The Innovative Medicines Initiative: Building new models of collaborative research across Europe

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IMI, Belgium

www.imi.europa.eu
What is IMI?

An European Public-Private Partnership
Focused on
Needs Common to
Pharmaceutical Industry and Patients
The Innovative Medicines Initiative: the Largest PPP in Life Sciences R&D

IMI Research funding
for
Academia, SMEs, patients organisations, Regulatory Authorities, etc.

* Research performed by EFPIA member companies
= in kind contribution

IMI Research Projects

Public Private Partnerships Boost Alzheimer's Disease Drug Discovery.
IMI Official Satellite Symposium of the AD/PD 2011 Conference,
9th March 2011, Barcelona Spain
IMI Objectives

• Making the pharmaceutical R&D process faster and more effective, rather than directly delivering new drugs

• Accelerating the development of safer and more effective medicines for patients in Europe

• Improving the environment for pharmaceutical R&D in Europe

• Boosting the biopharmaceutical sector in Europe
...Burden of Mental Disorders is huge..

15% Cardiovascular disease
7% Respiratory disease
4% Sense organ disease
3% Infectious/parasitic disease
3% Digestive disease
3% Diabetes

25% Mental Illness
12% Cancer
15% Others

Serious mental illness costs ~ 320Billion/year
~100B Direct Costs
~ 200B Indirect Costs

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Efforts to discover and develop new drugs for brain disorders, particularly those that might revolutionize disease treatment, have been relatively unsuccessful, some of the reasons being:

- Most brain disorders are heterogeneous and multi-factorial
- Target validation is challenging
- Complexity of symptoms is not simply the sum of its parts
- Diagnosis is based on subjective criteria
- Animal models are inadequate
...Current R&D Models Show no Significant Impact on R&D Innovation

Munos B., Nature Reviews Drug Discovery 8, 959-968 (December 2009)

1+1=1

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The Health-care Ecosystem is changing….

- Health care reform and health IT, are driving the system to include many companies not traditionally involved in the health care business.

- Patients from been traditionally relatively passive participants in health delivery are been empowered by technological progress to become educated super-consumers with a much more active role in management of their health care.
The New Environment of “Big Pharma”

Regulators

Patients

Pharma

Biotechs

Academia

Governments

Physicians

CROs

Insurers

Social media

Digital healthcare

MedTech

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Key Concepts

- Open Innovation
- Pre-competitive research
Open Industry-Academia Networks are Key to Achieve Innovative Medicines

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 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

Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland, USA.
IMI Supports Precompetitive Research

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IMI is an Industry driven initiative

Call definition
- Research Agenda
- Annual Implementation Plan
- Call with Topics
  - EFPIA consortia

Evaluation Stage 1
- Expressions of Interest
  - Applicant consortia
- 1st Peer Review
  - Applicant consortium + EFPIA consortium
- Invitation to join for Full Project Proposal
  - Applicant consortium

Evaluation Stage 2
- Full Project Proposal
  - Full Project Consortium
- 2nd Peer Review
- Grant Agreement & Project Agreement
  - Full Project Consortium
Building a IMI Consortium

Step 1: A set of EFPIA companies define a topic on which they commit to collaborate

Step 2: Consortia eligible for EU funding compete through expressions of interest which are ranked by independent experts

Step 3: The top-ranked EU-fundable consortium join the EFPIA companies to form the final consortium which develops the full proposal, subject to peer-review before final approval
EMA supports IMI activities

The European Medicines Agency’s participation in Innovative Medicines Initiative (IMI) Research projects

The European Medicines Agency’s position regarding participation in IMI consortia:
The agency fully supports the overall goals of IMI, recognising its benefits for public health. We may therefore be willing and able to participate in select projects, contingent upon a number of considerations. These include:

- **Considerations of resources**: Participation in an IMI project may be labour intensive and we need to be conscious of its internal resource constraints.

- **Potential for conflicts of interest (CoI)**: Since IMI projects will be designed to, *inter alia*, develop methodologies to be applied to drug development (e.g. biomarkers, novel approaches to analysis of clinical trials, etc), it is probable that some of these novel methodologies will, at a later stage, become part of a marketing authorisation dossier or a scientific advice procedure for e.g. biomarker qualification that will be assessed by the European Medicines Agency’s Scientific Committees and Working Parties. This may create a situation of potential CoI.

- **Relevance of our contribution to the consortium**: We recognise that participation of (a) regulatory agency(ies) is critical for some but not all IMI call topics and consortia.
The Missing Voice of Patients in Drug-Safety Reporting

Ethan Basch, M.D.

A patient wants to know about symptoms she may have from a prescription drug she is taking. Consulting the label’s “Adverse Reactions” section, she finds a wealth of data. Little does she realize that drug-development cycle if reporting by patients were standard practice.

Before a drug has received marketing approval from the Food and Drug Administration (FDA),...
### IMI Projects overview Call 1 & 2

<table>
<thead>
<tr>
<th></th>
<th>Call 1</th>
<th>Call 2</th>
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<tr>
<td><strong>Projects</strong></td>
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<td><strong>EFPIA Companies</strong></td>
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<td><strong>Academic teams</strong></td>
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<td><strong>SME teams</strong></td>
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<td>23</td>
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<td><strong>Patients’ organisat.</strong></td>
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<td>2</td>
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<tr>
<td><strong>Total Budget (M€)</strong></td>
<td>281</td>
<td>172</td>
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IMI Four Strategic Pillars

- SAFETY
  - Non-clinical Safety
  - Pharmacovigilance

- KNOWLEDGE MANAGEMENT
  - Translational KM
  - KM Platform

- EDUCATION & TRAINING
  - Integrated drug development
  - Mobility

- EFFICACY
  - Cancer
  - Brain
  - Inflammation
  - Metabolic
  - Infections

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First call (2008) funded projects

<table>
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<tr>
<th>Acronym</th>
<th>EFPIA Coordinator</th>
<th>Budget (M€)</th>
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<tr>
<td>SAFE-T</td>
<td>Novartis Pharma</td>
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<tr>
<td>PROTECT</td>
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<tr>
<td>SUMMIT</td>
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<td>NEWMEDS</td>
<td>Lundbeck</td>
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<tr>
<td>EUROPAIN</td>
<td>AstraZeneca</td>
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<td>PROactive</td>
<td>Chiesi Farmaceutici</td>
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<tr>
<td>MARCAR</td>
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<tr>
<td>SafeSciMET</td>
<td>F. Hoffman-La Roche</td>
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15 Projects

Total budget: 281 M€

3 Neuroscience
Projects

Total budget nearly 60 M€

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3rd Call Topics

- Early prediction of drug-induced liver injury
- Risk minimization of antibodies to biopharmaceuticals
- Immunosafety of vaccines
- Translational research on autism spectrum disorders
- Personalized medicine in type II diabetes
- New strategies to treat tuberculosis
- Patient awareness on pharmaceutical innovation
Mechanism matters

The path of drug development is fraught with hurdles. Gaining a clear understanding of how a drug works before it enters clinical trials is the intelligent route to drug discovery and could increase the likelihood for drug success.

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

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.
The Translational Process of Drug R&D


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Biomarkers are Critical for the R&D of Innovative Drugs

No drug candidate should enter the clinic without a species-independent biomarker as the central element of translational medicine.
### The Translational Process of Drug R&D

<table>
<thead>
<tr>
<th>Animal species n</th>
<th>Molecule, receptor</th>
<th>Cell</th>
<th>Tissue, physiological system</th>
<th>Whole organism</th>
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<tr>
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<td>Cell</td>
<td>Tissue, physiological system</td>
<td>Whole organism</td>
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</tbody>
</table>

**Biomarker**

**A. F. Cohen, Nature Reviews Drug Discovery 9, 856-865 (2010)**

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Prediction of Cognitive Properties of New Drug Candidates for Neurodegenerative Diseases in Early Clinical Development

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Thank you for your attention!