

A USER GUIDE TO THE INNOVATIVE MEDICINES INITIATIVE (IMI)

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ABOUT IMI

Introducing IMI

The Innovative Medicines Initiative (IMI) was set up in 2008 as a public-private partnership between the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by EFPIA, the European Federation of Pharmaceutical Industries and Associations).

At IMI, our goal is to improve the medicines development process and make it more efficient, and to ensure that patients will have faster access to better and safer medicines. We do this by funding collaborative projects that bring together all key groups involved in life science research. Through our projects, we are finding innovative solutions to the most pressing medical burdens of our time, including antimicrobial resistance, dementia, and diabetes.

Over a decade in, we are globally recognised as a pioneer of open innovation and an attractive model for successful public-private partnerships (PPPs) in research.

Interested? Find out more.

How IMI works

IMI owes its success to the involvement in its activities of a wide range of stakeholders working to bring innovative health solutions to patients.

These include people from industry, universities and research institutes, small and medium-sized enterprises (SMEs), hospitals, patient groups, and regulatory authorities - working together for a shared goal.

How to submit a proposal for a new project

IMI projects are born out of open, competitive Calls for proposals

When a Call for proposals is launched, any organisation carrying out work relevant to

our objectives can participate in the application process. You will need to **form a consortium, or join a consortium**, in order to apply for support in response to an open Call for proposals.

Details on the Call topics, eligibility and the application process are published with each Call and outlined below.

Participate in an ongoing project

Joining an IMI project that has already started as a full project partner is unusual. However, some of our projects have open calls, generating interesting opportunities for SMEs and other researchers. If you are interested in a specific ongoing project, we recommend that you contact the project coordinator to explore any opportunities for collaboration.

The IMI funding model

For the 2014-2020 period, IMI's total budget is EUR 3.276 billion. Of this, EUR 1.638 billion (half the budget) comes from Horizon 2020, the European Union's funding programme for research and innovation. EFPIA companies have committed EUR 1.425 billion to the programme, and up to EUR 213 million can be committed by other organisations that decide to contribute to IMI as Associated Partners in individual projects.

EFPIA companies and IMI Associated Partners **do not receive any EU funding** through IMI, but contribute to IMI through 'in-kind' contributions. These contributions are mostly in the form of:

- Personnel costs (the time their staff spend working on IMI projects);
 - Other direct costs (e.g. samples, compounds, data);
 - A financial contribution (e.g. to a university in the consortium);
 - Subcontracting (e.g. for data management, communication, and project management services).
- ▶ www.imi.europa.eu/about-imi



HOW TO APPLY FOR IMI FUNDING

Apply for IMI funding

You can apply for funding as part of a consortium, and in response to an IMI Call for proposals.

Who can apply

It is important to note that IMI cannot fund individuals.

If you want to be part of an IMI project, it is crucial that you are affiliated with an organisation.

Individuals interested in being part of an IMI project should form a consortium to prepare an application on a specific topic, in response to an IMI Call for proposals.

Consortia applying for IMI funding typically include experts from universities, research centres, SMEs and mid-sized companies in the biotech and medtech fields (e.g. diagnostics, animal health, IT, imaging), patient organisations, hospitals, and medicines regulators.

Who is eligible for IMI funding?

Organisations eligible to receive IMI funding are:

- Academic institutions
- Small & medium-sized enterprises (SMEs)
- Mid-sized enterprises (\leq EUR 500m)
- Non-profit organisations such as: research organisations, patient organisations, NGOs, public bodies, intergovernmental organisations

They must be based in Europe.

Organisations based outside Europe may be eligible for funding in exceptional circumstances.

Which topics

Each Call for proposals may contain a number of topics in different research areas. We publish indicative information on future topics as early as possible, so as to allow potential applicants to be ready. If all the conditions are fulfilled at the application and evaluation stage, each topic will result in a project funded by IMI.

When to apply

We launch Calls twice a year: indicatively, in January and June.

It is important to start working on gathering the right partners for your applicant consortium as early as possible. We recommend that you don't wait until a topic is published to start building your network, but to invest in networking and having a solid circle of potential partners before relevant topics are published.

How to apply

We publish all information related to our Calls for proposals on the IMI website.

IMI Calls for proposals are open and competitive. Winning proposals are selected following evaluations by independent experts, and approved by the IMI Governing Board. Most Calls for proposals involve a two-stage process as outlined below.

Details of the rules and processes for each Call are always set out in the Call documents, and you should read these carefully as, on occasion, they may differ from the standard process described below.

The application is done via the electronic submission system of the **EU Funding and Tenders Portal**:

► www.ec.europa.eu/info/funding-tenders/opportunities/portal

A step-by-step guide to the IMI Call process

Before the Call launch: Topic development

A consortium of EFPIA companies and, in some cases, IMI Associated Partners, agree on the need to work together and with other stakeholders on a specific issue. These issues must be aligned with IMI's objectives and the IMI Strategic Research Agenda. Ideas for topics can come from EFPIA companies or Associated Partners, or from suggestions submitted by external organisations.

The topic text is drafted by the EFPIA/ Associated Partner consortium and, following extensive discussion with the European Commission and consultation with IMI advisory bodies groups - the IMI Scientific Committee and

the States Representatives Group - the Call text is sent to the IMI Governing Board for approval.

Stage 1: Call launch, submission and evaluation of short proposals

Once the Governing Board has given its green light, the Call for proposals is published on the IMI website and the European Commission's Funding & Tenders Portal.

All interested parties from academia, small and medium-sized enterprises (SMEs), mid-sized companies, patient organisations, regulatory agencies, health technology assessment bodies, etc. are invited to form consortia and submit a short proposal, via the EU Funding & Tenders Portal, in response to the Call.

At this stage, EFPIA companies or IMI Associated Partners should not be included in the consortium. Typically, the submission deadline is around three months after the Call launch.

The proposals are first screened for eligibility. All eligible proposals are evaluated by independent experts, and scored based on three top-level criteria: excellence; impact; and quality and efficiency of the implementation. The applicant consortium that submitted the top-ranked application is then invited to proceed to Stage 2.

Stage 2: Submission and evaluation of full proposals

The top-ranked applicant consortium and the EFPIA/Associated Partner consortium behind the topic form a full consortium, and submit a full proposal. Consortia usually have around three months to prepare the full proposal.

The full consortium's proposal undergoes the second stage of evaluation by independent experts. If the scores are above the thresholds set out in the rules, the consortium is given the green light, and can start preparations to launch the project.

Future topics

Topics at an advanced draft-stage are often published on the Future Topics page of our website to give potential applicants additional time to prepare applications:

► www.imi.europa.eu/apply-funding/future-topics

Finding project partners

Start early

Putting together a consortium takes time. We publish indicative information on Call topics several weeks before the Call launch. As soon as you see a topic that could be relevant for you, you should get to work.

Be proactive - invest time and energy

Whether you are leading the formation of a consortium, or trying to find and get into an existing one, you should be prepared to invest a significant amount of time and energy in the exercise. You will also need to be extremely proactive in terms of reaching out to potential partners and explaining why you would be a good partner for their consortium.

The Call text sets out in detail the expertise expected of the consortium. When you get in touch with



potential partners, you should highlight the areas where your involvement would be valuable.

You should also flag up to potential partners your experience of working in large, multidisciplinary, international projects; as well as managing IMI, other EU or other public funds.

Where to look for partners

- **Use your contacts:** the most effective way of getting into a consortium is to use your existing professional and personal contacts.
- **Network at events:** IMI organises webinars on all Call topics. These are also a good opportunity to identify potential partners and network. In addition, the IMI States Representatives Group, National Contact Points, and national pharmaceutical associations also organise

events locally, and are able to provide you with tailored information.

- **Partner search tools:** You can use the Partner Search tool on the EU Funding and Tenders Portal. The German representative on the IMI States Representatives Group has a dedicated partner search platform for IMI Calls for proposals.
- **Use social media:** you can promote your interest in a Call for proposals via the IMI LinkedIn group and other relevant groups. Don't hesitate to use other platforms like Twitter as well.

How many partners should our consortium have?

From a legal point of view, most IMI2 projects must have a minimum of three partners based in three different EU Member States or countries associated to the Horizon 2020 programme.

In practice, in order to carry out the work required to achieve the project objectives, most projects will require more than three partners. The exact number will depend very much on the size and scope of the project.

It is important to demonstrate to the reviewers that your consortium contains all the expertise required to deliver what is expected of it, as set out in the Call documents, while avoiding unnecessary redundancy between partners.

Find out more:

www.imi.europa.eu/apply-funding

- Latest & upcoming funding opportunities
- Tips for applicants
- Finding partners
- Get support



**INVEST IN
IMI**

Leveraging your investment

Are you a representative of a large company in the pharmaceutical, diagnostic, IT or imaging field? Do you work in a philanthropic organisation or a charity that runs its own health research programme? If you are not already participating in IMI, you may want to consider joining our growing international research community.

The two simplest ways to invest in IMI are by becoming an IMI Associated Partner, or by becoming a member of EFPIA. Under the IMI funding model, the European Union matches contributions made to IMI projects by EFPIA members and IMI Associated Partners. This means that investing in an IMI project is a good way to leverage precious funds while benefiting from the skills, expertise and resources of your project partners. IMI projects are at the cutting edge of medical research in areas ranging from dementia and diabetes to cancer and infectious disease. Our project portfolio also covers big data and knowledge management, as well as digital health and diagnostics.

Even though most of the companies in our projects come from the pharmaceutical sector, we also welcome and encourage the participation of companies from other sectors, such as biomedical imaging, medical information technology, and diagnostic and animal health industries. If you are not a member of EFPIA, you may join EFPIA as a Partner in Research, or join a specific IMI project as an IMI Associated Partner.

Contribute to IMI as an EFPIA member

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe.

All EFPIA members (including corporate members, members of national EFPIA associations, and EFPIA 'Partners in Research') are entitled to contribute to our projects and see that contribution matched by EU funding. As EFPIA members, Partners in Research are also fully represented on the IMI Governing Board, and can contribute to EFPIA's broader research policies. For details on the different categories of EFPIA membership, you can contact EFPIA directly:

▶ www.efpia.eu

Join IMI as an Associated Partner

The Associated Partner scheme was created with the goal of opening up IMI's activities to a wider range of stakeholders. As such, examples of organisations that could become IMI Associated Partners include philanthropic organisations and charities that run their own



health research programmes, as well as organisations and companies working in sectors related to healthcare, such as IT, imaging, diagnostics, animal health, etc.

As investors in, and contributors to a specific IMI project, Associated Partners are involved in the definition of the project from the very beginning. Once the project is up and running, IMI Associated Partners join a vibrant, collaborative health innovation ecosystem, and enjoy benefits such as access to complementary skills, expertise, technology and data; the opportunity to share knowledge and risks in a non-competitive space; and the more efficient use of resources.

To find out more about the Associated Partner scheme, please visit:

► www.imi.europa.eu/get-involved/associated-partners

IMI Associated Partners

Accelerate Diagnostics • Autism Speaks • Autistica • BD Switzerland Sarl • Bill and Melinda Gates Foundation • Bio-rad Laboratories • Cepheid Europe • CHDI Foundation • Children's Tumor Foundation • Coalition for Epidemic Preparedness • Datapharm • Diamond Light Source • European Hematology Association • International Diabetes Federation • Invicro • JDRF • KTH Royal Institute of Technology • Leona M. and Harry B. Helmsley Charitable Trust • McGill University • Medicines for Europe • Medicines for Malaria Venture • Obesity Action Coalition • Ontario Institute of Cancer Research • Parkinson's UK • Simons Foundation Autism Research Initiative • Software AG • SpringWorks Therapeutics • T1D Exchange • TB Alliance • Trial Nation • University of Dundee • The Wellcome Trust



BENEFITS OF PARTICIPATING IN IMI PROJECTS

Why participate in an IMI project?

The successes of our projects show that by bringing together the knowledge, expertise, resources and experience of different stakeholders, it is possible to make progress and make a difference in even the most challenging disease areas.

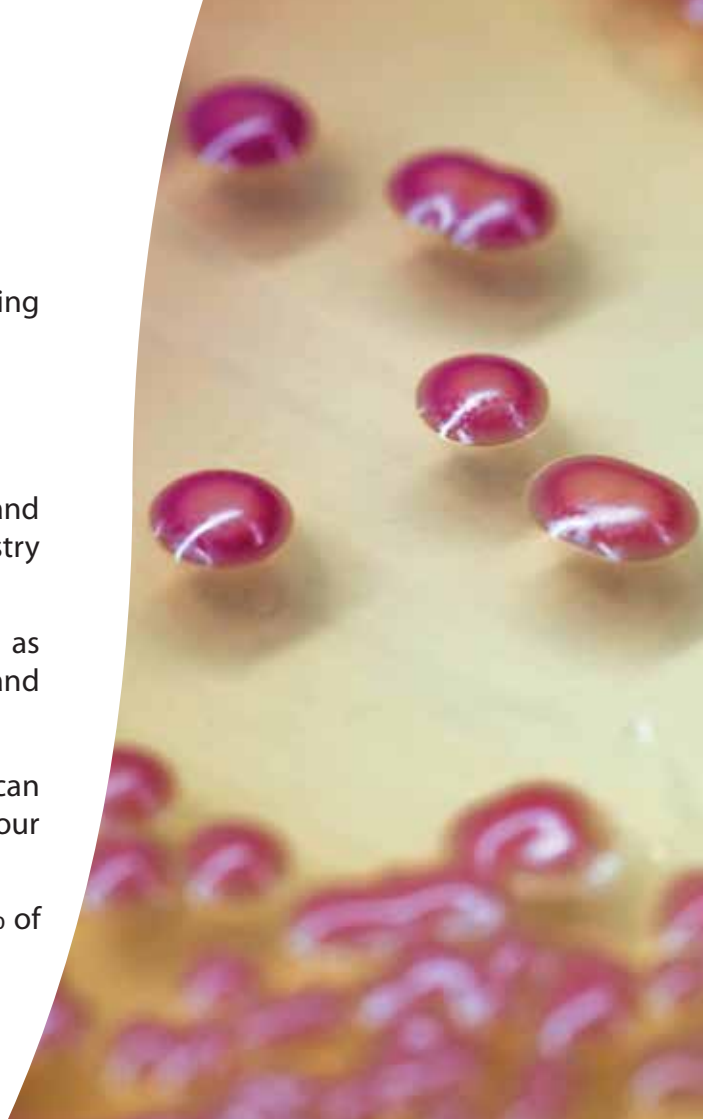
Being part of an IMI project will allow you to help tackle some of the biggest challenges in medical research and drug development, while sharing risks in highly challenging areas.

Doing research alongside the best people in your field will also translate into learning new ways of working, gaining access to the latest knowledge and resources, and rapidly validating results.

Whether you represent industry, an SME, academia, or a patient group, there are specific and unique benefits to be gained by joining IMI.

Benefits for SMEs

- Forming new networks and partnerships, creating new spin-out projects and funding opportunities.
- Building reputation and visibility through the international recognition and promotion of IMI projects.
- Perfecting innovative services and products - and being able to pitch them to potential industry customers.
- Access to knowledge and resources, such as large biobanks, laboratories, clinical centres and databases.
- Accelerating business expansion: collaboration can enable growth, help gain new customers and favour new market expansion.
- Access to funding: in IMI projects, SMEs get 100% of their eligible costs reimbursed.



Benefits for academia

- Forming new networks and partnerships with top teams, often resulting in spin-out projects and new funding opportunities.
- Building reputation and visibility: IMI research has a citation impact of nearly twice the EU average.
- Access to infrastructure, technology and resources, such as clinical trials, compounds, infrastructure and cutting-edge technology.
- Learning industry standards and gaining insight into the drug development process.
- Becoming more objectives-driven and impacts-oriented.
- Access to funding: In IMI projects, universities and research centres get 100% of their eligible costs reimbursed.



Benefits for patients

- Influence research into your disease or condition: within projects, patients can influence study design to make clinical studies more patient-friendly, or provide their unique perspective on benefits / risks.
- Receive funding: most patient organisations in the EU and countries associated with EU research programmes are eligible to receive funding from IMI. This will support your participation in an IMI project.
- Form networks with leading researchers: patients in our projects work alongside top researchers from academia and industry. This enables patients to benefit from their expertise in the longer term.
- Access the latest science: our projects are at the cutting edge of their fields and involve patients in the latest developments in their field. This allows the information to be passed on to the wider patient community.



Benefits for industry

- Addressing bottlenecks in drug discovery: outputs of IMI projects are already being used to speed up the drug development process.
- Working together in a pre-competitive space, allowing otherwise competing companies to join forces.
- Sharing knowledge and skills with other companies, but also academia, patients and small and medium-sized enterprises (SMEs).
- Data pooling: partners in our consortia share data in unprecedented ways to advance future research.
- Building consensus: IMI researchers collaborate to develop standards and protocols, often with the very valuable input of regulators.





INTELLECTUAL PROPERTY & OPEN ACCESS

Rewarding innovation

The IMI Intellectual Property (IP) provisions govern the IP regime of all IMI projects and apply equally to all project partners.

The IP provisions are designed to promote the creation and exploitation of knowledge generated and reward innovation, while respecting the assets and interests of all project partners.

IP issues should be agreed before the launch of the project. The flexibility of the provisions, coupled with IMI's neutral role in negotiations, have allowed IMI project partners to share resources and knowledge in unprecedented ways and deliver results that would not have been possible otherwise.

The IMI policy on scientific papers published by projects is that they must be open access.

In addition, IMI supports the 'FAIR data principles', i.e. data should be findable, accessible, interoperable and reusable.

We encourage IMI-funded projects to make their access to data as open as possible and as closed as necessary.

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