The Innovative Medicines Initiative (IMI)

Concept, Organisation and Opportunities

II Conference of Technology Platforms in Biomedical Research
Madrid 27 January 2009

Alain Vanvossel,
IMI JU Interim Executive Director
History

2000  **Lisbon Strategy**  Europe most competitive and dynamic knowledge-based economy by 2010

2002  **Barcelona Council**
Countries spending 3% GDP in R&D by 2010

2004  **European Technology Platforms (ETP)**
stakeholders under the lead of industry develops Strategic Research Agendas addressing bottlenecks to competitiveness

=> one ETP on “Innovative Medicines Initiative” (IMI)
ETP on Innovative Medicine Initiative (IMI)

R&D productivity is stagnating
European pharmaceutical research is moving abroad

Note: Data collected from 22 global companies
Source: IMI (EFPIA Research Directors Group & IFPMA)
ETP on Innovative Medicine Initiative (IMI)

• The ‘brain drain’ of researchers away from Europe is increasing

• 7 out of 10 European-born US doctorate recipients who graduated between 1991 and 2000 had no plans to return to Europe

Source: According to the European Commission 2003 ‘Brain Drain Study’
IMI aims at removing major bottlenecks in drug development, where research is the key.
The recommendations to address the research bottlenecks in drug development and a plan to guide their implementation have been developed in the IMI Strategic Research Agenda (SRA).

These recommendations represent the outcome of an extensive consultation between Europe’s key stakeholders in the biomedical sector, organised within the European Technology Platform on Innovative Medicines Initiative.
**History**

- **2000**: 
  - **Lisbon Strategy**: Europe most competitive and dynamic knowledge-based economy by 2010

- **2002**: 
  - **Barcelona Council**: Countries spending 3% GDP in R&D by 2010

- **2004**: 
  - **European Technology Platforms**: Stakeholders under the lead of industry develops Strategic Research Agendas addressing bottlenecks to competitiveness

- **2007**: 
  - **7th Framework Programme for Research**: Major novelties: European Research Council and Joint Technology Initiatives

- **2008**: 
  - **Establishment of the Joint Undertakings**: To implement the Joint Technology Initiatives
Joint Technology Initiatives

- Long term public-private partnerships in research at European level
- Coordinated research efforts responding to industry needs
- Focus on fields of high industrial and policy relevance
- Building on European Technology Platforms
- To be implemented through new legal entities - Joint Undertakings
- 20 December 2007 Council Decision to establish four Joint Undertakings: IMI, Clean Sky, ARTEMIS, ENIAC
COUNCIL REGULATION (EC) No 73/2008 of 20 December 2007

setting up the Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines

Official Journal 04.02.2008
IMI is an ambitious public-private partnership

2 Billion EURO

1 Billion Euro
IMI

1 Billion Euro
Private Partnership

Public Partnership

Immunopatological Diseases (IPD)
IMI goals (I)

• Long term goal to re-invigorate the European bio-pharmaceutical sector and foster Europe as the most attractive place for pharmaceutical R&D, thereby, in the long term, enhancing access to innovative medicines for patients.

• IMI will support ‘pre-competitive pharmaceutical research and development’: no new medicines will be developed as such. The focus shall be on the delivery of new approaches, tools, methods and technologies, improve knowledge management of research results and data, and support the training of professionals.
IMI goals (II)

• IMI will support research activities following open and competitive calls for project proposals, peer review evaluation and the conclusion of Grant Agreements and Project Agreements

• The research will be funded by a combination of a financial contribution from the IMI JU to academia, SMEs, patients associations, etc. and a contribution ‘in kind’ from the participating EFPIA member companies

• The call and evaluation process is tailor made to serve the objectives of IMI

• IMI shall foster collaboration between all stakeholders, e.g. industry, public authorities (including regulators), organisations of patients, academia and clinical centres
The IMI Intellectual Property policy is aligned with the objectives of IMI - findings (Foreground) must be widely and readily available for research into the discovery and development of medicines.

The IMI Intellectual Property policy provides incentives for all actors to participate (i.e. the ownership interest, direct exploitation and the fair return on investment must be preserved).
IMI expected outcomes

• Modernisation of the development process of medicines

• More and better quality jobs for scientists, reversing the brain drain

• Better European Expertise and know how in technologies to attract biomedical R&D investment to Europe

• Stronger competitive advantage for smaller companies (SMEs, spin-offs and start ups) by collaboration with a multitude of stakeholders to enhance Europe’s competitiveness
IMI Governance (I)

IMI JTI = IMI JU + External Advisory Groups

- IMI Joint Undertaking (IMI JU)
  - Governing Board
    - Executive Director (+ staff)
  - Scientific Committee
- Stakeholder Forum
- IMI States Representatives Group
IMI Governance (II)

- **Governance Board**
  - Executive Director (+ staff)
  - Overall responsibility for the operations of IMI

- **Scientific Committee**

- **2 Founding Members**
  - One Chair and one Vice-Chair

- **IMI Joint Undertaking (IMI JU)**

- 3 meetings organised in 2008
Responsible for day-to-day management

Selection process to recruit the Executive Director being launched

Interim Executive Director from EC

15 members

Scientific Advise to the Board

In formation

IMI Governance (III)

Governing Board

Executive Director (+ staff)

Scientific Committee

IMI Joint Undertaking (IMI JU)
IMI Governance (IV)

Annual meeting open to all stakeholders

Communication

One representative per Member and Associated State

Interface with stakeholders in MS/AS and communication

Chair observer in Governing Board

Constituted and 2 meetings organised in 2008

Stakeholder Forum

IMI States Representatives Group
Pharmaceutical Industry (EFPIA companies) and Academics, SMEs, Patients organisations are participants in a typical IMI research project.

Research performed by the pharmaceutical industry is funded by own resources (equal to in-kind contribution for €960M).

Research performed by the public sector and SMEs is funded by the EC (IMI JU) (equal to cash contribution for €960M).

The IMI Joint Undertaking receives a maximum of €40M for running costs.

The EC provides cash of €1000M, including a maximum of €40M for running costs.
Examples of programmes implementation

**ERC Scheme**
- Implementation by ERC Executive agency
- € FP7
- EC individual grants

**Classical Scheme**
- Implementation by Commission (e.g. DG RTD)
- € FP7
- EC collaborative grants

**IMI Scheme**
- Implementation by IMI JU (Board=EC+EFPIA)
- € FP7
- € (in kind)
- Consortium of Academic/SME + Large industry
- Large industry (mainly EFPIA companies)
IMI JU Call process

Call definition
- Research Agenda
- Annual Implementation Plan
- Call with Topics
  - EFPIA consortia

Evaluation Stage 1
- Expressions of Interest
  - Applicant consortia
- 1st Peer Review
- Invitation to join for Full Project Proposal
  - Applicant consortium
  - EFPIA consortium

Evaluation Stage 2
- Full Project Proposal
  - Full Project Consortium
- 2nd Peer Review
- Grant Agreement & Project Agreement
  - Full Project Consortium
IMI JU first Call: specific features (I)

• Call Published: 30 April 2008

• Call Budget: M€ 122.7 from EC and M€ 172 estimated ‘in kind
contribution’ from EFPIA member companies

• 18 topics opened:
  ➢ 6 in “Safety”
  ➢ 7 in “Efficacy”
  ➢ 5 in “Education and Training”
IMI JU first Call: specific features (II)

- Topics included in the first call are based on IMI’s Scientific Priorities for 2008 and are derived from the IMI Research Agenda.

- Areas in the IMI Research Agenda not addressed in 2008 will be addressed in consecutive calls (e.g. pillar on Knowledge Management).

IMI Project “Islet Cell Research”

• R&D Bottleneck
  – Diabetes relevant β-cell screening and monitoring systems
• Focus Academia / SME
  – Novel approaches and delivery of candidate systems
• Focus EFPIA Partners
  – Characterization and assessment of relevance for development
• Expected Deliverables
  – Translational in vitro / in vivo models
  – Tools to monitor β-cell function & mass
138 Expressions of Interest received

At least one Expression of Interest received in each topic, i.e. all topics opened in the 1st IMI JU Call for proposals have been covered

Teams from nearly all EU Member States participated, also from several Associated countries, and USA, Australia, Russia

Almost 1300 participating teams
Expressions of Interest per topic (II)

• **At least one Expression of Interest received in each topic**, i.e. all topics opened in the 1st IMI JU Call for proposals have been covered

• **Safety**: 30% of the Expressions of Interest for 33% of the topics opened
  ✓ One topic with 1 EoI (Immunogenicity)
  ✓ One topic with 3 EoIs (Translational safety biomarkers)

• **Efficacy**: 56% of the Expressions of Interest for 39% of the topics opened
  ✓ No topic with less than 5 EoIs received
  ✓ 3 topics related to brain research have received the highest number of EoIs

• **E & T**: 14% of the Expressions of Interest for 28% of the topics opened
  ✓ Topics 14 and 17, proposing more global programmes, have received highest number of EoIs
Participation in Expressions of Interest (I) (preliminary data)

<table>
<thead>
<tr>
<th>PILLAR</th>
<th>Academic</th>
<th>SMEs</th>
<th>Patients organisations</th>
<th>Regulatory agencies</th>
<th>Large non-EFPIA companies</th>
<th>Industry associations</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>269 (69%)</td>
<td>98 (25%)</td>
<td>5 (1%)</td>
<td>18 (5%)</td>
<td>0</td>
<td>0</td>
<td>390</td>
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<tr>
<td>Efficacy</td>
<td>592 (81%)</td>
<td>102 (14%)</td>
<td>32 (4%)</td>
<td>2 (0.5%)</td>
<td>3 (0.5%)</td>
<td>0</td>
<td>731</td>
</tr>
<tr>
<td>E &amp; T</td>
<td>139 (80%)</td>
<td>20 (12%)</td>
<td>7 (4%)</td>
<td>3 (2%)</td>
<td>0</td>
<td>4 (2%)</td>
<td>173</td>
</tr>
<tr>
<td>TOTAL Eols</td>
<td>1000 (77%)</td>
<td>220 (17%)</td>
<td>44 (3.5%)</td>
<td>23 (2%)</td>
<td>3 (0.2%)</td>
<td>4 (0.3%)</td>
<td>1294</td>
</tr>
</tbody>
</table>
Participation in Expressions of Interest (I)

- Participation of **all Member States**, except Malta
- Participation from **7 FP7 Associated Countries**: Croatia, Iceland, Israel, Norway, Serbia, Switzerland, Turkey
- Participation from **3 FP7 Third Countries**: Australia, Russia, USA
30
1294 participating teams

% participating teams

- Academics
- SMEs
- Patients
- Regulatory
- Industry
- Associations

17
3,5
2
0,2
0,3
77

IMI JU first Call Stage 1: stakeholders
IMI JU First Call for proposals from Stage 1 to Stage 2

• Evaluation of Expressions of Interests by peer review

• Exploratory discussions between the Applicant Consortia and the EFPIA Consortia to investigate feasibility of preparing full proposals

• Preparation and submission of Full proposals

• Peer review of Full Proposals: 20 January 2009

• Establish Grant Agreements (contract between IMI JU and the project consortia) and Project Agreements (between partners in a consortia)
18 Eligible full project proposals

- 340 M€ Total
- 152 M€ in “kind” contribution
- 131 M€ requested
- Evaluation: February
- Selection and Board: March
- Contract negotiations
IMI Partnership: What is required

- Change of behaviors
  - Partners vs. competitors/contractors.
- Honesty
  - Long term team consensus vs. short term individual advantage.
- Courage
  - Working out of traditional roles and comfort zones.
- Reliability
  - Deliverables are highly interdependent.
- The Gain
  - To be part of an exciting new way of bringing the best ideas to reality for the benefit of patients.
Near future

- Finalisation first call – second stage
- "Lessons learned" from first call!
- Preparation second call (2009) (Q2?)
- Scientific committee SRA
- Autonomy of IMI JU in 2009
  - Key personnel: ED; Account
  - Legal; financial; material;
- Implement communication strategy
Thank you for your attention!

www.imi.europa.eu
www.imi-europa.org

Alain.van-vossel@ec.europa.eu