WELCOME!
Introduction to the 3rd Call for Proposals

Michel Goldman, MD, PhD
Executive Director

Open Info Day, Brussels, 22 October 2010
Why to Apply?

- Looking for additional funding
- Interested in patient-centric biomedical/pharmaceutical research
- Open to collaboration with large pharmaceutical companies
EFPIA Member Companies

Participating companies (September 2010):

- Almirall
- Bristol-Myers Squibb
- Johnson & Johnson
- Novartis
- sanofi aventis
- AMGEN
- Chiesi
- Lilly
- Novo Nordisk
- Servier
- AstraZeneca
- ESTEVE
- Lundbeck
- Orion
- Astellas
- Bayer
- Genzyme
- MERCK SERONO
- Pfizer
- Boehringer Ingelheim
- GSK
- MERCK SHARP & DOHME
- Roche
- Sigma-Tau
- UCB
- EFPIA
Innovative Medicines Initiative: the Largest PPP in Life Sciences R&D

IMI

2 Billion Euro

1 Billion € (Public) 1 Billion € (Private)

Public Partnership

Private

EFPIA

EU
Towards the Pharma 3.0 Ecosystem

Adapted from Progression Pharma 3.0, Ernst & Young, 2010
Key Concepts

- Open Innovation

- Pre-competitive research
COMMENTARY

Open innovation networks between academia and industry: an imperative for breakthrough therapies

Teri Melese, Salima M Lin, Julia L Chang & Neal H Cohen

The demand to bring transformative therapeutics to patients and the escalating costs of doing so are driving the life science industry to seek collaborations with academia to stimulate innovation. Despite the opportunities afforded by working together, companies and universities lack a systematic approach for capturing the full potential of such relationships. Detailed here are a few suggested strategies to help these collaborations succeed.

The term ‘open innovation’ was coined by Henry Chesbrough to describe “how useful knowledge and technology was becoming increasingly widespread,” such that newly developing technologies and products benefited from integrating knowledge and expertise from multiple sources. He also made the case that the economics of innovation is a key driver for companies to open their innovation process. Pharmaceutical and large biotechnology companies, as an example, increased their research and development (R&D) spend...
Precompetitive Research: A New Prescription for Drug Development?

J Woodcock

“Precompetitive research” is being recommended by some as a treatment for the current malaise in drug development. What is this prescription, and why do the patients seem so reluctant to try it? Precompetitive research is science participated in collaboratively by those

There is some confusion between “translational research” and precompetitive research. Translational research usually refers to the scientific activities involved in moving candidate medical products from the laboratory into and through clinical evaluation. Translational
Drug development is a risky business. According to the US Food and Drug Administration (FDA), only eight percent of drugs that enter clinical trials are eventually approved. For a drug to gain FDA approval, it must be safe and show some efficacy. Because the FDA does not require any understanding of the mechanism by which a drug acts, it could be tempting to move into clinical trials without this knowledge. However, this may set the stage for failure. An investigational mechanism matters.

It is true that we use many highly prescribed drugs without a clear idea of how they work—which targets they hit, what processes they alter and which of these actions are required for therapeutic efficacy. For instance, lithium, used to treat bipolar disorder, modulates many molecular targets, but which—or how many—of these are required for its beneficial effects is uncertain. Nevertheless, understanding a drug’s mechanism could guide drug development and help to prevent late-stage failures such as Dimebon’s.
Overall Structure of Research Projects

“Applicants consortium”
IMI beneficiaries

“EFPIA consortium”
EFPIA in kind contribution
(no public funding)
IMI Executive Office as a Neutral Third-Party

- To implement programmes and activities in the common interest of all stakeholders
- To monitor the combined use of public funds and industry investment
- To guarantee fair and reasonable conditions for optimal knowledge exploitation and dissemination
# Ongoing Projects (1st Call)

### 15 Projects

### 395 Teams

**Total budget:** 281 M€

<table>
<thead>
<tr>
<th>Acronym</th>
<th>EFPIA Coordinator</th>
<th>Budget (M€)</th>
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<td>SAFE-T</td>
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<td>SafeSciMET</td>
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Lessons from Ongoing Projects

• **IMI is more than an industry-academia PPP:** successful involvement of regulatory agencies, patients’ organisations and SMEs

• **First successes and enthusiasm** provide « **proof-of-concept** » evidence for IMI-type PPPs

• **Boundaries of pre-competitive research and IP rules** sometimes difficult to define
Proposals under Finalisation (< 2\(^{nd}\) Call)

*Topics*

- Knowledge Management
- Cancer
- Rapid diagnosis for infections
- Inflammatory disorders
3rd Call Topics

- Drug-induced liver injury
- Immunogenicity of biopharmaceuticals
- Immunosafety of vaccines
- Translational research on autism spectrum disorders
- Personalized medicine in type II diabetes
- Pre-clinical models for tuberculosis therapies
- Patient awareness on pharmaceutical innovation
3rd Call Modalities

- Indicative duration of each project = 5 years
- Maximum IMI financial contribution = 114 million EUR
- Size of consortium compatible with sound management, scientific goals and expected key deliverables
- Clarifications provided in the Rules for Submission & Participation
- IP Guidance Note
- Partner search tool
3rd Call Timeline

**Official Launch end Oct**

**Open Info day 22 Oct**

**Deadline EoI submi. 18 Jan**

**Eval. Panels 24 Jan - 18 Feb**

**Gov Board Dec. stage 1 mid March**

**Deadline Full propos. submi. 15 June**

**Eval. Panels Early July**
# Webinars 3rd Call topics

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<tr>
<th>Topic</th>
<th>Webinar Date</th>
<th>Time</th>
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<td>13:00-14:30</td>
<td>Daniel Kramer</td>
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New IMI Partner Search Tool

Welcome, Michel Goldman

Participant Search

You can combine any search criteria from the list of below participant characteristics.
(devided in 2 sections)

I'm looking for a partner having experience with...

- Prediction of drug induced liver injury in man
- Immunogenicity
- Immunosafety of vaccines
  - Pre-clinical expertise
  - Clinical expertise
  - Vaccine Safety
  - Vaccine-induced Inflammation
  - Inflammation
  - Allergy
  - Autoimmune diseases
  - Clinical Sample availability

www.imi.europa.eu
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