

FREQUENTLY ASKED QUESTIONS

IN BRIEF

IMI will:

- fund pan-European public-private partnerships in biomedical research;
- have a total budget of € 2 billion- focus on cancer and brain disorders, as well as on inflammatory, metabolic and infectious diseases;
- creates an environment in which small and medium-sized enterprises, spin-offs and start-ups can prosper
- provide academic institutions opportunities to work with other innovators and industry scientists;
- help to enhance and strengthen Europe's competitiveness and innovation.

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GENERAL

Why create IMI?

The IMI provides an opportunity for Europe to take a lead in biomedical innovation by developing new approaches to overcome scientific bottlenecks in the research and development of innovative medicines. The IMI will help to boost biomedical innovation through an ambitious pan-European initiative to bring together academic and industry researchers and to involve many other stakeholders. The European Commission has identified biomedical research as a strategic priority to enhance the competitiveness of the European Union. This is why the European Commission and the European pharmaceutical industry association [EFPIA](#), joined forces to set up IMI.

Why is IMI so urgent?

Similar initiatives are under development or have been initiated in the US and elsewhere in the world. To ensure patients benefit from European innovation and investment it is essential that the IMI is established as soon as possible. Delay risks the focus of investment being in the US (the US Biomarker Consortium has already been established as have initiatives under FDA Critical Path) and in other countries outside Europe.

Where and what are the 'bottlenecks' in the current biomedical R&D process?

IMI proposes a number of clear, practical paths that will accelerate the discovery and development of more effective innovative medicines with fewer side effects that reach patients faster and address the principle causes of delay or 'bottlenecks' in the current biomedical R&D process. These bottlenecks have been identified as: predicting safety, predicting efficacy, bridging gaps in knowledge management as well as in education and training. For example it is often not known until clinical trials have been undertaken or until a medicine is on the market place whether there are side effects that require termination of development or, in extreme cases, the withdrawal of medicines from the market. New technologies offer opportunities to be better able to predict side effects earlier in the process – ideally before clinical trials are undertaken (i.e. the IMI will not develop new medicines but focus on precompetitive research). The Strategic Research Agenda (SRA) describes the recommendations to address these bottlenecks and a plan to guide their implementation.

How will IMI work?

The European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) will hold joint responsibility for creating and operating a Joint Technology Initiative (JTI) that will implement IMI's Strategic Research Agenda. It will be an international not-for-profit organization managing the involvement of stakeholders as well as the operations required to support the implementation of the Strategic Research Agenda.

This organisation will award research grants to European Public-Private Collaborations. The public money will fund academic and patient participation and support Small and Medium-sized Enterprises. Large biopharmaceutical companies will fund their own contributions to 100%. Public money will therefore go exclusively to other participants such as SMEs, patient groups and academics, not to large biopharmaceutical companies.

The organization will have an Executive Office, which will publish calls for proposals addressing specific topics of interest from the Strategic Research Agenda. Groups of partners (academic institutions, SMEs, biopharmaceutical companies, regulatory authorities, patients etc.) will form Public-Private Collaborations to propose research projects and apply for funding to IMI.

How can I participate in IMI?

Once the international not for profit organisation is established, IMI will publish calls at regular intervals. These calls will be open to participants from European Union Member States, Associated States and Candidate Countries.

How do I become a member of IMI?

IMI does not have a membership structure. Participation in research is open to all European stakeholders. IMI will have a stakeholder forum, which will convene once a year to disseminate information on IMI activities and give stakeholders the opportunity to provide input on the future direction of IMI. This forum will be open to all stakeholders for participation.

I am from a non-European organisation, can I participate in IMI?

Yes, providing that your organization has a legal entity in Europe as all IMI supported research must be undertaken in Europe.

FUNDING

Why should public money be used? Isn't the pharmaceutical industry going to conduct this research anyway?

A public-private collaborative approach is essential in this type of research activities as:

- The nature of diseases is highly complex - a collaborative approach is needed to address this challenge using the best brains and talent that exist across Europe;
- The findings will be of value to the biomedical community as a whole;
- Information sharing is an essential feature of this type of research;
- The costs would be prohibitive for a single pharmaceutical company.

Public money will support the participation of academic institutions, SMEs and patients and will not be used to fund pharmaceutical companies.

How will the IMI benefit those Member States without a pharmaceutical industry?

IMI will benefit the EU biomedical community as a whole. Academia, clinicians, research institutions, small companies and start-ups throughout the EU can become IMI project partners and enter into cross-border partnerships. In particular although some Member States may not have a pharmaceutical industry, many have SMEs, all have academics and all have patients that will benefit and could participate in IMI clinical research.

What will be the pharmaceutical industry's contribution to IMI?

Pharmaceutical companies will fund their own participation 100% and provide R&D resources such as staff, laboratory facilities, materials and clinical research. Through the industry association, EFPIA, companies will fund half of the cost of the IMI Executive Office (which will not exceed 4% of the total budget). Public money will go exclusively to other participants (public sector, SMEs, patient groups, academics).

Will IMI result in cheaper medicines?

The main objective of the IMI is to leverage new scientific advances to improve the medicine discovery and development process. Currently, it is not possible to predict the impact of new discoveries on prices, since prices depend on a number of different factors including specific market conditions, competition and national price and reimbursement control measures.

STAKEHOLDER INVOLVEMENT

What's in IMI for small biotech companies?

Biotechnology companies are one of the key sources of new technologies and their participation in IMI will be important to its success. They have been involved in establishing the IMI research priorities, through consultative workshops and through work with representative associations such as European Biopharmaceutical Enterprises (EBE) and [EuropaBio](#). Small biotech companies will also have representation in the governance structure of IMI through the Stakeholder forum.

The collaborative approach fostered by IMI will reduce risks for small companies and help them –like pharmaceutical companies - to develop medicines more efficiently, through access to new tools and ways of

working. The project also offers opportunities for companies specialized in the development of tools and technologies supporting medicine development, such as in vitro, in vivo and in silico modelling.

What's in IMI for patients?

It is anticipated that research under IMI will lead to more efficient discovery and development of better medicines, for a wide variety of conditions. This can only be positive for patients. Patient representatives will play an active role in the IMI governance structure through the Stakeholder forum and are likely to be involved in many projects. They will contribute to discussions on new concepts for clinical trials and risk assessments with regulatory authorities, as these areas affect them and their access to innovative medicines directly.

What's in IMI for academics?

Academics are a key engine for novel scientific breakthroughs and their role in IMI will be essential. They will be represented in the IMI governance structure through the Stakeholder forum. IMI will constitute a framework within which academics will be able to bid for work and establish European collaborations. Additionally IMI will help them to define competitive and relevant R&D programmes, as well as offer them improved infrastructure with state-of-the-art technological equipment. The Education and Training pillar of the IMI will foster the development of new courses, networks and an academy.

Why would this initiative mobilise more stakeholders than current instruments?

Current instruments have a high administrative burden and do not have the flexibility for industry and partners to work together easily. The IMI will enable industry to work more effectively with other stakeholders than previous framework programmes have allowed, providing a specific framework and co-ordination geared towards medical research.

RESEARCH CONTENT

What areas of research will the IMI involve?

Types of research will include the application of genomics and other technologies, which offer an opportunity to address the challenges of drug discovery and development. Better prediction of safety and efficacy of an investigational compound as early as possible in the drug development process can be delivered, for example, by applying advances in predictive toxicology (toxicogenomics, toxicoproteomics and metabonomics), or by developing a better understanding of disease mechanisms through the use of approaches such as system biology, modelling, improved animal models and experimental medicine.

The knowledge management area will be key to leveraging the potential of new technologies such as genomics and proteomics and to analyse the huge amount of information in an integrated way. The education and training project will identify and address specific gaps in expertise, to achieve excellence in the European biomedical education landscape.

Why aren't neglected diseases or diseases of the developing world included in IMI?

The diseases chosen through the consultation process for the IMI Strategic Research Agenda are primarily areas of unmet medical need affecting European citizens. However, the aim of the IMI is to deliver progress on new tools and technologies that can be applied to research across disease areas, including neglected diseases. The IMI will not seek to duplicate the work of other initiatives such as the European and Developing Countries Clinical Trials Partnership ([EDCTP](#)).

Will the IMI research alternatives to animal testing?

Through the development of new tools and technologies it is hoped that the IMI may improve the medicines discovery process sufficiently to ultimately avoid or reduce the use of animals in many circumstances.

There are a number of existing initiatives at national and EU level directly working on alternatives to animal testing. These include the European Centre for the Validation of Alternative Methods ([ECVAM](#)), the European Partnership for Alternative Approaches to Animal Testing ([EPAA](#)), the UK's National Centre for the Replacement, Refinement and Reduction of Animals in Research ([NC3Rs](#)) and the 3R Research Foundation Switzerland ([3R](#)). The IMI will not seek to duplicate the activity of these initiatives.

STRATEGIC RESEARCH AGENDA

How can I affect the content of the Strategic Research Agenda?

From the summer of 2005 all European stakeholders had the opportunity to comment on the Strategic Research Agenda. If you have comments on the Strategic Research Agenda, please [go to the Contact Us page](#) of this website and submit the Contact Form. Express your views by completing the Message field within the Contact Form and upload relevant documents for the attention of IMI staff.

As IMI is implemented, the Stakeholder Forum, -which will convene a meeting once a year-, will give the stakeholders the opportunity to provide advice and input on how they believe IMI should proceed.

Where can I find the IMI Strategic Research Agenda?

A copy of the IMI Strategic Research Agenda can be found in the [Publications](#) section on this site.

The Strategic Research Agenda is equally available on a CD ROM obtainable [via the request form](#) on this site.

GOVERNANCE & TRANSPARENCY

How will a project work from pre-approval to completion?

The **Executive Office** will publish calls for research proposals that address the topics in the Research Agenda. Groups of partners (for example, universities, small/medium sized companies, larger biopharmaceutical companies, public authorities and patients) will then form Public-Private Collaborations (PPCs) to propose research projects and apply to IMI for funding. Each proposal will be prioritized and approved via a peer review process, on the basis of stringent scientific criteria and its potential impact on bottlenecks identified through the IMI. At a minimum, a Public-Private Collaboration will consist of one academic institution and/or one SME plus two biopharmaceutical companies which are members of EFPIA.

There will be two contracts needed to implement a Public-Private Collaboration:

1. **The Grant Agreement:** is the legal document that will govern the relationship between the Project Participants and the IMI Joint Undertaking (IMI JU). The Grant Agreement will define the specific project and the financing, as well as the application of the IMI Intellectual Property Policy that relates to the specific project. It will be signed by the IMI JU and Project Participants, or one or more representatives of the Participants serving as Project Co-ordinators.
2. **The Project Agreement:** is the legal document that will govern the relationship between the Project Participants, including detailed Intellectual Property Rights based on the IMI Intellectual Property Policy. This system allows flexibility so that contractual obligations can be based on the project specifics, and to ensure the project agreement fairly reflects the scientific and other interests of all Participants. It will be signed by all Project Participants and will cover the rights and obligations between the Participants with respect to execution of the project plan and the detail of onward access rights to the project IP.

The Grant and Project agreements are inter-dependent, with the Project Agreement being signed before the Grant Agreement. Model agreements will be made available by the Executive Office.

Why are there two types of agreements?

The Grant and Project agreements serve different purposes. The Grant Agreement provides the framework for the distribution and management of funding that will be received by partners such as SMEs, universities and patient groups from the IMI Joint Undertaking. It also ensures that there should be no unforeseen intellectual property barriers from Participants, either during the project or once it is completed. Together, the financial and IP management provided by the Grant Agreement provide a structure to align the project with IMI objectives. However, it is the collaborative work done by the Participants that will be critical to delivering on those objectives. The Project Agreement will function as a typical collaboration agreement, describing - for example - responsibilities for different elements of the research plan; specifics of intellectual property ownership and IP licensing in line with the IMI IP Policy; share of the Grant; and collaboration management. The goal is to have an efficient process between the IMI Joint Undertaking and all project participants for both the Grant and Project Agreements.

INTELLECTUAL PROPERTY

What Intellectual Property protection will be included in the IMI?

There will be two categories of Intellectual Property (IP) in IMI projects:

- Background: existing information which participants will provide to help progress IMI projects;
- Foreground: information generated during an IMI project;

Who will own 'foreground' generated through an IMI project?

Unless agreed otherwise by the Participants, the foreground will be owned by the Participant(s) who generated it, or where no individual Participant can be identified it will be jointly owned by those Participants who have together carried out the work which generated it. However the Project Agreement may allocate ownership in accordance with the wishes of the Participants.

Who will have access to this foreground?

Participants will have access to Foreground for completing the project. They will also have access to Foreground after the project for research purposes as will third parties under fair and reasonable terms. Beyond the research use, Participants may use, exploit sublicense or otherwise commercialize the Foreground they own as they see fit.

Sometimes third parties will need Background to use Foreground in their work - how will the commercial interests of Participants be protected?

The principle here is that there should not be restrictions on the research use of Foreground generated in IMI projects, therefore Background that is necessary for the research use of Foreground will be made available under fair and reasonable terms for research use.

With the advance agreement of the IMI JU a participant may also, in exceptional circumstances, limit access to certain elements of background to protect their commercial interests. Any limit of this type will be described in the project proposal and therefore visible to all stakeholders at the time of the award of the grant, and will be embodied in the Grant Agreement

How else will Background be used?

Background will be used by Project Participants in order to undertake IMI projects

Why does the IMI need an IP Policy – why doesn't it follow the IP rules in FP7?

The IP Policy needs to reflect the specific collaborative research approach and funding model of the IMI.

Funding Model - there are differences between the IMI and FP7 in the funding model. For example, pharmaceutical companies will not receive funding but will provide in kind resources including research information, expertise and laboratory space.

Research Use - Unlike other FP7 schemes, the IMI IP Policy recognises that the use of project findings in the discovery and development of diagnostic or pharmaceutical products is a different concept to that of direct commercialisation of the results, and that different provisions should apply in order to meet the stated aims of the IMI JU. The IMI IP Policy terms the use of results in discovery and development of diagnostic or pharmaceutical products as "Research Use", while other uses for example direct commercialization of the results is termed 'Direct Exploitation' (see also above). Other FP7 schemes apply only the term "use", which does not distinguish between these different circumstances.

How does the IP Policy provide incentives for academic institutions and SMEs to take part in IMI projects?

The IMI will help academic institutions and SMEs to develop their ideas into potential commercial opportunities that can be applied to drug discovery and development. This is particularly valuable where considerable investment or collaboration is required to develop the IP quickly. In addition access for third parties to such IP for research use will be remunerated as provided in the IP Policy (non-exclusive under fair and reasonable terms) and the conditions for direct exploitation can be set by the Participant who owns this IP as he sees it fit with his specific commercial partner.

What incentives are there for pharmaceutical companies as they will be able to use the IP generated in research without participating in specific projects?

The IMI offers a framework to develop technologies which can be applied to drug discovery and development. It will provide a network of collaborators and innovators to help move specific ideas and concepts on quickly or to gain regulatory acceptance for new approaches. Taking part in IMI projects will also allow a pharmaceutical company to contribute to the scientific direction of a project and have an "inside track" on how to apply the

technology to drug discovery and development. In particular, participation will allow access to the information during the project whereas third parties may only obtain such access after completion of the project.

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