



Boosting biomedical innovation across Europe

A COLLABORATIVE APPROACH

→ IMI will fund pan-European public-private partnerships in biomedical research

A unique initiative designed jointly by the European Commission and the European pharmaceutical industry association (EFPIA), IMI will bring together public authorities, patients, academia, hospitals and industry with the aim to address complex aspects of pre-competitive R&D, where advances can only be achieved through collaboration and co-ordination.

NEW FUNDS FOR RESEARCH

→ IMI will have a total budget of € 2 billion over five years

The European Commission has made €1 billion available for IMI from the 7th Framework Programme for Research (2007-2013). This investment will be matched by the pharmaceutical industry. Research projects will be selected for funding according to strict criteria. Public funds will go exclusively to the public sector and small companies.

BETTER PATIENT CARE

→ IMI will focus on cancer and brain disorders, as well as on inflammatory, metabolic and infectious diseases

The aim of the IMI is not to produce specific treatments but to address the key 'bottlenecks' in the biomedical R&D process, namely: (a) predicting medicine safety, (b) predicting medicine efficacy, (c) knowledge management and (d) education and training. Progress in these four areas will lead to faster discovery and development of better medicines, for a wide variety of conditions, providing new tools which can be applied to different therapeutic areas, including neglected diseases.

SMALL COMPANIES FIRST

→ IMI will give small and medium-sized enterprises, spin-offs and start-ups a sustainable competitive advantage

The collaborative approach fostered by IMI will reduce risks for small companies and help them develop new products faster, through access to shared resources, tools and infrastructure. 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.

EUROPE IN THE LEAD

→ IMI will help strengthen Europe's competitiveness and innovativeness

Similar initiatives are under development in the US and elsewhere in the world. Whichever initiative is established first will secure a competitive advantage, attracting academic interest and industry attention.

RAPID ADOPTION IS ESSENTIAL!

EFPIA calls on the Commission, Member States and the European Parliament to ensure maximal industry participation in IMI, through swift adoption of legislation that enables IMI objectives to be realized with streamlined and efficient processes and procedures.

Practical Information

1. Organization & Structure

IMI will be set up as a **not-for-profit organization** (article 171 of the Treaty) and run jointly by the European Commission and the European Federation of Pharmaceutical Industries and Associations (**EFPIA**). The IMI **Executive Office** will be jointly funded and operated by the Commission and EFPIA and will manage the involvement of stakeholders, as well as the operations required to support implementation of the **Strategic Research Agenda** (SRA – see point 4). In addition it is proposed that the IMI will have:

- A **Governing Board**, responsible for directing the operations of the IMI and overseeing the implementation of the SRA.
- A **Scientific Committee** with an advisory role, which should be composed of 15 members reflecting public and private stakeholders: academia, patients, industry and regulators. Its members will represent expertise from across the medicine discovery and development process, and provide recommendations on the scientific strategy of IMI.
- An **IMI States Representatives Group**, with nominees from all Member States, will approve the composition of the Scientific Committee. It will help disseminate information and ensure co-ordination with Member State activities. It will also play a leading role in the implementation of strategic parts of the IMI, such as Education & Training.
- An annual **Stakeholders' Forum**, where IMI activities will be presented and discussed to ensure openness and transparency to all stakeholders. In addition, the Forum will advise the Governing Board on IMI activities.

2. Funding

Half of the funding for IMI will be made available through the **7th Framework Programme** (FP7). The other half will be provided by companies belonging to EFPIA's Research Directors Group, namely: AstraZeneca, Bayer HealthCare, Boehringer Ing., Chiesi, Eli Lilly, Esteve, Genzyme, GlaxoSmithKline, Johnson & Johnson, Lundbeck, Merck KGaA, Merck Sharp & Dohme, Novartis, Novartis Vaccines, Novo Nordisk, Organon, Pierre Fabre, Pfizer, Roche, Sanofi-Aventis, Servier, Solvay, UCB and Wyeth. The contribution of these companies will include R&D resources such as staff, laboratories, materials and clinical research capabilities. It is important to note that FP7 funds will be used exclusively to boost the R&D capabilities of the public sector and small and medium sized companies, not the larger biopharmaceutical companies listed above.

3. Applications

The **Executive Office** (see point 1) will publish calls for research proposals that address the topics in the Research Agenda (see point 4). 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 prioritised and approved via a peer review process, on the basis of stringent scientific criteria and its potential impact on bottlenecks identified through the Strategic Research Agenda (see point 4). At a minimum, a Public-Private Collaboration will consist of two academic institutions or SMEs plus two biopharmaceutical companies which are members of EFPIA (see point 2).

4. Research Agenda

Both the Commission and EFPIA have co-ordinated the production of a **Strategic Research Agenda** (SRA), the 'roadmap' for IMI. It contains recommendations to address the key 'bottlenecks' in four areas of the biomedical R&D process: **predicting drug safety and efficacy, knowledge management and education and training**. These recommendations result from an extensive consultation process with over 350 key stakeholders, with contributions from the biopharmaceutical industry, academia, patients, regulators and the European Commission. The SRA can be found at www.imi-europe.org.

5. Adoption Process

The IMI legal package (governance, structure, calls for proposals and intellectual property rules) was adopted by the European Commission on 15 May 2007, and will be examined under the Portuguese Presidency of the EU (European Parliament consultation; Competitiveness Council adoption) with a view to its adoption and subsequent implementation in early 2008. If the adoption process is completed by January 2008, the first calls for proposals could be launched shortly after, so that the first research projects could begin in the second half of 2008.

More on www.imi-europe.org