Introducing the Innovative Medicines Initiative

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Public-private partnerships in health care

- Public interest
  - cost minimization and lean management structures
  - leverage the risk of setting up infrastructural measures to improve health care that would otherwise not seem beneficial to the private sector

1. **Product development PPP**: access to medicines and diagnostics in middle to low income countries
2. **Precompetitive PPP**: new solutions to outstanding problems requiring pharmaceutical research
IMI – Europe’s partnership for health
Goals of IMI2 programme

✓ Improve the drug development process by creating tools to assess the efficacy, safety and quality of medicines
✓ Develop biological markers to diagnose diseases and assess treatments
✓ Speed up the earlier stages of drug development
✓ Increase the success rate of clinical trials of priority medicines
✓ Develop new therapies for diseases with a high unmet need / limited market incentives
✓ Reduce the failure rate of vaccine candidates in clinical trials

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of 6 May 2014
establishing the Innovative Medicines Initiative 2 Joint Undertaking
(Text with EEA relevance)
IMI 2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines

Aligned with WHO priorities
Figure 1. The position of the European Lead Factory in the drug research value chain.

Figure 3. The composition of the Joint European Compound Library (JECL).
IMI End-to-End R&D accelerator

Understand Resistance

Target validation

Hit to Lead

Clinical trials Networks

Clinical development

Business models and stewardship

DRIVE AB RE-INVESTMENT IN R&D AND RESPONSIBLE ANTIBIOTIC USE

European Lead Factory

RESCEU REpistratiphy Rsyncytial virus Consoritum inou Europe

IMI End-to-End R&D accelerator
New Drugs for Bad Bugs (ND4BB)

Early discovery & preclinical → Phase I → Phase II → Phase III → Regulatory review → Phase IV

Translocation
Penetration barriers & efflux

ENABLE
Drug discovery engine

Clinical trial networks

COMBACTE-NET
Observational and epidemiology studies
MEDI4893 in *S. aureus* infections
Minoclycline in *A. baumannii* infections

COMBACTE-CARE
Clinical management & outcomes of patients with CRE
Microbiological analysis and biomarkers
ATM-AVI clinical development

COMBACTE-MAGNET
Epidemiology network and support
MEDI3902 anti-*P. aeruginosa*
First-in-Human trial AIC499

DRIVE-AB
New economic models

iABC Programme
Inhaled antibiotics in bronchiectasis and cystic fibrosis
Bronchiectasis patient registry (EMBARC)

Total budget >650 million Euro

IMI2 Call 9
Epidemiology, best practices, burden of CDI
<table>
<thead>
<tr>
<th>Project</th>
<th>Description</th>
<th>Status</th>
<th>Keywords</th>
</tr>
</thead>
<tbody>
<tr>
<td>EBODAC</td>
<td>Communication strategy and tools for optimizing the impact of Ebola vaccination deployment</td>
<td>Ongoing</td>
<td>Infectious diseases, Ebola and related diseases, Vaccines, Ebola, Tools for predicting/monitoring efficacy</td>
</tr>
<tr>
<td>Ebola+</td>
<td>Ebola and other filoviral haemorrhagic fevers</td>
<td>Ongoing</td>
<td>Infectious diseases, Ebola and related diseases, Vaccines, Diagnostics, Ebola, Manufacturing technologies</td>
</tr>
<tr>
<td>EbolaMoDRAD</td>
<td>Ebola virus: modern approaches for developing bedside rapid diagnostics</td>
<td>Ongoing</td>
<td>Infectious diseases, Ebola and related diseases, Diagnostics, Ebola</td>
</tr>
<tr>
<td>EBOMAN</td>
<td>Manufacturing and development for rapid access Ebola vaccine</td>
<td>Ongoing</td>
<td>Infectious diseases, Ebola and related diseases, Vaccines, Ebola, Manufacturing technologies</td>
</tr>
<tr>
<td>EBOVAC1</td>
<td>Development of a prophylactic Ebola vaccine using an heterologous prime-boost regimen</td>
<td>Ongoing</td>
<td>Vaccines, Ebola, Clinical trial design, Conducting clinical trials</td>
</tr>
<tr>
<td>EBOVAC3</td>
<td>Bringing a prophylactic Ebola vaccine to licensure</td>
<td>Ongoing</td>
<td>Infectious diseases, Ebola and related diseases, Vaccines, Ebola, Conducting clinical trials</td>
</tr>
</tbody>
</table>
IMI – an ecosystem for innovative collaboration

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients’ lives

IMI is a neutral platform where all involved in drug development can engage in open collaboration on shared challenges.
IMI Governance

**Governing Board (EC + EFPIA)**
Overall strategic orientation & operations

**Associated Partners**

**States Representatives Group**
Consultation, opinions

**Scientific Committee**
Advice on scientific issues

**Stakeholder Forum**
Input, Information & feedback

**Strategic Governing Groups**
Identify specific priority areas

**IMI Executive Director |** Day-to-day management
**IMI Programme Office |** Day-to-day implementation
IMI Scientific Committee position papers and recommendations

Sustainability
Suitability for PPP

*Big data and data integration (2)*

*Regulatory engagement*

*Drug repurposing*

*Equitable access*

*Rare Diseases*
Evolvement of the Innovative Medicines Initiative

IMI1
- precompetitive
- drug discovery
- manufacturing

IMI2
- (pre)competitive
- clinical development

(IMI3)
- Digital technologies
- Food technologies
- Other technologies

IMI IHI
Partners is future Health PPP program (IHI?)

- COCIR – European Coordination Committee of the Radiological, Electromedical and Healthcare IT industry
- EBE – Emerging Biopharmaceutical Enterprises
- EFPIA – European Federation of Pharmaceutical Industries and Associations
- EuropaBio – European Associates for Bioindustries
- MedTech Europe – European Association of medical technology industries comprising medical devices, diagnostics and digital health
- Vaccines Europe