Introduction to IMI Procedures and Recent Project Achievements
Why to Apply?

- Looking for additional funding
- Interested in patient-centric biomedical/pharmaceutical research
- Interested in collaborating with large pharmaceutical companies
Key Concepts

• Non-competitive research for EFPIA companies

• Competitive calls for IMI beneficiaries

• Open collaboration in final consortia
Building a IMI Project (1)

**Call definition and launch**

1. **IMI Research Agenda (multi-annual plan)**
   - Contains EFPIA priorities
   - Advice of Scientific Committee (SC)
   - Consultation of States Representatives Group (SRG)
   - Approval by IMI Governing Board

2. **Annual Scientific Priorities**
   - Proposed by EFPIA
   - Consultation of SC and SRG
   - Approval by IMI Governing Board

3. **Definition of research topics**
   - Proposed by EFPIA

4. **Detailed description of research topics**
   - EFPIA + IMI Executive Office
   - Consultation of SC and SRG
   - Approval by IMI Governing Board

5. **Launch of the Call**
   - IMI Executive Office
Building a IMI Project (2)

Submission of Expressions of Interest

• By applicants’ consortia (academics, SMEs, Patient org….)

First Peer review

• Independ. experts + EFPIA coordin.

• Independ. experts

First ranked consortium

• Approved by IMI Governing Board

Invitation to submit Full Project Proposal

• to first ranked applicants’ consortium + EFPIA consortium

Competition between applicants’ consortia (potential IMI beneficiaries)
Building a IMI Project (3)

Joint Preparation of Full Project Proposal

Submission of Full Project Proposal  
• By full project consortium (first ranked applicants’ consortium + EFPIA consortium)

Second Peer review (including ethics)  
• Independent experts

Approval of Full Project Proposal  
• by IMI Governing Board
Building a IMI Project (4)

1. **Preparation of Project Agreement**
   - by full project consortium
   - by IMI Executive Office

2. **Approval of Project budget**
   - by IMI Governing Board

3. **Signature of Project Agreement**
   - by full project consortium

4. **Signature of Grant Agreement**
   - by full project consortium
   - by IMI Executive Office

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Contract negotiation
Eligibility for IMI JU funding

- **Eligible for funding**
  - Academia
  - SMEs (EU definition)
  - Patient Organisations
  - Non-profit research organisations
  - Intergovernmental organisations

- **Non-eligible for funding**
  - EFPIA companies (*in-kind contribution*)
  - Companies not falling within the EU definition of SMEs
  - Others
Funding Rules

- Direct costs (personnel, consumables, equipment,…)

- Indirect costs = overheads
  Flat-rate of 20% of direct eligible costs
  or
  actual indirect costs (NEW!)

- Funding rates
  - Research activities
    -> 75% of total eligible costs
  - Other activities, including management and training
    -> 100% of total eligible costs
Intellectual Property Policy: guiding Principles

• Aligned with IMI objectives
  - to *promote* knowledge creation
  - to *facilitate* dissemination and exploitation
  - to achieve *fair allocation* of rights
  - to *reward* innovation
  - to achieve a *broad participation* of private and public entities

• Provides *flexibility* for participants
Ownership: basic principles

• **Background** remains the exclusive property of each participant

• **Foreground** (Project results) are owned by the generator(s)

• Possibility to **freely license, assign or otherwise dispose** of its ownership rights provided access rights to other partners are respected

• **Possible transfer** of ownership
Access Rights: basic principles

- Granted on **written request**, unless otherwise agreed
- **Non-exclusive** basis approach
- **No sub-licences**, unless otherwise agreed
- Not affected by the termination of participation
- Guiding framework for participants, affiliates and third parties
- Terms: royalty-free basis / fair and reasonable / to be negotiated
Calls 1 & 2: Consolidated Figures

<table>
<thead>
<tr>
<th></th>
<th>Call 1</th>
<th>Call 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projects</td>
<td>15</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>EFPIA Companies</td>
<td>21</td>
<td>21</td>
<td>23</td>
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<tr>
<td>Academic teams</td>
<td>195</td>
<td>103</td>
<td>298</td>
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<td>SME teams</td>
<td>24</td>
<td>23</td>
<td>47</td>
</tr>
<tr>
<td>Patients’ organisat.</td>
<td>9</td>
<td>2</td>
<td>11</td>
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<tr>
<td>Total Budget (M€)</td>
<td>281</td>
<td>172</td>
<td>453</td>
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</tbody>
</table>
NEWMEDS

Develops biomarkers and tools and models to allow better targeted treatments for schizophrenia and depression

19 Partners
- 9 EFPIA companies
- 7 Public organisations
- 3 SMEs

First achievements
- Has assembled the largest known repository of antipsychotic clinical trial data.
- The database contains information on 23,401 patients from 67 industry sponsored studies.
- Bringing together data from public projects and 3 companies on the genetics and clinical response in 1,800 well characterized patients with depression.
By comparing data from several hundreds of people, the team will characterise different kinds of severe asthma, paving the way towards a new classification of asthma and personalised treatments for patients.

38 Partners
- 9 EFPIA companies
- 23 Academic institutions
- 3 Patients’ organisations
- 3 SMEs
- 1 non-SME company

First achievements
✓ Consensus statement on the definition of severe refractory asthma

Diagnosis and definition of severe refractory asthma: an international consensus statement from the Innovative Medicine Initiative (IMI)

Elisabeth H Bel,1 Ana Sousa,2 Louise Fleming,3 Andrew Bush,4 K Fan Chung,5 Jennifer Versnel,6 Ariane H Wagener,1 Scott S Wagers,7 Peter J Sterk,1 Chris H Compton,6 on behalf of the members of the Unbiased Biomarkers for the Prediction of Respiratory Disease Outcome (U-BIOPRED) Consortium, Consensus Generationa

Thorax, in press
Builds a large searchable database containing drug toxicity-related data extracted from relevant pharmaceutical pre-clinical legacy reports.

Develops innovative methodological strategies and novel software tools to better predict in silico the toxicological profiles of new molecular entities in early stages of the drug development pipeline, using its database background.

25 Partners
- 13 EFPIA companies
- 8 Public organisations
- 4 SMEs

First achievements
✓ An innovative multi-scale modelling strategy for the prediction of cardiotoxicity has been developed, successfully tested and published.

Addresses the current lack of sensitive and specific clinical tests to diagnose and monitor drug-induced injury to the kidney, liver and vascular tissues in man, which is a major hurdle in drug development.

20 Partners
- 11 EFPIA Pharma Companies
- 5 Academic Institutions
- 4 SMEs

First achievements

- 153 potential biomarker candidates for drug-induced injury of the kidney, liver and vascular system have been evaluated and are currently undergoing clinical evaluation.
- The strategy adopted has been agreed with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA).
IMI Education & Training Projects

- First course in Nov 2010 on drug discovery development
- Certificate and Master courses in pharmacovigilance and pharmacoepidemiology in Sept 2011
- EU syllabus on pharmaceutical medicine
- Database on over 700 master courses, 110 professional development courses, 380 learning tools

www.imi.europa.eu
CALL 4 TOPICS (1)

Cluster A: Medical Information System
• A European medical information framework (EMIF) of patient-level data to support a wide range of medical research
• eTriks: European translational information and knowledge management services

Cluster B: Chemistry, Manufacturing and Control
• Delivery and targeting mechanisms for biological macromolecules
• In vivo predictive biopharmaceuticals tools for oral drug delivery
• Sustainable chemistry – Delivering medicines for the 21st century
CALL 4 TOPICS (2)

Cluster C: Technology and Molecular Disease Understanding

- Human induced pluripotent stem (hiPS) cells for drug discovery and safety assessment
- Understanding and optimising binding kinetics in drug discovery

**Indicative total financial contribution from IMI JU for the 7 full projects**
Up to 105 M€
CALL 4 TIMELINE

- Open Info Day: 17 June 2011
- Official Launch: End June 2011
- Deadline submission of Expression of Interests: End October 2011
- Peer-review Evaluation: November 2011
- Deadline submission Full Project Proposals: March 2012
- Approval of Full Project Proposals: May 2012
Partner Search Tool

www.imi.europa.eu
WEBINARS on Call 4 Topics

<table>
<thead>
<tr>
<th>Call Topic</th>
<th>Webinar Date</th>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>Building up a European Medical Information Framework (EMIF)</td>
<td>21 June 2011</td>
<td>15:00 – 17:00</td>
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<tr>
<td>eTRIKS: European Translational Information &amp; Knowledge Management Services</td>
<td>22 June 2011</td>
<td>15:00 – 16:30</td>
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<tr>
<td>Delivery and targeting mechanisms for biological macromolecules</td>
<td>28 June 2011</td>
<td>12:00 - 13:00</td>
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<td><em>In vivo</em> predictive biopharmaceutics tools for oral drug delivery</td>
<td>28 June 2011</td>
<td>10:30 – 11:30</td>
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<td>Sustainable Chemistry – delivering medicines for the 21st century</td>
<td>28 June 2011</td>
<td>15:00 – 16:00</td>
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<td>Human Induced Pluripotent Stem (hiPS) Cells for drug discovery and safety assessment</td>
<td>27 June 2011</td>
<td>16:00 – 17:00</td>
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<td>Understanding and optimising binding kinetics in drug discovery</td>
<td>30 June 2011</td>
<td>15:00 – 16:00</td>
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→ Instructions and updates at  [www.imi.europa.eu/content/events](http://www.imi.europa.eu/content/events)
Further Questions?

• IMI Info Booth (lunch area)
  - IP Policy
  - Financial rules, Rules for participation ...
  - Partner Search Demo

• USB key + IMI website
  - Presentations
  - Call documents

• Latest updates: www.imi.europa.eu
THANK YOU!

www.imi.europa.eu