



IMI Key Messages

Background

What is the Innovative Medicines Initiative?

The Innovative Medicines Initiative (IMI) is a co-ordinated public and private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It will boost Europe's biomedical R&D base, help correct the relative under-funding of biomedical R&D in Europe compared to other regions of the world and create biomedical R&D leadership for Europe to benefit patients and society.

What is the IMI Strategic Research Agenda?

Over 350 senior representatives of: patient organisations, universities, hospitals, regulatory authorities as well as small and large biopharmaceutical companies worked together to produce the Strategic Research Agenda. This document describes recommendations on predicting safety and efficacy of new medicines as well as plans to bridge gaps in knowledge management and in education and training. These are the principal causes of delays in the complex process of discovering and developing new medicines. The Strategic Research Agenda can be found at: <http://www.imi-europe.org>.

Why is the implementation of IMI needed?

1. IMI contributes to the European Union's Lisbon Objective of building the most competitive and dynamic knowledge-based economy in the world by 2010.
2. IMI provides clear practical paths to accelerate the discovery and development of more effective innovative medicines with fewer side-effects that reach patients faster.
3. IMI contributes to maintaining healthy European citizens.
4. IMI is a unique pan-European public and private sector collaboration between large and small biopharmaceutical companies, academia, regulators and patients.
5. IMI provides a more attractive professional environment for scientists and will help address the brain drain issue.
6. IMI will create European expertise and know-how in new technologies and will attract biomedical R&D investment in Europe.
7. IMI will create and support sustainable competitive advantage for Small and Medium-sized Enterprises (SME) and help enhance Europe's economy.

How will IMI be implemented?

The European Commission and the European Federation of Pharmaceutical Industries and Associations are proposing to create and operate a new Public Private Partnership; a 'Joint Technology Initiative' to lead and co-ordinate the development of IMI Projects. IMI Projects will accelerate the discovery and development of more effective innovative medicines. The



creation of the IMI Public Private Partnership is dependent of a favourable decision by the Member States in 2007.

Key Message 1: The implementation of IMI is urgent. Why?

1. The biopharmaceutical industry is ready to launch IMI now, if this does not happen soon, other economies such as the US, Singapore, India and particularly China will attract new industry investment as they launch their pre-competitive initiatives – companies are only likely to participate in a few such partnerships globally.
2. The Asia Pacific is currently starting to incubate initiatives such as IMI. Today the EU with IMI still has the opportunity to gain a leadership position which could be easily lost if IMI does not progress fast - hence the importance for Europe to act now.
3. Every year the biopharmaceutical Industry is investing about €22 billion on R&D in Europe, productivity of pharmaceutical and biopharmaceutical research remains a challenge as new regulatory hurdles and scientific challenges emerge: it is urgent to address these challenges for the industry to continue to invest in R&D in Europe.

Key Message 2: The role of the Member States in IMI is essential. Why?

1. The role of the Member States is essential since the European Competitiveness Council needs to discuss and approve the creation of the IMI Joint Technology Initiative.
2. Member States drive the EU focus on innovation by:
 - Maintaining and expanding national (and/or regional) public research infrastructure in biomedical science;
 - Maintaining the national education systems to participate fully in European collaborations, in particular IMI;
 - Work with national funding agencies to identify areas of pre-competitive collaborative research that can be funded nationally;
 - Leveraging the collaborative philosophy created by IMI in biomedical research.
3. Member States will have a direct input to the IMI to ensure its successful implementation by:
 - Appointing a national representative to the IMI Member States Group;
 - Nominating the members of IMI's Scientific Committee based on a proposal from the IMI Governing Board;
 - Mobilising national stakeholders' awareness of IMI;
 - Proactively communicating and discussing the benefits of IMI within the national biomedical R&D community;
 - Developing initiatives to help public and private researchers participate in IMI;
 - Liaising with IMI management through the IMI States Representatives Group to co-ordinate national biomedical R&D priorities with IMI, and identifying areas of potential synergy.



Key Message 3: IMI matters to new Member States. Why?

1. The new member states have excellent scientists who are fully able to compete for and win funds from IMI for research collaborations.
2. IMI will support new member states in developing clinical research capability and capacity via networks of clinical centres that will allow local hospitals to take part in clinical trials, which in turn will attract investment to the country.
3. IMI's member state group will allow for greater dissemination and coordination of national research efforts and will help scientists from new member states participate in international collaborations.
4. Patients in new member states will benefit both from early access to innovative medicines as well as through exposure to patient organisations.

Key Message 4: IMI will not induce extra costs to the Member States. Why?

1. IMI will be funded by the Seventh Framework Programme and by the Industry and should not introduce any extra costs to the Member States.
2. IMI will not introduce additional costs to the Member States but will give the Member States the opportunity to leverage national research investments through better co-ordination and connectivity with the other European countries.

Key Message 5: IMI will use resources effectively and Member States will have access to the information documenting this. How?

1. IMI governance structure and processes are defined in order to combine the EU rules for control of public funds with the industry requirements for performance and agility.
2. To ensure the appropriate use of resources in IMI, quality control measures will be implemented at both IMI project level and IMI management level:
 - For IMI projects reporting procedures and rules for advances of project funds will be established to ensure that the IMI projects deliver with a minimum of risk to Community funds.
 - Every year IMI's annual accounts and balance sheets for the preceding year shall be submitted for audit to the Court of Auditors of the European Communities. The Court of Auditors in accordance with its current procedures shall execute the audit.

Key Message 6: IMI cannot be implemented with existing instruments. Why?

1. Implementing IMI with the existing instruments would mean losing the connectivity and focus that the industry and its partners have identified in the Strategic Research Agenda.
2. The integration of Knowledge Management and Education and Training into the scientific programme as underpinning themes is not possible within the existing instruments.



3. A 50/50 Public Private Partnership approach which allows for a continued focus on industrial needs is not possible with existing instruments

Key Message 7: Choosing IMI does not exclude other JTI's. Why?

1. The Joint Technology Initiatives will be funded from the thematic areas that they belong under in the Seventh Framework Programme.
2. This means that IMI will be funded from the Health budget in the Seventh Framework Programme, the Aeronautics JTI will probably be funded from the Transport budget (potentially also from Security and Space), etc.
3. It is likely that IMI will be submitted as the first JTI for approval by the Competitiveness Council. If IMI is not approved by the Council, there is a significant chance that the European Commission will hesitate to submit further JTI's for approval.

Key Message 8: Industry is strongly committed to IMI. Why?

1. 16 companies are participating in the pilot project InnoMed funded through the Framework Programme Six (total budget of 18 million euros).
2. The increased number of companies represented in EFPIA's Research Directors' Group, which has the strategic leadership of IMI (15 companies in 2004 to 24 companies today – Sept 2007).
3. The investment made so far by individual companies to develop the IMI Strategic Research Agenda and IMI Governance structure. This investment can be loosely estimated to represent about 2 million euros in 2 years based on significant contribution in kind from companies.
4. Controlling processes will be established to ensure matching of EU funds in kind by companies and transparency of the industry's contribution. Planning discussions have been initiated in the EFPIA Research Directors' Group and have been followed by internal company's discussion on the implementation of IMI.
5. In a press release from EFPIA on September 18th, 2006 the industry publicly announced its commitment to implement IMI together with the European Union.

Key Message 9: The Implementation of IMI Needs a Partnership Between the European Union and the Industry. Why?

1. IMI is about improving our understanding of the human body and human disease to support the faster discovery and development of better medicines. It will use the latest knowledge and technologies to facilitate and accelerate the development of new medicines. This task responds to a societal need that the private sector cannot address alone.
2. The challenges in biomedical sciences have become so complex that international multi-disciplinary collaborations are needed between scientists from the public and private sectors. Academia and SMEs need funding to participate in such collaborations and the European Commission is the only funding agency experienced in supporting and co-



ordinating pan-European research collaborations for the best interest of the European scientific environment.

3. For the knowledge generated by IMI to have a real business impact, a strong link between IMI and the regulatory authorities at the EU level is needed. The European Union is playing a critical role to ensure support of the EMEA to IMI.
4. The European Union is playing a key facilitator role to encourage companies to collaborate on pre-competitive research topics, and for companies to collaborate with the other stakeholders in a co-ordinated pan-European manner.

Key Message 10: Implementing IMI will positively affect R&D expenditure in Europe.
Why?

1. Currently there is no significant pre-competitive EU level R&D programme in Europe, IMI will change this.
2. If IMI is not implemented, other countries and regions around the world are actively seeking partnerships with industry. If IMI is not implemented in Europe the bottlenecks in the R&D process will be addressed by US initiatives such as the FDA Critical path or the US Biomarker Consortium, or by initiatives in Japan such as the Translational Medicine Centre recently established in Kobe.
3. Furthermore the types of pre-competitive research envisaged would build on infrastructures that will attract further clinical and preclinical spending to Europe. Since most companies invest the greatest proportion of their R&D budget on clinical spend¹, this should drive clinical R&D investment in Europe.

¹ Translational science and biomarkers have a large emphasis in the IMI proposal



Companies in EFPIA's Research Directors Group

AstraZeneca	Novartis
Bayer HealthCare AG	Novartis Vaccines
Boehringer Ingelheim	Novo Nordisk
Chiesi Farmaceutici	Orion
Eli Lilly & Co	Pierre Fabre
Esteve	Pfizer
Genzyme	Roche
GlaxoSmithKline	Sanofi-Aventis
Johnson & Johnson	Servier
H.Lundbeck A/S	Solvay
Merck KgaA	UCB
Merck Sharp & Dohme	Wyeth Pharmaceuticals