	
IMI2 C22	3	3	3						3			
IMI2 C23*	6	6	6						6			
<b>IMI2 JU</b>	<b>123</b>	<b>93</b>	<b>20</b>	<b>21</b>	<b>27</b>	<b>9</b>	<b>21</b>	<b>0</b>	<b>98</b>	<b>30</b>	<b>33</b>	
<b>Totals</b>	<b>182</b>	<b>96</b>	<b>20</b>	<b>21</b>	<b>27</b>	<b>9</b>	<b>21</b>	<b>1</b>	<b>104</b>	<b>32</b>	<b>37</b>	

\* The estimated number of projects and reports is based on the ongoing GAPs.



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. 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**

104 project periodic reports will be submitted in 2022 (for ongoing projects and those finalised in 2021 see column in the above table– 'Project periodic report due in 2022 – 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 2022, the analysis of the IMI project scientific outputs in terms of publications and collaboration among IMI researchers will be continued. Where feasible, monitoring and analysis approaches will be refined in line with observations from the European Court of Auditors (ECA) to ensure the highest possible standards.

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

In 2022, 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**

The Programme Office will continue to take active steps to engage with patients and promote patient involvement at all levels. Building on the experience of patient involvement so far, IMI2 JU will undertake significant efforts to create opportunities for patients and carers to work as equal partners in research in an open and transparent way. The patient engagement strategy will continue to focus on a two-way process of interacting with the patient–carer community, and provide the necessary framework to enhance the quality of IMI projects from the patient perspective.

The systematic involvement of patients and carers in various IMI activities via different initiatives as is the IMI pool of patient experts will be further supported and strengthened. The Programme Office will organise different activities on every step of the patient engagement ladder aiming to support the involvement of patients at all levels with the goal to increase the flow of patient participation towards the level of involvement where this is most powerful and meaningful. Moreover, IMI2 JU will hold meetings covering specific disease areas/topics which will optimise its approach to patient-centricity 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 that will facilitate the implementation of its 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 to ensuring that safe and effective medicines reach the market for the benefit of patients. To ensure that the science generated by IMI projects is translated into patient-centred healthcare IMI2 JU will continue to engage with all relevant regulatory authorities, in particular, the European Medicines Agency (EMA). IMI2 JU will also continue to encourage and support consortia to interact with regulators to ensure acceptance of project outputs of regulatory relevance. When possible and relevant, IMI2 JU aims to strengthen engagement with other international agencies and competent national authorities, as well as, relevant health technology assessment (HTA) bodies, for instance in order to progress the goal of end-to-end integration in medicine development.

Moreover, the Programme Office will follow on the progress of the work performed by Critical Path Institute Limited through the framework contract for services to support the regulatory acceptance of IMI results. In particular, the Programme Office will monitor the tasks for the selected project results towards recommendation on the regulatory pathway for acceptance, gaps data analysis and strategy to generate them and preparation of the dossier for interaction with the regulatory agencies. In addition, the Programme Office will ensure dissemination to other IMI projects of the best practices on planning regulatory strategy and implementing engagement using the regulatory processes available identified by the study.

## Other industries and stakeholders

Especially in consideration of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe:

- IMI2 JU will continue to interact with charities, foundations, and industries and stakeholders outside of the pharmaceutical sector as the healthcare challenges faced by society are global;
- 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.

In order to share best practices between IMI projects and develop potential synergies, IMI2 JU will continue to encourage its projects to organise cross-projects meetings. This is particularly important in helping disseminate information about IMI2 JU and the uptake of project results, while 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.

In addition, IMI2 JU will continue to explore how to make better use of EU specific dissemination tools and channels for the promotion of IMI projects and their results by actively participating in the European Commission's Dissemination and Exploitation Network (D&E Net) and intensively promoting the Innovation Radar, the Horizon Results Portal and the Horizon Results Booster among both IMI staff and IMI projects.

In 2022, IMI2 JU expects to receive approximately 37 final project reports. This number is greater than foreseen due to consortia requests for no-cost extensions as a result of the impact of the COVID-19 pandemic. 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 most of the projects ending late 2021 and in 2022, close-out meetings will be organised around the time of submission of the final report. 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 Programme 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 IMI project.

## **2.2.7 Impact assessment of the IMI projects**

An important part of evaluating the performance of IMI2 JU consists in assessing the - impact of the IMI projects. As set out in the Strategic Research Agenda for IMI2, the Programme Office remains focused on the needs of patients and society, and on delivering tools and resources to speed up the development of urgently-needed treatments.

In 2019 and 2020, IMI2 JU conducted a new Socio-economic Impact Assessment Report that covered 44 IMI1 finished projects. The analysis was commissioned to the Centre for Innovation in Regulatory Science by Clarivate Analytics and the report was published in January 2021<sup>2</sup>. This study was conducted employing the same methodology previously in use that consisted in reviewing the projects' final reports and in some cases complementing the analysis with on-line surveys to projects' stakeholders.

In 2021 the Programme Office has ideated and initiated a small-scale Impact Assessment pilot involving a limited set of IMI2 finished projects in the field of Nervous System Disorders, experimenting a new methodology. The new methodology includes the leadership of the Impact Assessment by an independent expert as well as the engagement of the key project stakeholders through web-assisted interviews. Depending on the outcome of the pilot the Programme Office may decide to publish the results and expand the study to a larger pool of projects in the same or in different therapeutic fields as of 2022.

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<sup>2</sup> [https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI1\\_SocioEconomicImpactReport\\_2020.pdf](https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/IMI1_SocioEconomicImpactReport_2020.pdf)

## 2.3 Support to Operations

### 2.3.1 Communication

#### Focus on results and impact

As more projects draw to a close, the 2022 IMI 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, building a continuum between IMI's communication and dissemination activities.

In order to amplify the reach of project success stories and results, IMI2 JU will keep working 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, as well as with the Publications Office, responsible for drafting products such as the Results in Brief and the Research EU magazine (including those included in Results Packs).

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.

#### Setting the ground for a new communications strategy

In the context of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe, the Communications team will develop a new logo, a new corporate visual identity, together with a new website.

In addition, the Communications team will prepare a launch package that will include a launch event and fit for purpose publications (infographics, factsheet, social media cards).

#### Communication channels

The Communication team 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 of the new partnership, once adopted:

- 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.

### 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.

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 2022.

### 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.

IMI2 JU is part of common governance of IT operations and infrastructure, together with five Joint Undertakings that are also located in the same premises. This provides efficiency, economy of scale and gains in the operation of the organisation.

Another very important key success factor is cooperation, shared services and knowledge sharing within ICTAC (Information and Communication Technologies Advisory Committee, part of the European Union Agencies Network) and with EC services.

In order to achieve the afore-mentioned goals and in continuity with the successful work in the past years, the IT team will focus its 2022 activities on the following areas:

#### *1. Stable, secure and agile IT infrastructure and office automation, more and more focused on modern (anywhere, anytime) ways of working*

We will continue monitoring and maintenance of the common Infrastructure-as-a-Service (IaaS) infrastructure and end-user office-automation support covering incidents, service requests and improvements.

Jointly with other JUs, and following common DPIA, we will further implement and extend use of Microsoft 365 Software-as-a-Service (SaaS) which eventually became the main office automation tools. The Programme Office will continue following general IT trend in adoption SaaS solution both from the market (e.g. SYSTAL) and from the European Commission and other EU institutions and agencies.

#### *2. Business operations information systems*

IMI2 JU's business operations will continue to be based mainly on the eGrants IT tools for the management of evaluations and grants. The IT team will monitor satisfactory functioning for all end-users, in close liaison with the European Commission services, including SPOC functions.

SOFIA will be maintained as main tool for managing still ongoing IMI1 projects and as a complementary tool for missing IMI2 specific requirements in eGrants (e.g. EFPIA and Associated Partners annual reporting of in-kind contributions, Overview of Project Outputs).

The Programme Office will also continue further development of IMI data warehouse and QlikSense analytical platform and mashups with particular focus on data quality and reliability.

The IT team will support existing and migration to new European Commission tools.

#### *3. Collaboration, communication and administration management information systems*

The IMI Intranet will continue its evolution and will be completely re-build on M365 SharePoint technology. It has already proved its effectiveness as main internal communication tool, enabling collaboration, and supporting business activities. The core part of new intranet are service pages by teams/area of activities with the main purpose of informing other colleagues.

Collaborative platforms, providing support to the governance bodies will be rebuild in SharePoint as well.

In the context of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe, the Office will create new official website and collaboration platforms, and handle the update of local reporting and information systems – IMI data warehouse, QlikSense reporting platform and SOFIA.

## 2.3.4 Human Resources

The 2022 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, equal opportunities and a smooth transition into the new programme. This objective will be implemented through the following four main themes:

### *Talent management*

In 2022 the total number of staff will be 54 temporary and contract agents (of which 39 temporary agents and 15 contract agents), as well as 1 Seconded National Expert (SNE).

2022 will be a transitional and complex year for the Programme Office. The Programme Office will have to manage a large and complex legacy from IMI1 and IMI2 projects while leading the transition and setting up the new programme. This will have a significant impact on the management of the Programme Office human resources, which will explore measures to minimize potential impacts and to ensure business continuity.

Selection and recruitment processes will therefore remain key areas of IMI2 JU HR in order to guarantee that the best talents, with the necessary set of competences and skills will be recruited, and existing talents are retained to meet current demands and being prepared for future challenges. The HR team will ensure alignment throughout the organization establishing a strong link between HR processes and business results, connecting the Programme Office overall strategic goals with staff performance management.

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. To handle the transition process, to cope with peaks of work and guarantee business continuity some interims staff might be recruited.

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 optimize the daily management of HR activities, in 2022 other SYSPER II modules may be implemented according to the need of the JU. Finally, SYSTAL, the new selection tool shared with the other JUs, will be fully operational in 2022.

### *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. The COVID-19 outbreak has shown that new ways of working are possible and revision of some existing rules might be needed to adapt to the "new norm".

### *Organisation and talent 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. In view of the new programme, particular attention will be given to retrain IMI2 current staff to equip them with the necessary set of competences and skills.

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 activities, and particular attention will be given to performance management.

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, the Programme Office will: (i) keep paying particular attention to the well-being of its staff, by developing tailor-made well-being activities to increase wellness in the workplace (e.g. well-being lunchtime sessions, workshops, etc); (ii) develop teambuilding activities to strengthen the collaboration among staff members, to enhance the team spirit and culture, and to help staff get acquainted with the "new norm" after the pandemic; (iii) remain vigilant and reiterate its strong commitment to a zero tolerance towards psychological and sexual harassment and disrespectful work environment.

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 2022, the JUs will continue to share the human-resource IT tools (e.g. SYSTAL) where necessary, common Calls for tender, learning and development training courses for JUs staff and managers as well as a common approach to implementing rules of the EU staff regulations.

### 2.3.5 Administrative budget and finance

The administrative budget for the financial year 2022 is based on the currently available information.

The administrative budget for the financial year 2022 has been defined in line with the figures revised by the European Commission for 2022, in view of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe.

The overall budget of administrative expenditure will slightly increase by 2% in 2022 compared to 2021, mainly due to promotions and prices indexation.

The budget has been reallocated between chapters, in line with the operational needs of different areas.

A comparison table of the financial years 2022 and 2021 is set out below.

	Heading	Financial year 2021	Financial year 2022	Evolution	Comments
Title Chapter		Budget EUR	Budget EUR		
1	<b>Staff expenditure</b>				
11	Staff in active employment	5,851,000	6,032,000	3%	it includes 2% promotions and indexations as well as prices indexation of services provided by PMO and OIB
12	Staff recruitments - miscellaneous expenditure	10,000	5,000	-50%	no increase in number of staff
13	Missions and duty travels	50,000	80,000	60%	increased due to expected higher number of missions during 2022. 2021 was budgeted in the context of COVID-19
14	Socio-medical structure	202,000	212,000	5%	increased EU school, transport and trainings due to prices indexation
15	External staff services	125,000	125,000		
17	Representation	10,000	10,000	0%	
	<b>Total Title 1 (Staff expenditure)</b>	<b>6,248,000</b>	<b>6,464,000</b>	<b>3%</b>	

	Heading	Financial year 2021	Financial year 2022	Evolution	Comments
<b>Title Chapter</b>		Budget EUR	Budget EUR		
<b>2</b>	<b>Infrastructure expenditure</b>				
20	Office building and associated costs	650,000	660,000	2%	increased due to prices indexation
21	Information technology purchases	1,079,000	1,009,000	-6%	reallocation to meetings
22	Office equipment (movable property and associated costs)	5,000	5,000	0%	
23	Current administrative expenditure	127,000	124,000	-2%	reallocation to meetings
24	Telecommunication and postal expenses	38,000	38,000	0%	
25	Expenditure on formal meetings	28,000	70,000	150%	increased due to expected higher number of meetings during 2022. 2021 was budgeted in the context of COVID-19.
26	Administrative expenditure in connection with operational activities	140,000	200,000	43%	increased due to expected higher number of meetings during 2022. 2021 was budgeted in the context of COVID-19.
27	External communication, information and publicity	366,000	300,000	-18%	reallocation to meetings
28	Service contracts	419,000	410,000	-2%	reallocation from studies to meetings
29	Expert contracts and cost of evaluations	0	0	0%	will be transfer to title 3, as the expenses are connected to Calls to be launch and their number of topics
<b>Total Title 2 (Infrastructure expenditure)</b>		<b>2,852,000</b>	<b>2,816,000</b>	<b>-1%</b>	
<b>Total Title 1+2 (Administrative expenditure)</b>		<b>9,100,000</b>	<b>9,280,000</b>	<b>2%</b>	

The operational budget is covered under section 2.2.2. Scientific priorities for 2022.

Budget Plan 2022 – see Chapter 3.



## **Financial Management**

During 2022, the Programme Office will continue to ensure sound financial management through the implementation of the IMI2 JU Financial Rules<sup>3</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.

An effective and proper records management and archiving help meet the Programme Office's transparency obligations, in particular by facilitating public access to documents and implementing the principle of accountability of public actions.

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>3</sup> The latest 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 accomplish the 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 Scientific Committee (SC), the States Representatives Group (SRG) and the 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 Scientific Committee, the States Representatives Group, and the Stakeholder Forum and their working groups.

**The Governing Board (GB)** gathers representatives of IMI2 JU members. It has the responsibility for overseeing the operations of 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. Two meetings of the SC are planned for 2022. 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 the programme progress of IMI2 JU and achievement of its targets. Two meetings of the SRG are planned for 2022. The Chair will participate in the Governing Board meetings as an observer.

**The Strategic Governing Groups (SGGs)** are composed 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. 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 for proposals will be launched under IMI2 JU and the transition to the future programmes is expected in 2022, the majority of SGG activities will draw to a close. They may meet on an ad hoc basis to monitor project results and to explore, where possible, synergies with ongoing projects, both within IMI2 JU and those outside.

## 2.5 Internal Control framework

The overall target set by the Programme Office for 2022 on internal control is to build on the experience and lessons learned to implement and enhance the established internal control framework, ensuring in the process that all critical risks are mitigated; key priorities are achieved; legal and regulatory requirements are complied with; and evolving stakeholders' expectations are met.

Due consideration will be given during the year to the challenges and developments brought about with the transition to the Innovative Health Initiative JU and the incorporation of Horizon Europe objectives, obligations and *modus operandi*.

Specific actions will aim at:

- keeping financial procedures effective and up to date in order to ensure efficiency, effectiveness and flexibility;
- maintaining the risk management process integrated in the annual planning cycle, including the conduct of an annual full risk assessment exercise;
- developing guidance materials on control and quality performance in order to adhere to new applicable legal and procedural provisions.

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

#### Ex-ante controls

During 2022, the Programme Office will ensure the financial and administrative management of on-going actions.

These activities will be conducted in a timely and efficient manner according to the principle of sound financial management. They will be monitored through the defined set of KPIs, in particular time to pay and the budget and work plan execution.

Best practice and highest quality standards will be ensured through the implementation of the Manual on Financial Circuits and a set of Standard Operating Procedures and Checklists.

Specific attention will be placed on:

- 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;
- ensuring the implementation of recommendations resulting from internal and external audits or other review.

#### 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. Representative ex-post audits of participants will be launched on new cost claims accepted by the Programme Office since the last audited period to reach the audit coverage ratio set in its ex-post audit strategy. If necessary, risk based ex-post audits will be launched according to the Programme Office risk based audit strategy. Rejection of systematic errors identified in ex-post audits will continue to be extended to unaudited financial statements ('Form C') of the audited participants.

Ex-post audits of accepted declarations of in-kind contributions by EFPIA companies will not be carried out in 2022 as the Work plan on ex post audits of EFPIA companies under IMI JU has reached its end in 2021 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 of accepted declarations of in-kind contributions may nevertheless be initiated should a specific need arise.

As regards IMI2 JU, ex-post controls of grants are aligned with the harmonised strategy adopted for the entire H2020 Programme. 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 ex-post audits will be launched according to the Programme Office risk based audit strategy. The harmonised legal framework will enable the Programme Office to draw an additional element of assurance from the extension of systematic errors identified in ex-post audits to unaudited financial statements of common audited 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**

IMI2 JU audit arrangements are set up in accordance with Article 28 and 54 of the IMI2 JU Financial Rules. The audits provide reasonable assurance about the state of effectiveness of risk management, control and governance processes and serve 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, will follow up and assess the implementation of the Internal Audit Service (IAS) of the European Commission and the European Court of Auditors (ECA) recommendations with the objective to confirm their effective implementation.

Internal audits are carried out by the IAS in liaison with the Audit Manager.

In 2022 IAS will be finalising a Multi-entity audit on the performance framework for research. This audit is carried out in a sample of services and bodies implementing Horizon 2020 and Horizon Europe. IMI is one of the selected bodies. This audit engagement encompasses an audit topic identified as part of the IAS Strategic Internal Audit Plan 2019-2021 for IMI.

In 2022, the focus will be put on:

- finalising the implementation of the action plan from previous audit; coordinating and supporting IAS audit work.

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 2022 annual accounts will be audited by Baker Tilly, an external audit company that IMI contracted for the financial years 2020 and 2021. ECA will draw annual audit opinion on the basis of their work and issue a special annual report on joint undertakings. 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 2021 and 2022 accounts and following up on preliminary findings and recommendations;
- liaising with an independent external auditor and coordinating with ECA throughout the audit of accounts for financial year 2021 and 2022.

In accordance with the Framework contract BUDG-19-PO for Audits and Controls that IMI is using, the reopening of the competition for the audit of accounts (financial years 2022 and 2023) will be launched in 2022.

## **2.5.3 Anti-Fraud strategy**

In 2022, the Programme Office will continue to ensure the implementation of the JU Anti-Fraud Strategy, which will be furtherly improved based on the result of the ad hoc fraud risk assessment conducted in 2021. Prevention activities, raising awareness of JU staff and stakeholders and cooperation with the European Commission Research Services will be the priorities for the year.

### 3 Budget 2022

The budget for the financial year 2022 has been revised in line with the figures revised by the European Commission for 2022, in view of the transition to the new proposed cross-sectorial partnership in health under Horizon Europe.

An overview of the budget<sup>4 5</sup> for 2022 per chapters is set out below.

STATEMENT OF REVENUE				
	Heading Revenue	Budget 2022		Comments
Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
10	European Commission contribution (including EFTA contribution)	4,640,000	171,640,000	Commitment appropriations include EUR 4,640,000 for administrative costs. Payment appropriations include EUR 4,640,000 for administrative costs and EUR 167,000,000 for operational costs.
<b>European Commission contribution</b>		<b>4,640,000</b>	<b>171,640,000</b>	
20	EFPIA contribution	4,640,000	4,640,000	EFPIA contribution to IMI2 JU administrative costs.
21	Subsidy from other members (other than Union and Associated Partners, constituent or affiliated)			
<b>EFPIA and other members contributions</b>		<b>4,640,000</b>	<b>4,640,000</b>	
30	Associated Partners contributions			
<b>Associated Partners contributions</b>			<b>0</b>	
<b>Total revenue</b>		<b>9,280,000</b>	<b>176,280,000</b>	

<sup>4</sup> Subject to approval of European Union Draft Budget (DB) for 2022 by the Budgetary Authority (comprised of the Council of the European Union and the European Parliament) as proposed by the European Commission.

<sup>5</sup> This Annual Work Plan 2022 is independent from, and does not reflect the impact of the Commission proposal for Innovative Health (COM (2021) 87 final of 23.2.2021).

STATEMENT OF EXPENDITURE EUR				
	Heading	Budget 2022		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
<b>1</b>	<b>Staff expenditure</b>			
11	Staff in active employment	6,032,000	6,032,000	Salaries and allowances of current staff (TAs and CAs), SNE, promotion and indexation
12	Staff recruitments - miscellaneous expenditure	5,000	5,000	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	80,000	80,000	Missions expenditure
14	Socio-medical structure	212,000	212,000	Other staff costs: EU school, medical check-up, trainings
15	External staff services	125,000	125,000	Interim staff expenses
17	Representation	10,000	10,000	Representation expenses
<b>Total Title 1 (Staff expenditure)</b>		<b>6,464,000</b>	<b>6,464,000</b>	

Title Chapter	Heading	Budget 2022		Comments
		Commitment Appropriations (CA)	Payment Appropriation (PA)	
<b>2</b>	<b>Infrastructure expenditure</b>			
20	Office building and associated costs	660,000	660,000	Building related expenditure: rent, works, charges, maintenance, repairs, security and surveillance
21	Information technology purchases	1,009,000	1,009,000	IT purchases, software licences, software development
22	Office equipment (movable property and associated costs)	5,000	5,000	Purchases and rental of office equipment, maintenance and repair
23	Current administrative expenditure	124,000	124,000	Office supply, newspaper subscriptions, translation services, bank charges and miscellaneous office expenditure
24	Telecommunication and postal expenses	38,000	38,000	Data communication such as telephone, video and audio conferences and postal services
25	Expenditure on formal meetings	70,000	70,000	Official meetings such as States Representatives Group, Scientific committee, Governing Board and advisory groups created by the Governing Board
26	Administrative expenditure in connection with operational activities	200,000	200,000	Administrative expenditure in connection with research activities and objectives of IMI2 JU (workshops, meetings and events targeting IMI projects)
27	External communication, information and publicity	300,000	300,000	External communication and events such as Info Days, stakeholder forums
28	Service contracts	410,000	410,000	Ex-post audits, studies, audits, accounting services
29	Expert contracts and cost of evaluations	0	0	Costs linked to evaluations, expert contracts
<b>Total Title 2 (Infrastructure expenditure)</b>		<b>2,816,000</b>	<b>2,816,000</b>	
<b>Total Title 1 + 2 (administrative expenditure)</b>		<b>9,280,000</b>	<b>9,280,000</b>	

	Heading	Budget 2022		Comments
Title Chapter		Commitment Appropriation (CA)	Payment Appropriation (PA)	
3	<b>Operational expenditure</b>			
30	Implementing the research agenda of IMI2 JU		167,000,000	Payment appropriations - Payments FP7 and H2020
<b>Total Title 3 (Operational expenditure)</b>			<b>167,000,000</b>	
<b>Total expenditure</b>		<b>9,280,000</b>	<b>176,280,000</b>	

An overview of the 2022 Budget per budget lines is set out in the table below (EUR).

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
1100	Staff in active employment and costs linked to employees	3,662,000	3,662,000
1101	Family Allowances	370,000	370,000
1102	Transfer and expatriation allowances	510,000	510,000
1110	Contract Agents	953,000	953,000
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	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	0
1149	Other allowances	0	0
1172	Cost of organising traineeships within IMI2 JU	10,000	10,000
1175	Translation and typing services	0	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



Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
1182	Installation allowance	30,000	30,000
1183	Moving expenses	7,000	7,000
1184	Temporary daily allowance	15,000	15,000
1190	Weightings (correction coefficient)	5,000	5,000
1191	Salaries adaptation	0	0
<b>11</b>	<b>Staff in active employment</b>	<b>6,032,000</b>	<b>6,032,000</b>
1200	Miscellaneous expenditure on staff recruitment	5,000	5,000
<b>12</b>	<b>Staff recruitments - miscellaneous expenditure</b>	<b>5,000</b>	<b>5,000</b>
1300	Mission expenses	80,000	80,000
<b>13</b>	<b>Missions and duty travels</b>	<b>80,000</b>	<b>80,000</b>
1401	EU school costs	100,000	100,000
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>212,000</b>	<b>212,000</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>6,464,000</b>	<b>6,464,000</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)	200,000	200,000
2030	Cleaning and maintenance		
2040	Furnishing of premises	10,000	10,000
2050	Security and surveillance		
2090	Other expenditure on buildings		
<b>20</b>	<b>Office building and associated costs</b>	<b>660,000</b>	<b>660,000</b>
2101	Hardware, infrastructure and related services	325,000	325,000
2102	Software development, licenses and related services	684,000	684,000
2103	Other expenses maintenance and repair		
<b>21</b>	<b>Information technology purchases</b>	<b>1,009,000</b>	<b>1,009,000</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		
2321	Exchange rate losses		
2329	Other financial charges		
2330	Legal expenses	15,000	15,000
2350	Other operating expenditure	3,000	3,000
2351	Petty expenses		
2360	Library stocks purchase of books and subscriptions	51,000	51,000
2370	Translation, interpretation	5,000	5,000
<b>23</b>	<b>Current administrative expenditure</b>	<b>124,000</b>	<b>124,000</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	70,000	70,000
<b>25</b>	<b>Expenditure on formal meetings</b>	<b>70,000</b>	<b>70,000</b>

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
2600	Administrative costs in connection with operational activities	30,000	30,000
2601	Events targeting IMI projects	0	0
2602	Workshops	170,000	170,000
2603	Knowledge Management	0	0
<b>26</b>	<b>Administrative costs in connection with operational activities</b>	<b>200,000</b>	<b>200,000</b>
2700	External communication	60,000	60,000
2701	Events external communication	200,000	200,000
2702	Material	40,000	40,000
<b>27</b>	<b>External communication, information and publicity</b>	<b>300,000</b>	<b>300,000</b>
2800	Ex-post Audits	200,000	200,000
2801	Studies, consultancy	90,000	90,000
2802	Audit services	50,000	50,000
2803	Accounting services	70,000	70,000
<b>28</b>	<b>Service contracts</b>	<b>410,000</b>	<b>410,000</b>
2900	Evaluation Experts meetings	0	0
2901	Evaluation Facilities		
2902	Evaluations Exploring New Scientific Opportunities (ENSO)	0	0
<b>29</b>	<b>Expert contracts and cost of evaluations</b>	<b>0</b>	<b>0</b>
<b>Total Title 2 (Infrastructure expenditure)</b>		<b>2,816,000</b>	<b>2,816,000</b>

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3000	Implementing the research agenda of IMI JU		22,000,000
3001	IMI JU Call 1		
3002	IMI JU Call 2		
3003	IMI JU Call 3		
3004	IMI JU Call 4		
3005	IMI JU Call 5		
3006	IMI JU Call 6		
3007	IMI JU Call 7		
3008	IMI JU Call 8		
3009	IMI JU Call 9		
3010	IMI JU Call 10		
3011	IMI JU Call 11		
3012	Exploring New Scientific Opportunities (ENSO) 2012		
3013	Exploring New Scientific Opportunities (ENSO) 2013		
3020	Implementing the research agenda of IMI2 JU		145,000,000
3021	IMI2 JU Call 1		
3022	IMI2 JU Call 2		
3023	IMI2 JU Call 3		
3024	IMI2 JU Call 4		
3025	IMI2 JU Call 5		
3026	IMI2 JU Call 6		
3027	IMI2 JU Call 7		
3028	IMI2 JU Call 8		
3029	IMI2 JU Call 9		
3030	IMI2 JU Call 10		
3031	IMI2 JU Call 11		
3032	IMI2 JU Call 12		
3033	IMI2 JU Call 13		
3034	IMI2 JU Call 14		
3035	IMI2 JU Call 15		
3036	IMI2 JU Call 16		
3037	IMI2 JU Call 17		
3038	IMI2 JU Call 18		
3039	IMI2 JU Call 19		
3040	IMI2 JU Call 20		
3041	IMI2 JU Call 21		
3042	IMI2 JU Call 22		

Budget line Chapter	Description	Commitment Appropriations (CA)	Payment Appropriations (PA)
3043	IMI2 JU Call 23		
3100	Horizon Europe		
3900	Evaluations experts		
<b>30</b>	<b>Implementing the research agenda of IMI2 JU</b>		<b>167,000,000</b>
<b>Total Title 3 (Operational expenditure)</b>			<b>167,000,000</b>
<b>Total expenditure</b>		<b>9,280,000</b>	<b>176,280,000</b>

### 3.1 Staff Establishment Plan 2022

Grade	Posts filled on 31/12/2020	Establishment Plan 2021			Year 2022												
					Posts evolution						Organisational evolution			Establishment Plan 2022			
					Promotion / Career advancement			Turn-over (departures/ arrivals)			New posts (per grade)			Requested (Budget)			
					TEMP	PERM	TEMP	TOTAL	Offi- cials	TA - LT	TA - ST	Offi- cials	TA - LT	TA - ST	Perm	TA - LT	TA - ST
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	1	
AD9	5		7	7											7	7	
AD8	5		6	6											6	6	
AD7	4		2	2											3	3	
AD6	5		11	11											10	10	
AD5	8		1	1											2	2	
<b>Total AD</b>	<b>32</b>		<b>33</b>	<b>33</b>											<b>34</b>	<b>34</b>	
AST11																	
AST10																	
AST9																	
AST8	1		1	1											1	1	
AST7																	
AST6																	
AST5																	
AST4	3		4	4											4	4	
AST3	1																
AST2	0		1	1											0	0	
AST 1																	
<b>Total AST</b>	<b>5</b>		<b>6</b>	<b>6</b>											<b>5</b>	<b>5</b>	
SC6																	
SC5																	
SC4																	
SC3																	
SC2																	
SC1																	
<b>Total SC</b>	<b>0</b>		<b>0</b>	<b>0</b>											<b>0</b>	<b>0</b>	
<b>Overall Total</b>	<b>37</b>		<b>39</b>	<b>39</b>											<b>39</b>	<b>39</b>	

<b>Contract Agents Grade</b>	<b>Posts filled on 31/12/2020</b>	<b>Establishment plan 2021</b>	<b>Establishment plan 2022</b>
<b>FG IV</b>	3	3	4
<b>FG III</b>	11	11	11
<b>FG II</b>	1	1	0
<b>FG I</b>	0	0	0
<b>Total CA</b>	<b>15</b>	<b>15</b>	<b>15</b>

<b>Seconded National Experts</b>	<b>Posts filled on 31/12/2020</b>	<b>Establishment plan 2021</b>	<b>Establishment plan 2022</b>
	1	2	1

## 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>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>GAP</b>	Grant Agreement Preparation
<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>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>LFS</b>	Legislative Financial Statement
<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>	IMI2 JU 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>WHO</b>	World Health Organisation



