



## Innovative Medicines Initiative 2 (IMI2)

<p>Legal Frame- work</p>	<p>Article 25 in the <a href="#">Regulation</a> of the European Parliament and of the Council establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020).</p> <p>Joint Technology Initiatives (JTIs) are implemented through dedicated legal entities - Joint Undertakings (JU) - established under what was then the equivalent of the current Article 187 of the Treaty on the Functioning of the European Union (<a href="#">TFEU</a>). The Innovative Medicines Initiative 2 (<a href="#">IMI2</a>) JU is established by <a href="#">Council Regulation</a>. It has its own legal entity.</p>
<p>Structure</p>	<p>PPPs are one of the key actions of <a href="#">Leadership in Enabling and Industrial Technologies</a>, which is a specific objective of Priority II “Industrial Leadership” of Horizon 2020.</p> <p>PPPs are vehicles to implement technological roadmaps in particular areas and aim at leveraging private investment in Research and Innovation (R&amp;I). They are implemented either through JTIs or through dedicated calls for proposals and topics (contractual PPPs). JTIs are implemented by the European Commission (EC) where the scope of the objectives pursued and the scale of the resources required justify it taking full account of the relevant impact assessments, and where other forms of partnerships would not fulfil the objectives or would not generate the necessary leverage. They are run as Joint Undertakings that organise their own research and innovation agenda and award funding for projects on the basis of open calls.</p>
<p>Policy Con- text</p>	<p>The burden of chronic and degenerative diseases grows as Europe’s population gets older. But the risks and costs of developing new vaccines, medicines and treatments are soaring, as is the complexity of diseases and the scientific challenge. How can the EU provide priority medicines for all and keep public budgets under control? The EU esteems that no government, industry sector or research community can overcome these challenges on its own. Therefore cooperation at EU level between the public and private life science sectors is seen as the only way forward.</p> <p>IMI was launched in 2007 with a budget of €2 billion and has brought together over 6000 researchers in 650 teams, 409 industry (EFPIA) teams, 120 SME research teams, 25 teams in patient organisation and 17 teams in regulatory bodies. IMI2 is a Joint Technology Initiative (JTI) with members of the European Federation of Pharmaceutical Industries and Associations (EFPIA) but is also open to other industries and sectors. IMI2 takes the collaborative vision and public health focus of IMI1 to the next level and paves the way for breakthrough vaccines, medicines and treatments to tackle Europe’s growing health challenges through a concentrated and combined science and innovation effort.</p>
<p>Objective</p>	<ul style="list-style-type: none"> <li>• increase the success rate in clinical trials of priority medicines identified by the World Health Organisation (WHO);</li> <li>• where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;</li> <li>• develop new therapies for diseases for which there is a high unmet need, such as Alzheimer’s disease and limited market incentives, such as antimicrobial resistance;</li> <li>• develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;</li> <li>• reduce the failure rate of vaccine candidates in phase III clinical trials through</li> </ul>

	<p>new biomarkers for initial efficacy and safety checks;</p> <ul style="list-style-type: none"> <li>improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.</li> </ul>
Management	<p>Managed by a dedicated JU. The JU establishes its own strategic research agenda. IMI2's <a href="#">strategic research agenda</a> is based on the new WHO report 'Priority medicines for Europe and the world'.</p> <p>The JU's governance comprises two executive and three advisory bodies. They are:</p> <ul style="list-style-type: none"> <li>the <b>Governing Board (GB)</b> comprising representatives of the EC and private actors is the main decision-making body of the JTI. It takes strategic and funding decisions and supervises the implementation of its activities;</li> <li>the <b>Executive Director (ED)</b> assisted by the Programme Office. The ED is the legal representative of the JU. He or she is appointed by the GB, from a list of candidates proposed by the EC, following an open and transparent selection procedure. Under the responsibility of the ED the Programme Office is responsible for the day-to-day management of JCH2 (e.g. organising calls for proposals, managing R&amp;D agenda of JU) and the preparation of the (Multi-) <a href="#">Annual Work-Programme</a>;</li> <li>the <b>Scientific Committee</b>, comprising worldwide recognised experts from academia, industry and regulatory bodies, is an independent advisory body to the GB. Its priorities are to advise on the R&amp;D agenda and to evaluate the scientific achievements;</li> <li>the <b>States Representatives Group (SRG)</b> consists of one representative of each Member State (MS) and of each Associated Country (AC) to Horizon 2020. It has an advisory role to the GB and the representatives act as an interface between the IMI2 JU and the relevant stakeholders within their respective countries. The SRG reviews information and provides opinions on programme progress in the IMI2 JU, compliance and respect of targets, coordination with national programmes and more;</li> <li>the Stakeholder Forum has a formal advisory role to the GB and it is an important communication channel to ensure transparency and openness of the IMI2 JU's activities with its stakeholders. It is open to all public and private stakeholders, international interest groups from MS, AC as well as from other countries.</li> </ul>
Size of overall budget	<p>The budget of IMI2 is €3.276 billion. The EU will contribute up to €1.638 billion. This will match the EFPIA commitment of up to €1.425 billion and an additional amount of up to €213 million if other life science industries decide to contribute to IMI2 as members or associated partners in individual projects.</p>
Funding	<p>The IMI2 JU shall support indirect actions through open and competitive calls for proposals, and allocation of public funding within the limits of the budgets available.</p> <p>The Rules for Participation and Dissemination (<a href="#">RfP</a>) of Horizon 2020 will apply. However, given a specific operational need of this initiative, a derogation from these rules is necessary.</p> <p>A single reimbursement rate of maximum 100 % of the eligible costs shall be applied per action for all activities funded in Research and Innovation Actions (RIA). The maximum rate shall be fixed in the IMI2 Annual Work Plan (AWP). The IMI2 AWP will specify when use of unit costs applies.</p>
Eligible Countries/participants	<p>The following participants are eligible for funding:</p> <ul style="list-style-type: none"> <li>Independent legal entities established in a MS or an AS, or created under EU law, which fall within one of the following categories: micro-, small- and medium-sized enterprises and other companies with an annual turnover of EUR 500 million or less, secondary and higher education establishment, non-profit organisations, including those carrying out research or technological development as one of their main objectives or patient organisations;</li> <li>the Joint Research Centre (JRC) of the EC;</li> <li>international European interest organisations.</li> <li>EU funding may be granted to international organisations and legal entities established in a third country provided either their participation is deemed essential for carrying out the IMI2 JU action or such funding is provided for under a bilateral scientific and technological agreement or there is any other arrange-</li> </ul>

	<p>ment between the EU and the international organisation or, for entities established in third countries, the country in which the legal entity is established. Further information can be found in the <a href="#">summary</a> of the most relevant provisions for participating in IMI2 actions.</p>
Beneficiaries	Companies, universities, public laboratories, innovative SMEs, patient groups and regulators.
Expected results	<ul style="list-style-type: none"> <li>• a 30% better success rate in clinical trials of priority medicines identified by the WHO;</li> <li>• clinical proof of concept in immunological, respiratory, neurological and neuro-degenerative diseases in just five years;</li> <li>• diagnostic and treatment bio-markers for four diseases;</li> <li>• at least two new therapies for antimicrobial resistance or Alzheimer's disease.</li> </ul>
Timeframe/Duration	2014-2024
Application procedure	<p>Stage 1: Proposal must be handed in by at least three legal entities. Each of the three shall be established in a different MS or AC. All three legal entities shall be independent of each other.</p> <p>Calls will be published on the <a href="#">Participant Portal</a>.</p>
Selection procedure	Can be found in the IMI2 <a href="#">Manual</a> for submission, evaluation and grant award.
Of-fer/Activities supported	
Useful links	<p><a href="http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/Summary_of_provisions_for_particip_2014.06.26.pdf">http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/Summary_of_provisions_for_particip_2014.06.26.pdf</a></p> <p><a href="http://www.imi.europa.eu/content/imi-2">http://www.imi.europa.eu/content/imi-2</a></p> <p><a href="http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/AIP_1_MI1&amp;IMI2_GB_approved_2014.07.07.pdf">http://www.imi.europa.eu/sites/default/files/uploads/documents/IMI2_Call1/AIP_1 MI1&amp;IMI2_GB_approved_2014.07.07.pdf</a></p> <p><a href="http://ec.europa.eu/programmes/horizon2020/en/area/partnerships-industry-and-member-states">http://ec.europa.eu/programmes/horizon2020/en/area/partnerships-industry-and-member-states</a></p>