The Innovative Medicines Initiative

Innovative funding for biotechs & SMEs in Europe

Pierre Meulien, IMI Executive Director
BIO-Europe Conference, Berlin • 07.11.2017
IMI – Why Europe’s partnership for health?

- Because drug development - from biological mechanisms to clinical trial designs and regulatory pathways - is very complex, risky, lengthy and expensive.

- Because new ideas responding to and transformative outcomes for both industrial needs and public health challenge are needed.

- Because IMI funded projects streamline the innovation process through end-to-end integration.

- Because IMI creates a neutral integrated platform where all involved in life sciences – academics, industry, SMEs, patients, regulators, other sectors - can engage in open collaboration on shared challenges.
IMI phase 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
**IMI phase 2 - Budget (2014-2020)**

**EU funding goes to:**
- Universities
- SMEs
- Mid-sized companies
- Patient groups etc…

**IMI 2 total budget**
€3.276 billion

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

**EFPIA companies**

- Others
  - €213 m
  - €1.425 bn
  - €1.638 bn

**Other Partners**
e.g. charities, non-EFPIA companies
Why should SME and biotechs consider participating in an IMI project?

- By engaging with all stakeholders, sectors, initiatives and funders across Europe, IMI provides for a dynamic ecosystem for research and business network

- Collaboration with large pharmaceutical companies allows access to whole value chain of drug discovery

- IMI ecosystem creates opportunities for further development and validation of assets while protecting background IP

- 100% funding for EU-based entities
SME participation
As of June 2017

IMI2 SME participation & funding (cumulative)
Target: 20% funding, 20% participation

Based on calls 1-9. Beneficiaries receiving funding only.
x-Axis = project start dates for signed GAs, estimated start dates for FPs (dashed lines)
Some observations from IMI first phase 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.

- Scale is key to success.

- Administrative ressources and IP should be anticipated.
IMI IP policy to support innovation

- Opportunity of further development and/or validation of background assets
- Background and sideground assets protected (no transfer)
- New results owned by the generator(s) and right to transfer ownership / for non-exclusive license
- Result owner to design on the best protection modalities
- Access to expertise from the other partners on equal basis
- Access rights for exploitation purposes to be negotiated on a case-by-case basis
- Dissemination subject to conditions, such as respect of the legitimate interests
What does a IMI project look like?

Industry partners
- Boehringer Ingelheim, Germany
- F. Hoffman-La Roche, Switzerland
- Novartis, Switzerland
- Takeda, United Kingdom
- Eli Lilly, United Kingdom
- Janssen, Belgium
- Pfizer, United Kingdom

Public consortium partners
- Academisch Ziekenhuis Leiden - LUMC, Netherlands
- Alma Mater Studiorum - University of Bologna, Italy
- Centro de Investigacion Biomedica en Red, Spain
- Erasmus Universitair Medisch Centrum Rotterdam, Netherlands
- Stichting Buro ECNP, Netherlands
- Stichting Katholieke Universiteit, Netherlands
- Stichting VU-VUmc, Netherlands
- Universitair Medisch Centrum Utrecht, Netherlands
- University of Exeter, United Kingdom

SMEs
- Biotrial Sas, France
- Concentris Research Management GmbH, Germany
- Drug Target ID BV, Netherlands
- P1vital Limited, United Kingdom
- SBGNeuro Limited, United Kingdom
- European Federation of Associations of Families of People with Mental Illness, Belgium
**PRISM overview** (2016-2019 – 18M€)

- Accelerating the development of treatments for neuropsychiatry conditions such as schizophrenia, Alzheimer’s dementia and major depression for patients

- Two main axis:
  - To develop a quantitative biological approach to the understanding and classification of neuropsychiatric diseases to accelerate the discovery and development of better treatments for patients;
  - To define a set of quantifiable biological parameters for social withdrawal and cognitive deficits to cluster and differentiate schizophrenia (SZ), Alzheimer’s disease (AD), and to a lesser degree, patients with major depressive disorder (MD).
The IMI’s drug discovery platforms - ELF

**Target**  
**Screening**  
**Hit-to-lead**  
**Lead-to-candidate**  
**Preclinical**  
**Phase I**  
**Phase II**  
**Phase III**

**European Lead Factory**

- **Total Budget:** EUR 197 million
- **IMI funding:** EUR 80 million
- **SME funding:** EUR 54 million

**Joint European Compound Collection**
- **320 000 cpds** from 7 pharma companies
- **200 000 cpds** from public partners (SMEs)

**European Screening Centre**
- Advanced, ultra high throughput screening facilities & expertise on logistics, medicinal chemistry, etc.

‘The ELF provided the missing piece in the puzzle – a potent, selective compound that provides a strong starting point for further development towards the clinic’
– Dr. Margit Mahlapuu, ScandiCure
Topics under consideration for next Calls – November 2017

- Assessment of the uniqueness of diabetic cardiomyopathy relative to other forms of heart failure using unbiased pheno-mapping approaches
- Genome-environment interactions in inflammatory skin disease
- The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use
- Mitochondrial dysfunction in neurodegeneration
- Support and coordination action for the projects of the neurodegeneration area of the innovative medicines initiative
- A sustainable European induced pluripotent stem cell platform
- Linking digital assessment of mobility to clinical endpoints to drive regulatory acceptance and clinical practice
- Human tumour microenvironment immunoprofiling
- CONCEPTION – continuum of evidence from pregnancy exposures, reproductive toxicology and breastfeeding to improve outcomes now
- Improving the preclinical prediction of adverse effects of pharmaceuticals on the nervous system
- Translational safety biomarker pipeline (TRANSBIOLINE): enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease
- Federated and privacy-preserving machine learning in support of drug discovery
- Pilot programme on a clinical compound bank for repurposing (Cardiovascular diseases and diabetes, Respiratory diseases, Neurodegenerative diseases, Rare/orphan diseases)
### 2018-2020 Priorities - Think Big

<table>
<thead>
<tr>
<th>Category</th>
<th>Focus Areas</th>
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<tbody>
<tr>
<td><strong>Immunology</strong></td>
<td>• Treatment of non-response and remission</td>
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<td>• Non-invasive molecular imaging of immune cells</td>
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<td><strong>Antimicrobial resistance</strong></td>
<td>• Clinical trials networks</td>
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<td></td>
<td>• Accelerator of AMR R&amp;D</td>
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<td><strong>Digital Health/Big Data</strong></td>
<td>• Remote clinical trials</td>
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<td>• Biosensors/digital endpoints in clinical development</td>
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<td><strong>Modernisation of clinical trials and regulatory pathways</strong></td>
<td>• Addressing the challenge of platform trials (Integrated Research Platforms)</td>
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More information

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Thank you