The Innovative Medicines Initiative

Innovative Funding for SMEs in Europe

Pierre Meulien
Koln, 08.11.2016
IMI – Europe’s partnership for health

EU contribution from FP7 / H2020

Pharma contribution ‘in kind’

Partnership 2008 - 2020

> €5 bn

€2.5 bn

Pharma industry

€2.5 bn
Why do we need IMI?

Because drug development is very…

- complex
- risky
- inefficient
- lengthy
- expensive

Because…

- Biological mechanisms underlying disease are complex
- Clinical trial designs need to be adapted to scientific knowledge
- Regulatory pathways should be adapted due to scientific drivers
What does IMI do?

IMI facilitates bringing new knowledge closer to the patient through an integrated platform involving stakeholders from the public and private sectors.

IMI responds to both industrial needs and public health challenges.

Through IMI funded projects the innovation process is streamlined through end-to-end integration.
An international, cross-sector community

Over 9,000 researchers working for:
- open collaboration
- improved R&D productivity
- innovative approaches to unmet medical needs

Figures from June 2016
IMI2 overall objectives

- **improve the current drug development process** through development of tools, standards & approaches to assess **efficacy, safety & quality** of health products.

- **develop diagnostic & treatment biomarkers** for diseases clearly linked to clinical relevance & approved by regulators.

- **reduce time to clinical proof of concept** (e.g. for cancer, immunological, respiratory, neurological/neurodegenerative diseases).

- **increase success rate in clinical trials** of priority meds (WHO).

- **develop new therapies** for diseases with **high unmet need**, (e.g. Alzheimer’s) & **limited market incentives** (e.g. AMR).

- **reduce failure rate of vaccine candidates** in phase III trials through new biomarkers for efficacy & safety checks.

- *IMI2 legislation, Article 2b*
IMI budget breakdown

- Drug Discovery
- Metabolic disorders
- Drug safety
- Stem cells
- Data Management
- Cancer
- Inflammatory disorders
- Biologicals
- Geriatrics
- Vaccines
- Education and Training
- Lung diseases
- Sustainable chemistry
- Drug delivery
- Drug kinetics
- Other
- Infectious diseases
- Brain disorders

Figures from May 2016
EU funding goes to:
- Universities
- SMEs
- Mid-sized companies
- Patient groups etc…

IMI 2 total budget
€3.276 billion

IMI 2 budget (2014 – 2024)

- €1.638 bn
- €1.425 bn
- €213 m

EFPIA companies receive no funding. They contribute to projects ‘in kind’

Associated Partners e.g. charities, non-EFPIA companies
How does IMI work? Two stage procedure

**Topic definition phase**
- Industry consortium
- Definition of topics by industry consortium

**Stage 1**
- SP Submission & Evaluation
- 
  - Academic research teams
  - Hospitals
  - Mid-size enterprises
  - Regulators
  - SMEs
  - Patients’ organisations

**Stage 2**
- FP Submission & Evaluation
- Applicant consortium
- Industry consortium
- Start of the Granting phase
- Project launch!

**Granting phase**
- Signature of Consortium and Grant Agreements
Industrial partners align themselves around a real challenge for industry and agree to work together and commit resources.

New ideas from public sector, universities, SMEs etc. are needed to address the challenge.

Scale is a key to success and is provided through IMI funding. Outcomes should be transformative for the industry as well as having a clear “public” value.
Some Specific Examples
Medicines development

The challenge

High throughput screening is an important step in early drug development but…

- pharma companies’ huge compound collections are hard to access

- public compound collections are small and scattered across many institutions

IMI solution

European Lead Factory

- 7 pharma companies pooled 320 000 compounds = unprecedented levels of sharing

- Leading role for (10) SMEs

- State-of-the-art screening centre

- Delivering results!
The European Lead Factory – an IMI success

✓ Quality & diversity of compounds recognised
✓ Award-winning IP solution (Bio-IT World)
✓ 1 spin-out created
✓ 2 patents filed
✓ 40 scientific papers
✓ Programmes in cancer, infectious diseases, neglected tropical diseases, neurology, diabetes
✓ Facilitates research in high-risk areas
Zoonoses Anticipation and Preparedness Initiative
# 20 Partners in ZAPI consortium

<table>
<thead>
<tr>
<th>EFPIA partners</th>
<th>Public consortium partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Merial</td>
<td>Erasmus Medical Center NL</td>
</tr>
<tr>
<td>AstraZeneca / Medimmune</td>
<td>CVI Lelystad NL</td>
</tr>
<tr>
<td>EFPIA coordinator</td>
<td>Viroclinics Biosciences NL</td>
</tr>
<tr>
<td>EFPIA partner</td>
<td>Utrecht University NL</td>
</tr>
<tr>
<td>EFPIA partner</td>
<td>Leyden University NL</td>
</tr>
<tr>
<td></td>
<td>CSIC Madrid SP</td>
</tr>
<tr>
<td></td>
<td>FLI Riems DE</td>
</tr>
<tr>
<td></td>
<td>IRTA-CReSA SP</td>
</tr>
<tr>
<td></td>
<td>Institut Pasteur FR</td>
</tr>
<tr>
<td></td>
<td>TiHo Hannover DE</td>
</tr>
<tr>
<td></td>
<td>IABS-EU FR / BE</td>
</tr>
<tr>
<td></td>
<td>Aix-Marseille Univ. FR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SMEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyadic NDL Wageningen NL</td>
</tr>
<tr>
<td>Harbour Antibodies Amsterdam NL</td>
</tr>
</tbody>
</table>
ZAPI overview

- Common pipeline for the rapid identification of viral key immunogens and corresponding neutralizing reagents and their rapid and high-yield QC production
- Three target viruses for proof-of-concept models
  - Rift Valley Fever Virus (RVFV)
  - Schmallenberg Virus (SBV)
  - Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
- «Subunit» vaccines against at least 2 target viruses (incl. RVFV and SBV) and neutralizing reagents against at least 2 target viruses (inc. MERS-CoV)
IMI and Advanced Therapies

- Held 2 workshops
- Developed Concept paper
- Key issues identified:
  - *In vitro* and *in vivo* model systems for preclinical testing
  - Vector systems for gene therapy
  - Application of gene editing technology
  - Regulatory environment for preclinical testing
  - Demonstrations of clinical safety and efficacy - (control groups?)
  - Communication to the general public on the benefits of ATMPs
  - Manufacturing challenges related to specific products (cells, vectors etc)
    - Batch to batch consistency, regulatory frameworks, controlling raw materials etc
    - Need for common technology platforms? Common Standards?
  - Pricing, reimbursement, access etc. New business models
  - Hospital Exemption issue
Topics for the near future?

- Paediatric Clinical Trial Network
- Oncology
- Advanced Therapies
- Patient Engagement
- Digital Health
- Big Data (contd.)
- Biopreparedness
- Microbiome
Participation of new players

We need to be more inclusive as regards who partners with IMI

- We need other sectors to get involved (Dx, Imaging, ICT etc)
- Evolution of Generics space (repurposing of existing drugs, combinations etc)
- Smaller EU Countries
- Involvement of more SMEs
- Associated Partners of IMI and Partners in Research (through EFPIA)
- Partnerships with European infrastructures and or other initiatives like EIT-Health for example
Some observations from IMI – 1 regarding SME involvement

- SMEs who are founder funded (rather than VC funded) seem to fit better with IMI

- SMEs that are platform technology driven rather than new product development driven seem to find a good match with IMI projects

- These are observations and NOT rules

- We would like to hear your stories

- We recognise that IP can be an issue but please come and talk with us
How is IMI addressing the challenges in drug development?

Through IMI’s projects we are trying to...

- **put patients at the centre**
- **share risk** (among public & private players)
- **increase efficiency** (by developing common tools)
- **reduce duplication of effort** (esp. at early stages)
- **reduce timelines** (by using a personalised medicine approach)
- **integrate the latest science** into drug development
- **use data and knowledge management** to work more effectively

We do this by creating a neutral platform where all involved in drug development – academics, industry, SMEs, patients, regulators, others – can engage in open collaboration on shared challenges.
Thank you

infodesk@imi.europa.eu • www.imi.europa.eu