



**Innovative Medicines Initiative**

**WELCOME !**



**efpia**



Innovative Medicines Initiative

# Introduction to the 3rd Call for Proposals

*Michel Goldman, MD, PhD  
Executive Director*



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*Open Info Day, Brussels, 22 October 2010*



**efpia**

# Why to Apply ?

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



# EFPIA Member Companies

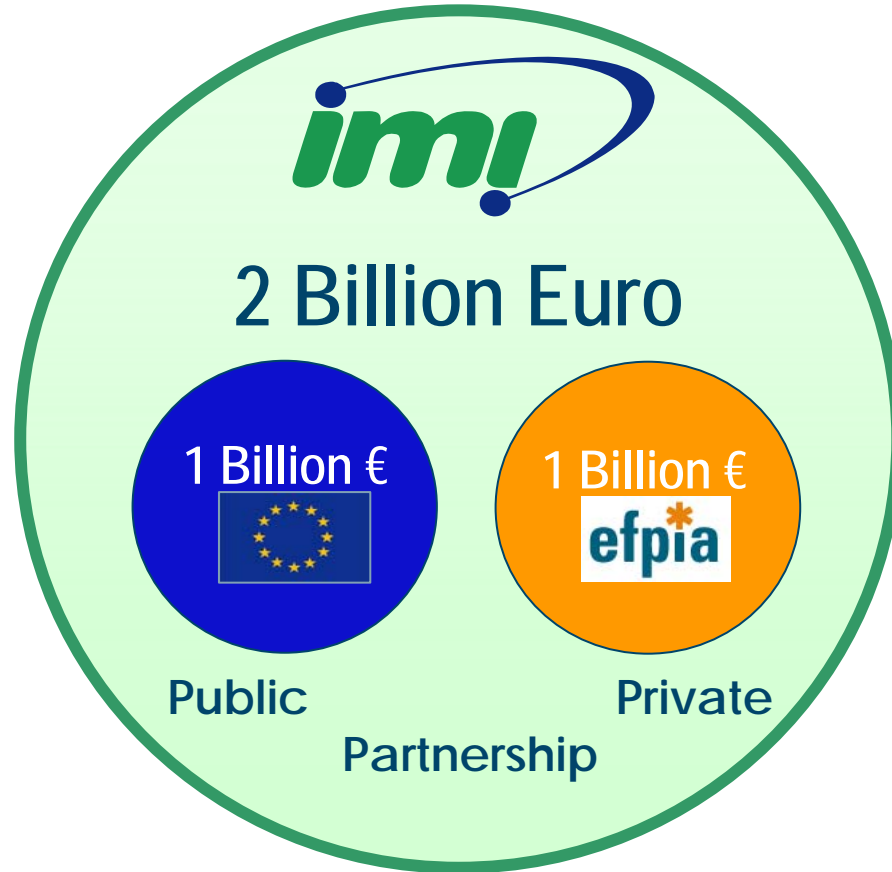


Participating companies (September 2010):



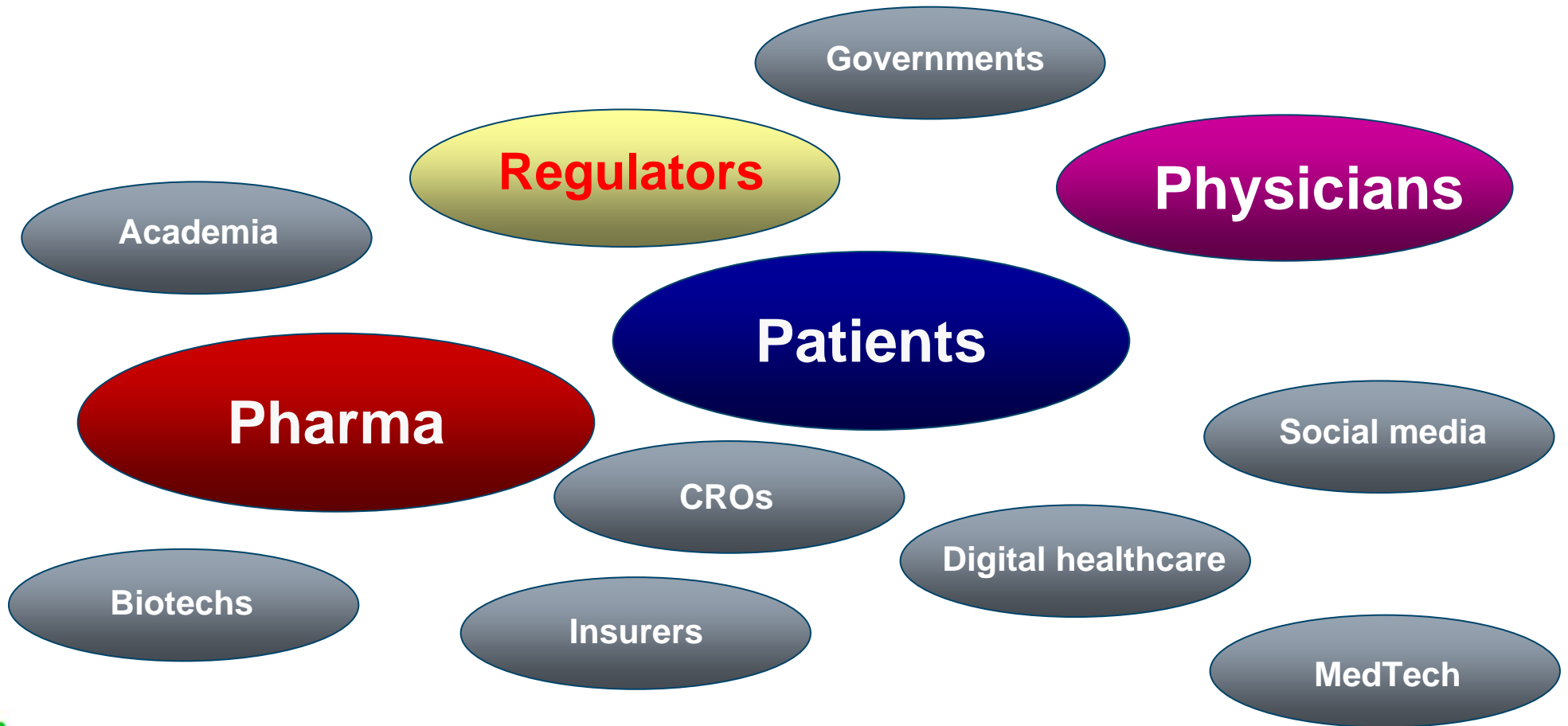
# Innovative Medicines Initiative: the Largest PPP in Life Sciences R&D

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# Towards the Pharma 3.0 Ecosystem

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# Key Concepts

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- Open Innovation
- Pre-competitive research



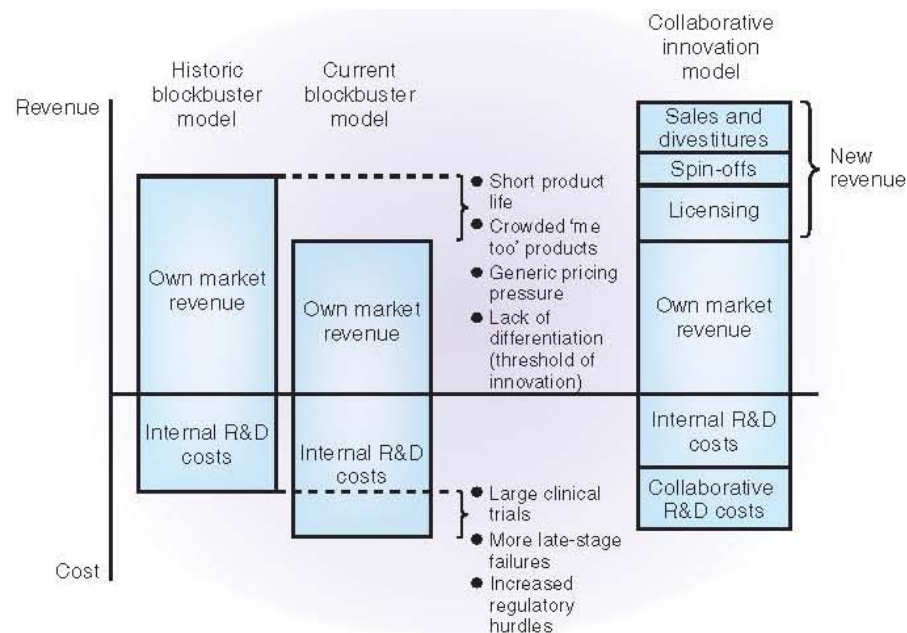
## COMMENTARY

# 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<sup>1</sup>. He also made the case that the economics of innovation is a key driver for companies to open their innovation process<sup>1,2</sup>. Pharmaceutical and large biotechnology companies, as an example, increased their research and development (R&D) spend





## MACROSCOPY

# Precompetitive Research: A New Prescription for Drug Development?

J Woodcock<sup>1</sup>

“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

tinct possibility that the slow progress of preclinical and clinical development science is holding back the movement of innovative discoveries into the market. For many decades, biomedical science has been divided into two realms. One sector, government- or nonprofit-

# The Path to Innovative Medicines

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## nature medicine

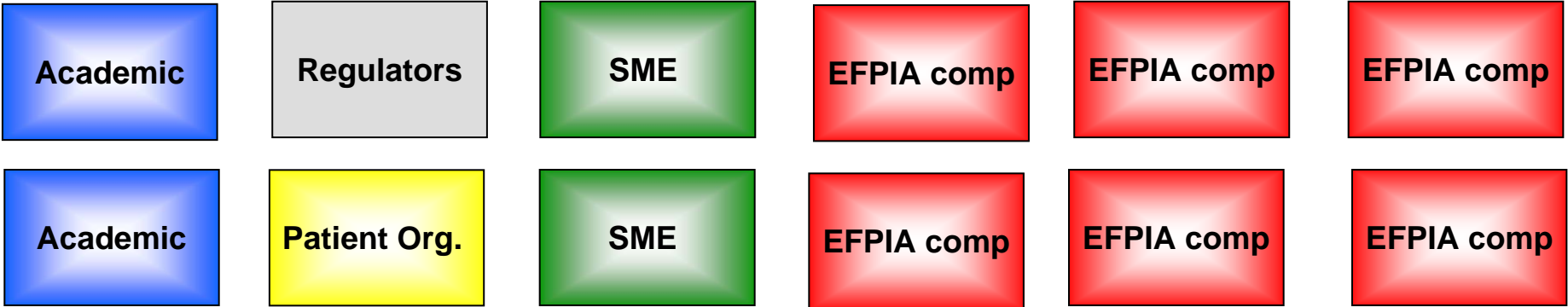
### Mechanism matters

**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.**

**D**rug 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.

# 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

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- 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€*

| <i>Acronym</i>      | <i>EFPIA Coordinator</i>          | <i>Budget (M€)</i> |
|---------------------|-----------------------------------|--------------------|
| <b>SAFE-T</b>       | <b>Novartis Pharma</b>            | <b>35.9</b>        |
| <b>PROTECT</b>      | <b>European Medicines Agency</b>  | <b>29.8</b>        |
| <b>SUMMIT</b>       | <b>Boehringer Ingelheim</b>       | <b>28.4</b>        |
| <b>PHARMA-COG</b>   | <b>GSK</b>                        | <b>27.7</b>        |
| <b>IMIDIA</b>       | <b>Sanofi-Aventis</b>             | <b>25.4</b>        |
| <b>NEWMEDS</b>      | <b>Lundbeck</b>                   | <b>24.0</b>        |
| <b>U-BIOPRED</b>    | <b>Novartis Pharma</b>            | <b>20.6</b>        |
| <b>EUROPAIN</b>     | <b>AstraZeneca</b>                | <b>18.2</b>        |
| <b>PROactive</b>    | <b>Chiesi Farmaceutici</b>        | <b>16.7</b>        |
| <b>MARCAR</b>       | <b>Novartis Pharma</b>            | <b>13.3</b>        |
| <b>E-TOX</b>        | <b>Novartis Pharma</b>            | <b>12.9</b>        |
| <b>EMTRAIN</b>      | <b>AstraZeneca</b>                | <b>7.7</b>         |
| <b>EU2P</b>         | <b>F. Hoffman-La Roche</b>        | <b>7.2</b>         |
| <b>Pharma Train</b> | <b>Eur. Federation of Courses</b> | <b>6.6</b>         |
| <b>SafeSciMET</b>   | <b>F. Hoffman-La Roche</b>        | <b>6.3</b>         |

# Lessons from Ongoing Projects

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- **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<sup>nd</sup> Call)

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## *Topics*

- Knowledge Management
- Cancer
- Rapid diagnosis for infections
- Inflammatory disorders



# 3rd Call Topics

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- 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

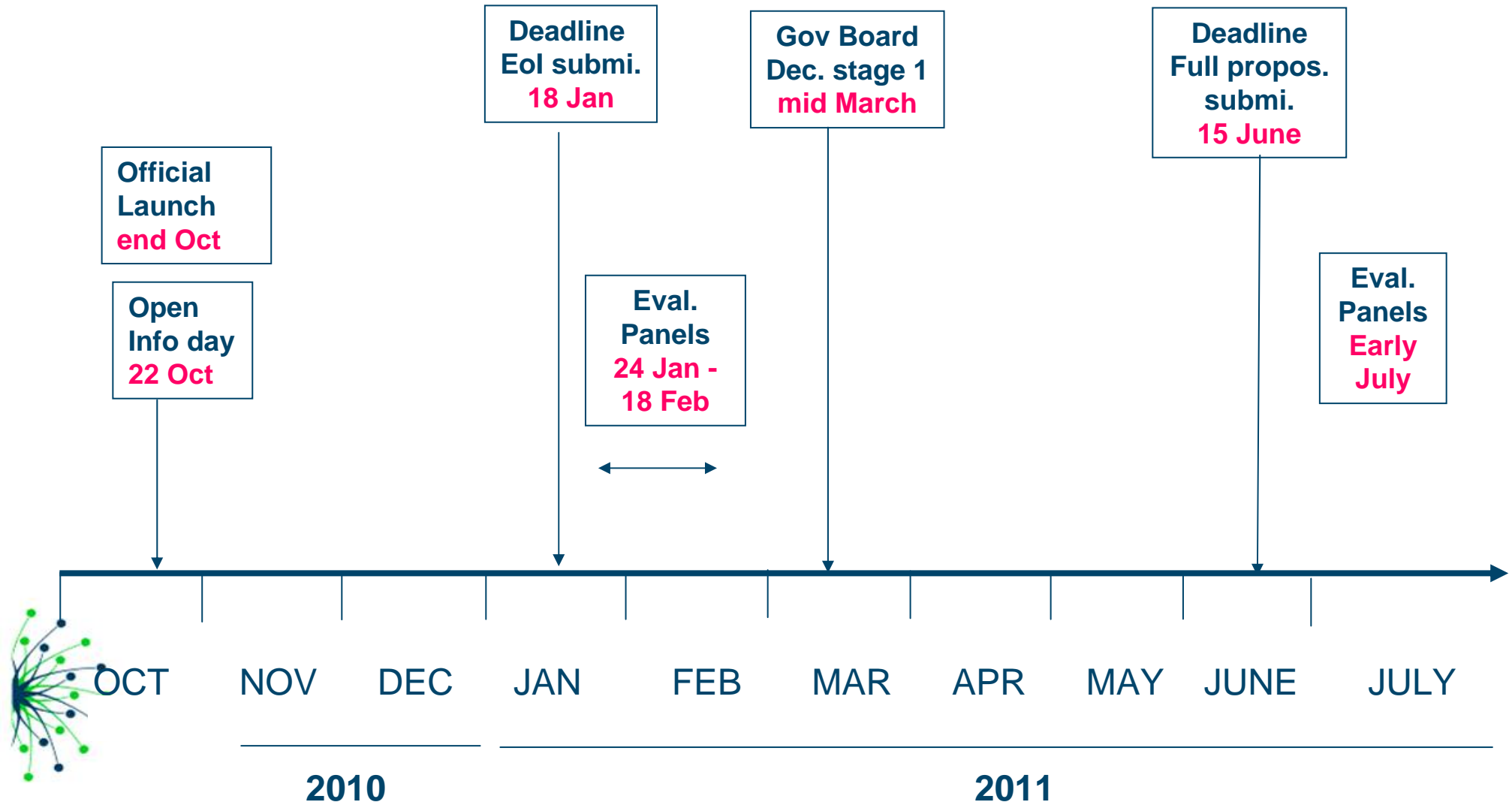
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- Indicative duration of each project = 5 years
- Maximum IMI financial contribution = 114 million EUR
- Size of consortium compatible with sound management, scientific goals and expected key deliverables
- Clarifications provided in the Rules for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



# 3rd Call Timeline



# Webinars 3rd Call topics

| Topic                     | Webinar Date     | Time         | Topic presenter                | IMI Scientific Manager    |
|---------------------------|------------------|--------------|--------------------------------|---------------------------|
| Immunogenicity            | 28 October 2010  | 13:00- 14:30 | Daniel Kramer                  | Maria Teresa De Magistris |
| Drug Induced Liver Injury | 4 November 2010  | 10:00-12:00  | Gerry Kenna,<br>Richard Weaver | Ann Martin                |
| Autism                    | 19 November 2010 | 10:30-12:00  | Will Spooren                   | Elisabetta Vaudano        |
| Tuberculosis              | 27 November 2010 | 10:30-12:00  | Martin Pan                     | Elisabetta Vaudano        |
| Immunosafety of Vaccines  | To be confirmed  |              | Aldo Tagliabue                 | Maria Teresa De Magistris |
| Diabetes                  | To be confirmed  |              | Hartmut Ruetten                | Fatiha Sadallah           |
| Patient awareness         | To be confirmed  |              | Fatiha Sadallah                | Fatiha Sadallah           |



# New IMI Partner Search Tool



Innovative Medicines Initiative



Contact Newsletter Links

Home

My Data

Participant Search

Log Out

Welcome, Michel Goldman

## Participant Search

You can combine any search criteria from the list of the below participant characteristics.  
(divided 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

### LATEST NEWS

No Tweets found

### UPCOMING EVENTS

22/10/2010 - Open Info Day:

3rd Call for proposals The

Innovative Medicines Initiative

hosts an Open Info Day about the

3rd Call for...

[www.imi.europa.eu](http://www.imi.europa.eu)

# Further questions?

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- 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](http://www.imi.europa.eu)





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**[www.imi.europa.eu](http://www.imi.europa.eu)**

**THANK YOU !**



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