

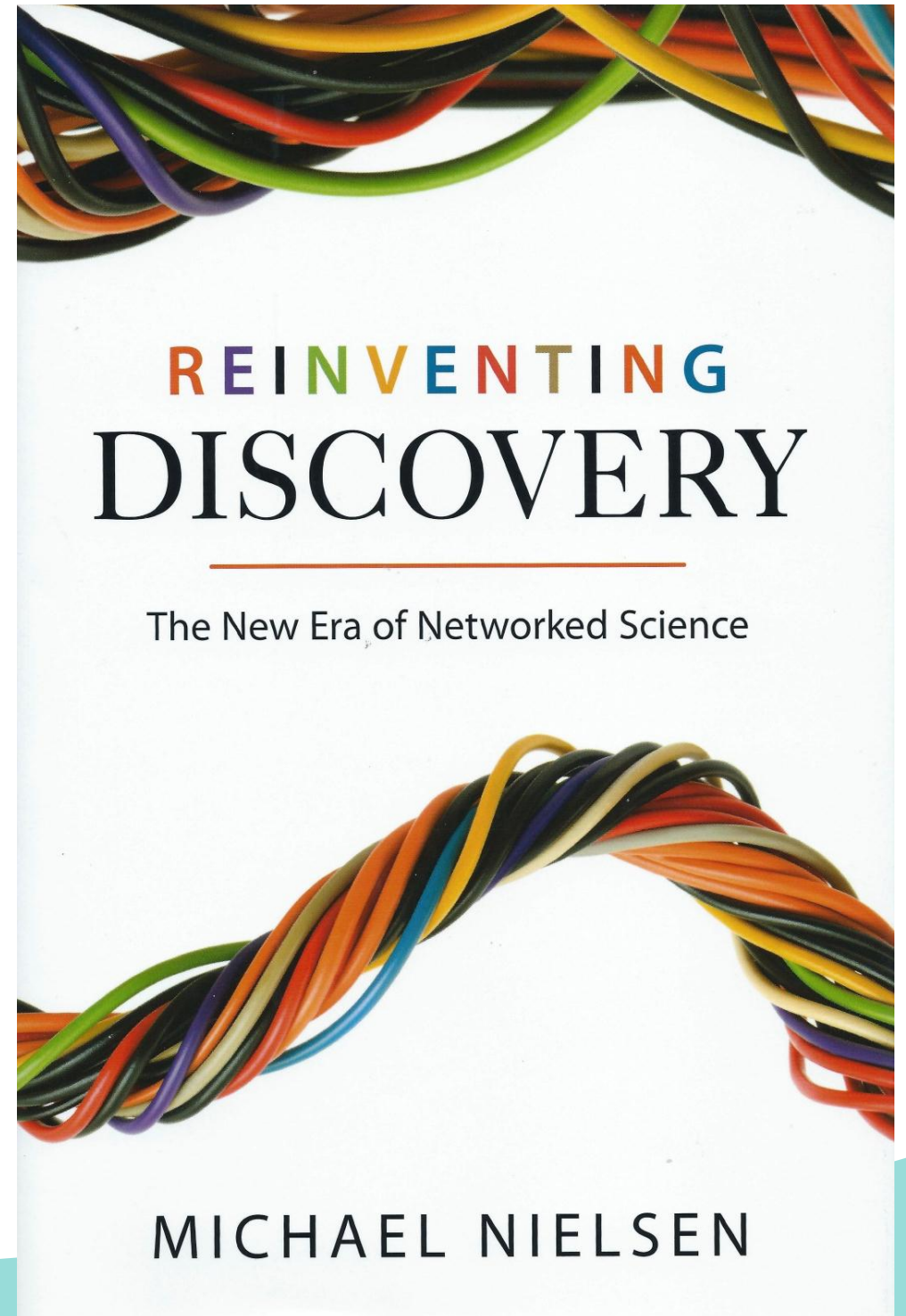
# The Innovative Medicines Initiative: an engine for therapeutic innovation

**Michel Goldman**

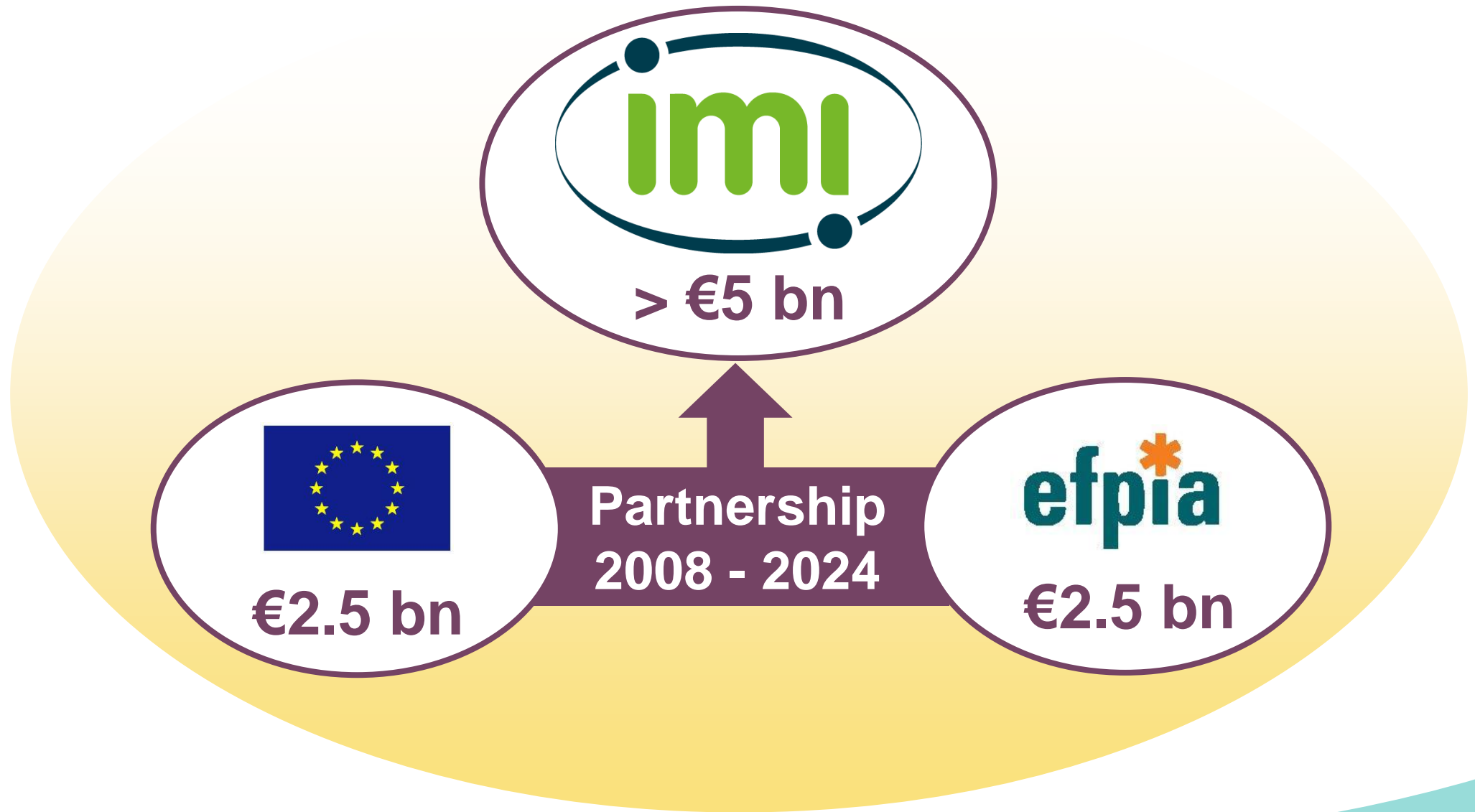
26.11.2014 • Brussels • Bringing health-related life science and  
technology sectors into IMI2

# The pillars of innovation

- Scientific excellence
- Market access
- Patient access
- Rewarding systems



# IMI – Europe's partnership for health



# IMI – key concepts

- Focus on unmet needs
- Non-competitive collaborative research
- Open innovation
  - Data sharing,
  - Dissemination of results...



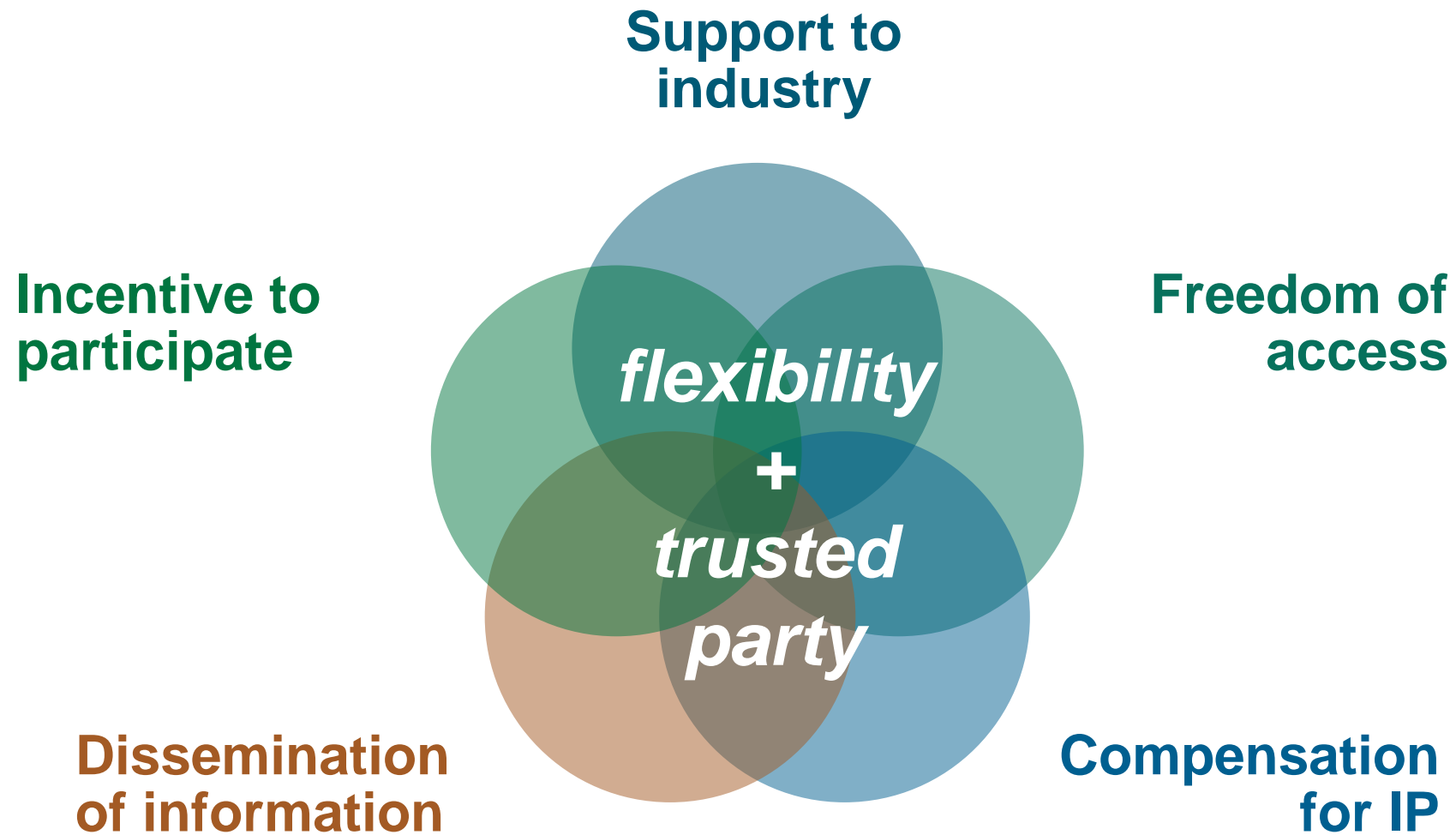
# IMI: a community without borders



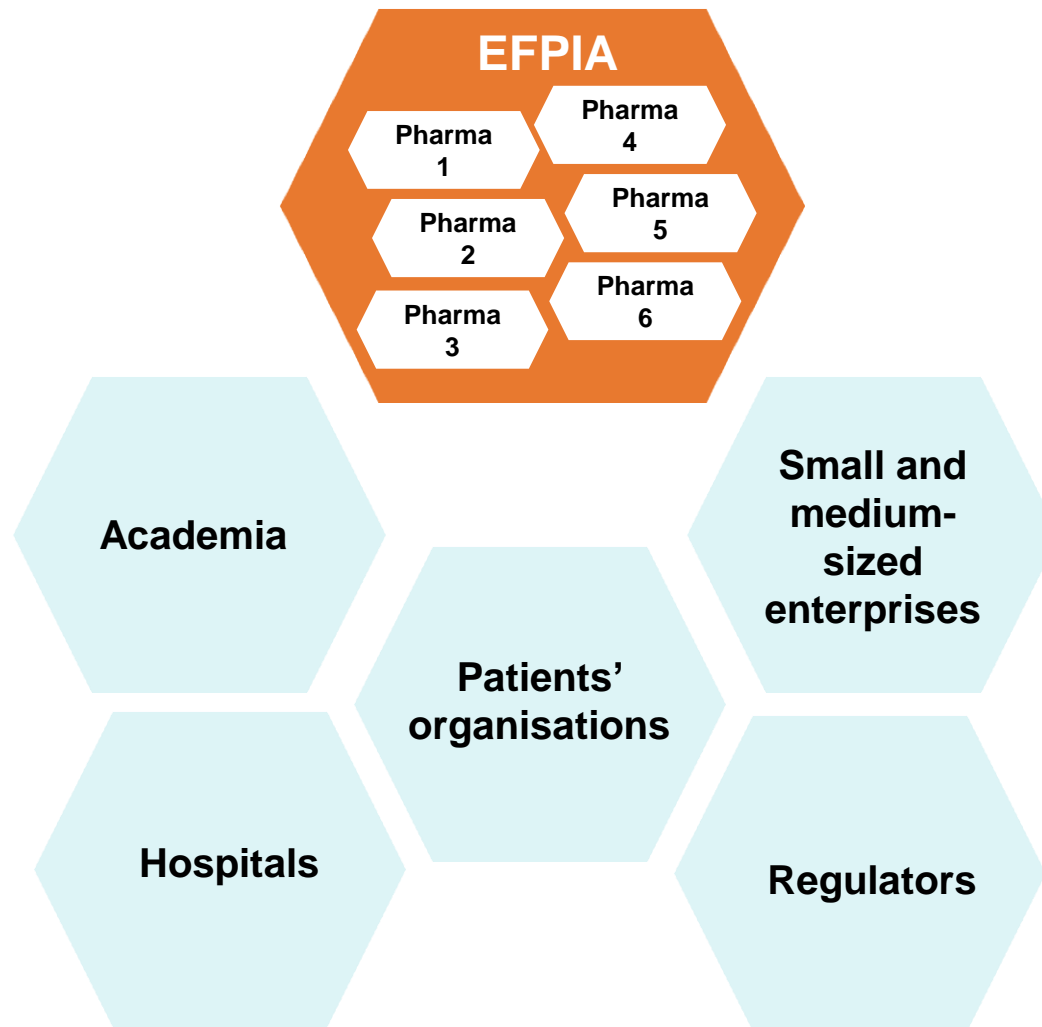
**Over 6 000 researchers**

**59 public-private consortia**

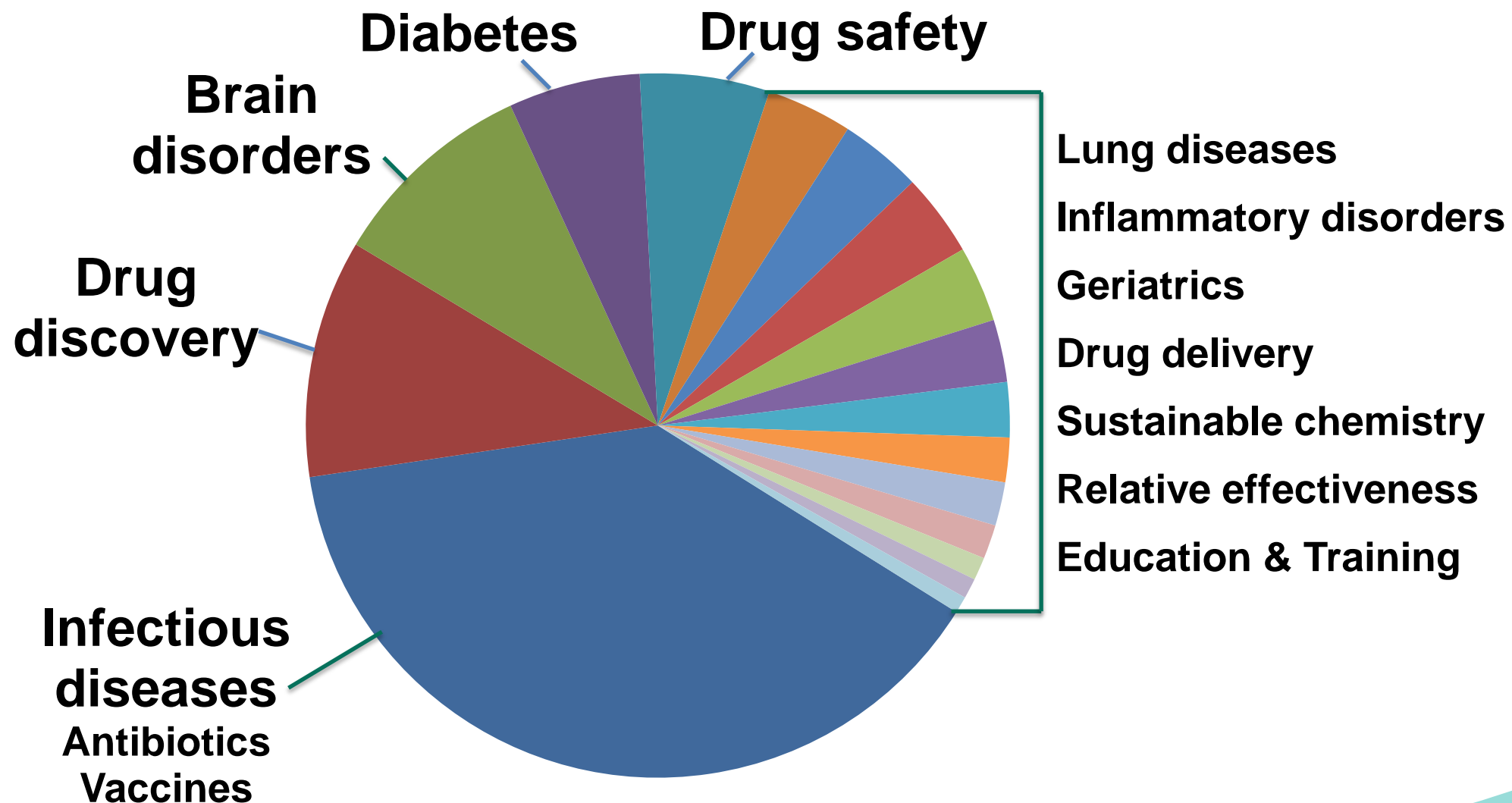
# IMI's flexible intellectual property policy



# A typical IMI consortium



# IMI 1 – € 2 bn budget breakdown

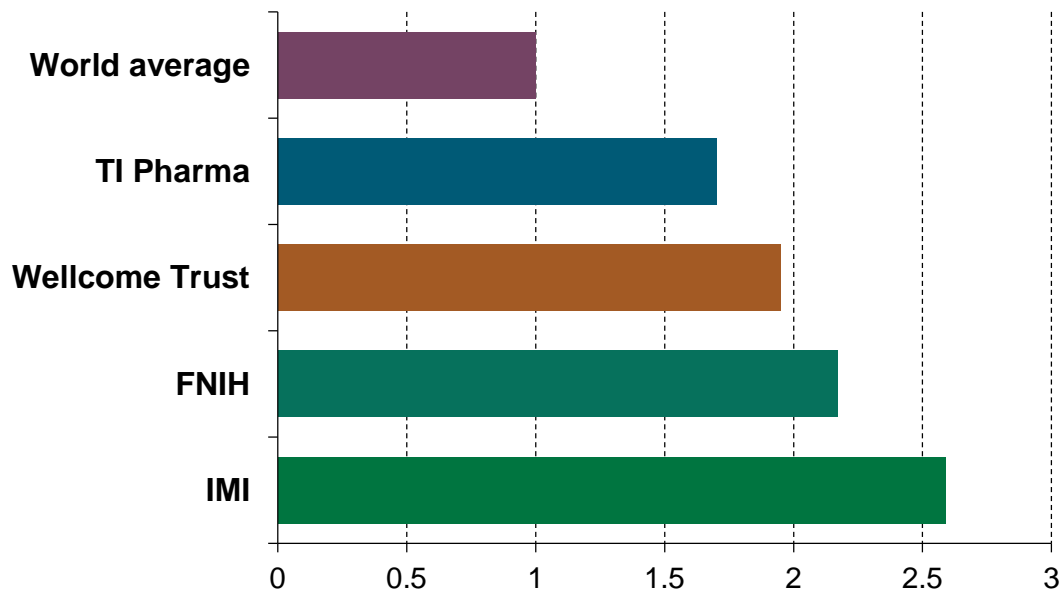




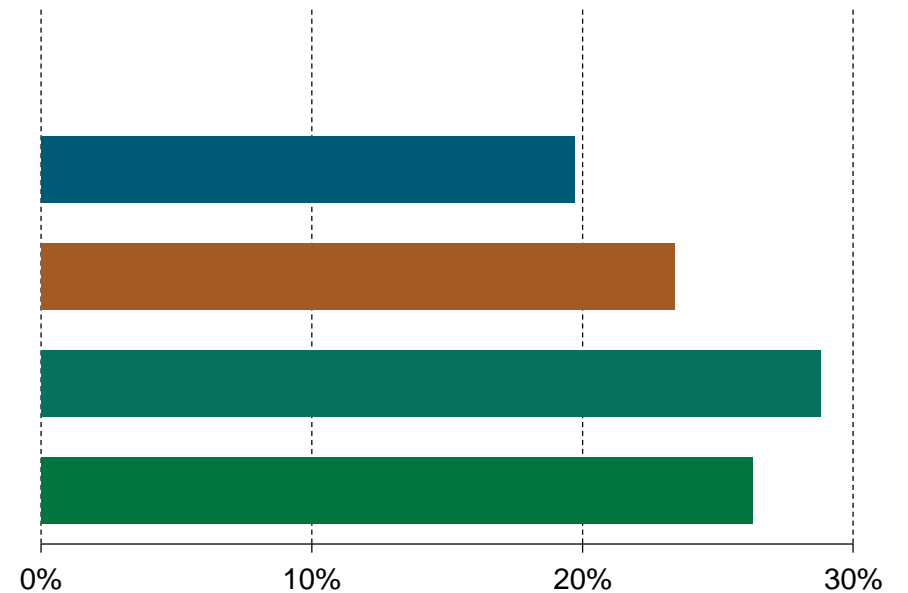
# Scientific output of IMI projects

*Thomson Reuters, 2014*

## Citation impact



## Percentage of highly cited papers



# Antimicrobial resistance – a growing threat

**25 000**

Europeans killed / year

**€1.5 bn**

costs to economy / year

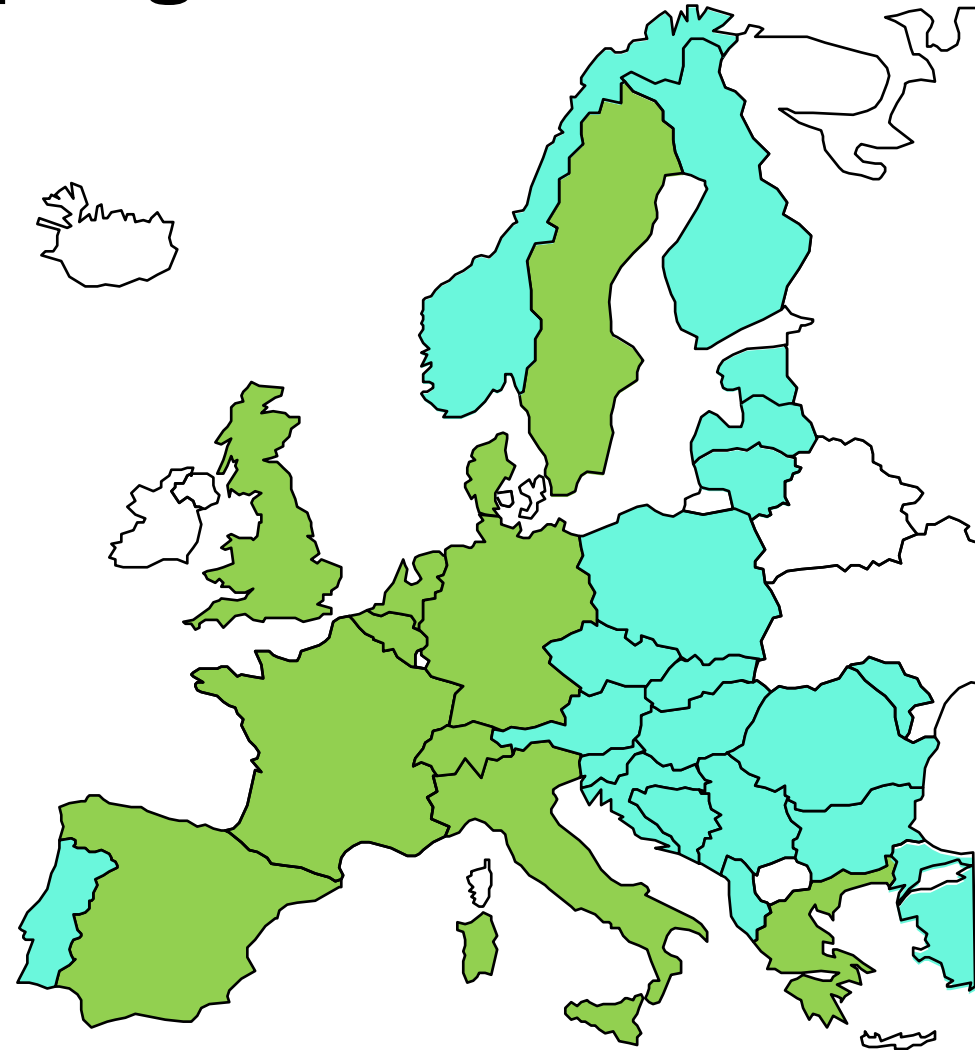


**2** new classes of antibiotics  
in the last 30 years

# How IMI addresses Anti-Microbial Resistance: the ND4BB programme

IMI already invested **€655 million** for:

- Solving **scientific challenges**
- Fostering **new models of industrial collaborations**
- Developing **clinical networks**
- Revisiting **regulatory rules**
- Providing **incentives to industry**



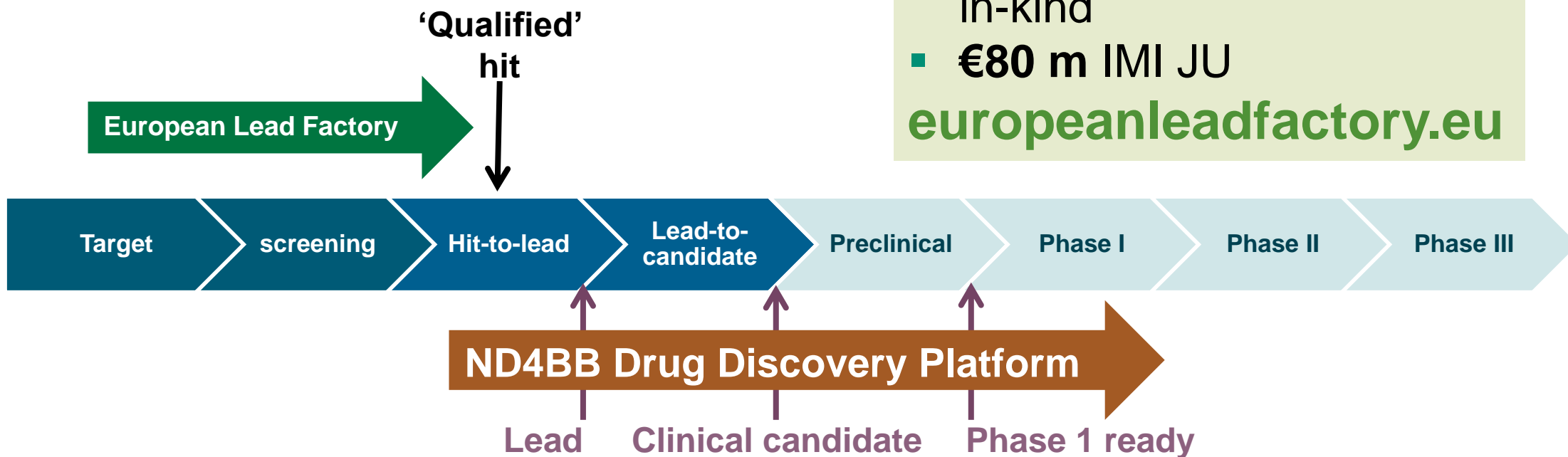
# IMI's drug discovery platforms

**European Lead Factory Focus:**  
identification of new hits

**ELF Budget:**

- €92 m EFPIA in-kind
- €80 m IMI JU

[europeanleadfactory.eu](http://europeanleadfactory.eu)



**ENABLE Budget:**

- €26 m EFPIA in-kind
- €58 m IMI JU

**ENABLE focus:** to move promising hits into early clinical development

[nd4bb-enable.eu](http://nd4bb-enable.eu)

# Schizophrenia: the power of shared data

- 5 companies (AstraZeneca, J&J, Eli Lilly, Lündbeck, Pfizer)
- 34 clinical trials testing second generation anti-psychotics
- 11,670 patients



## **Drug-placebo differences already significant:**

- after 4 vs.6 wks observation
- with 40% less patients

**when appropriate gender balance, symptoms and disease duration are selected**



Rabinowitz J et al., J Clin Psychiat 2014, in press



# Alzheimer's disease: an urgent need for new therapeutic strategies

Major public health need	Recent failures	Hurdles to drug development
<ul style="list-style-type: none"><li>▪ <b>10m</b> Europeans affected, will reach <b>14m by 2040</b></li><li>▪ Annual cost in EU: <b>€180b</b>, will reach <b>250b by 2030</b></li></ul>	<p><b>Inconclusive results of phase 3 clinical trials:</b></p> <ul style="list-style-type: none"><li>▪ solanezumab</li><li>▪ bapineuzumab</li><li>▪ human immunoglobulins</li></ul>	<ul style="list-style-type: none"><li>▪ Complexity of brain pathology</li><li>▪ Patients' heterogeneity</li><li>▪ Lack of validated markers for disease activity</li></ul>

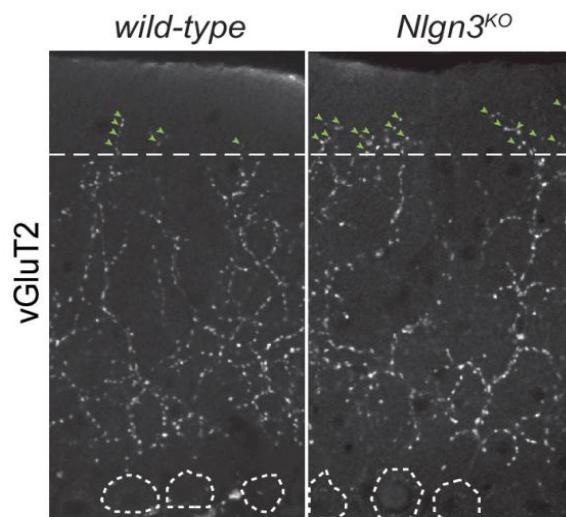
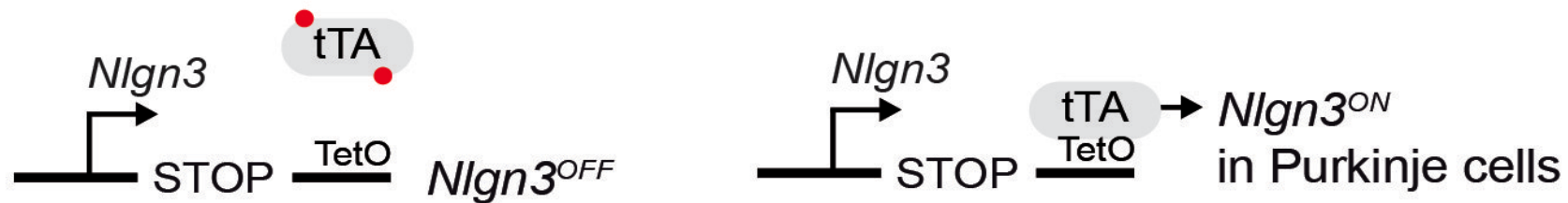
# How IMI addresses Alzheimer's disease

**IMI invests €167 million in 4 projects aiming at:**

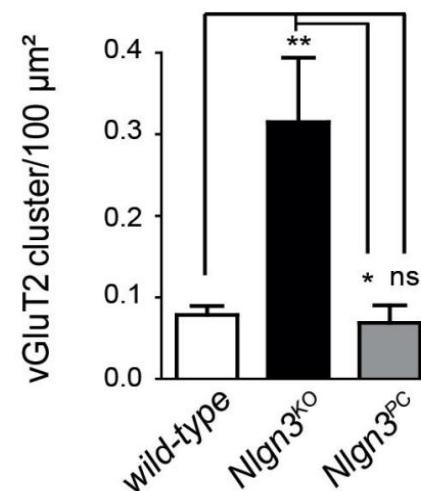
- Developing models to predict the efficacy of drug candidates
- Connecting data on 40 millions of individuals to decipher links between genetic background, biological abnormalities, brain imaging changes, mental symptoms and disease progression
- Identifying subgroups of the disease allowing to tailor therapies according to the different causal factors involved
- **Implementing adaptive trial designs**

# Neuronal alterations in autism models are reversible

Re-expression of Nlgn3 in adolescent mice restores normal mGluR1 protein levels and results in removal of ectopic synapses.



Density of ectopic vGluT2 clusters



Baudouin et al.,  
*Science*, 2012



# Two largest clinical trials for early detection and monitoring of ASD children



## Identification of biomarkers that precede ASD onset

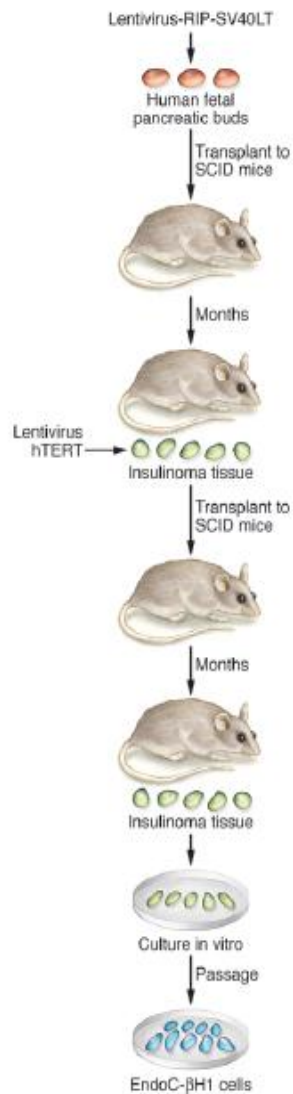
- Prospective study of 300 high-risk infants (3 and 7 months) with older siblings with ASD, and 100 low-risk
- Infant cognition, behavior, neuroimaging, neurophysiology
- Relation to symptoms/diagnosis of ASD at outcome



## Accelerated longitudinal study for validation of ASD biomarkers in children and adults

- 450 ASD patients and 300 controls
- Magnetic resonance imaging, event-related potential, eye-tracking

# IMIDIA: new tools for diabetes research

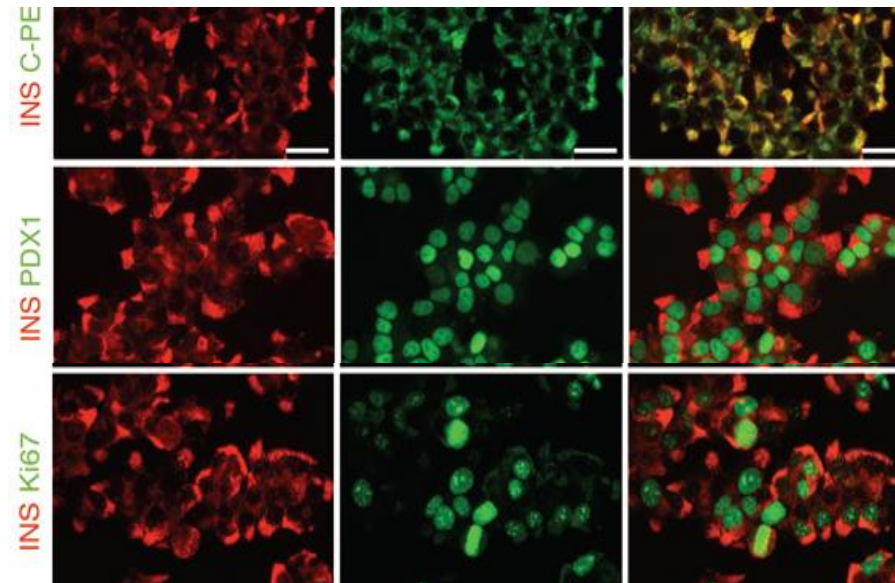


Related Commentary, page 3395  Technical advance

## A genetically engineered human pancreatic $\beta$ cell line exhibiting glucose-inducible insulin secretion

Philippe Ravassard,<sup>1,2,3</sup> Yasmine Hazhouz,<sup>2,4</sup> Séverine Pechberty,<sup>4,5</sup> Emilie Bricout-Neveu,<sup>2,4</sup> Mathieu Armanet,<sup>6,7</sup> Paul Czernichow,<sup>4</sup> and Raphael Scharfmann<sup>5</sup>

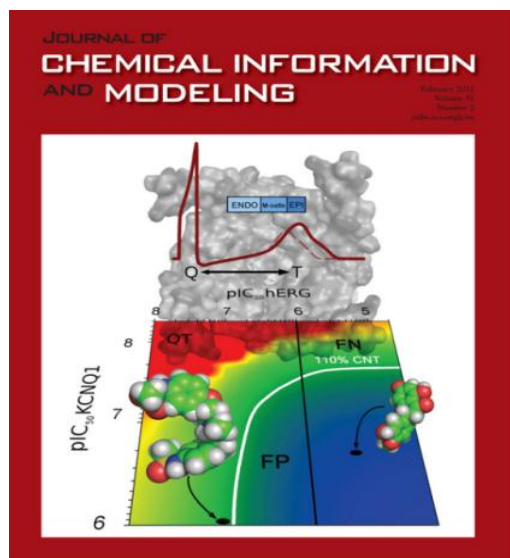
<sup>1</sup>Université Pierre et Marie Curie-Paris 6, Biotechnology and Biotherapy Team, Centre de Recherche de l'Institut du Cerveau et de la Moelle épinière (CRICM), UMRS 975, Paris, France. <sup>2</sup>CNRS, UMR 7225, Paris, France. <sup>3</sup>INSERM, U975, Paris, France. <sup>4</sup>Endocells, Paris, France. <sup>5</sup>INSERM U845, Research Center Growth and Signalling, Université Paris Descartes, Sorbonne Paris Cité, Faculté de Médecine, Hôpital Necker, Paris, France. <sup>6</sup>Cell Therapy Unit, Hôpital Saint Louis, AP-HP, and University Paris 7, Paris, France. <sup>7</sup>Inserm U872, Centre de Recherches des Cordeliers, Paris, France.



The Journal of Clinical Investigation <http://www.jci.org> Volume 121 Number 9 September 2011

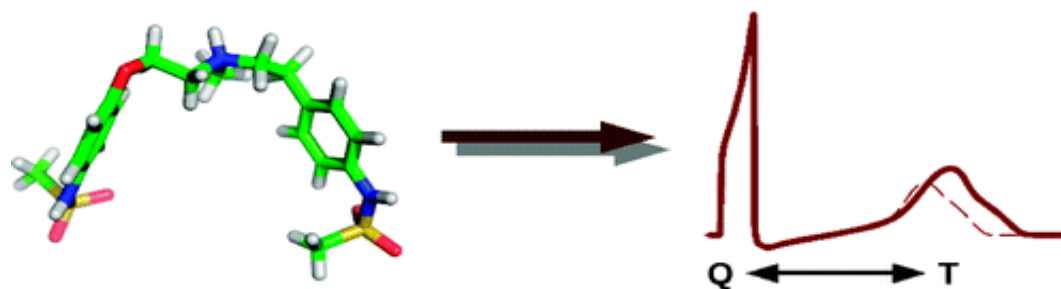
# Novel predictive systems for drug toxicity

- 13 EFPIA companies
- 12 Public organisations
- 5 SMEs
- Total Budget: 13.9 Mi €



## A Multiscale Simulation System for the Prediction of Drug-Induced Cardiotoxicity

Obiol-Pardo, C. et al. (2011). Chem. Inf. Model. 51:483-92

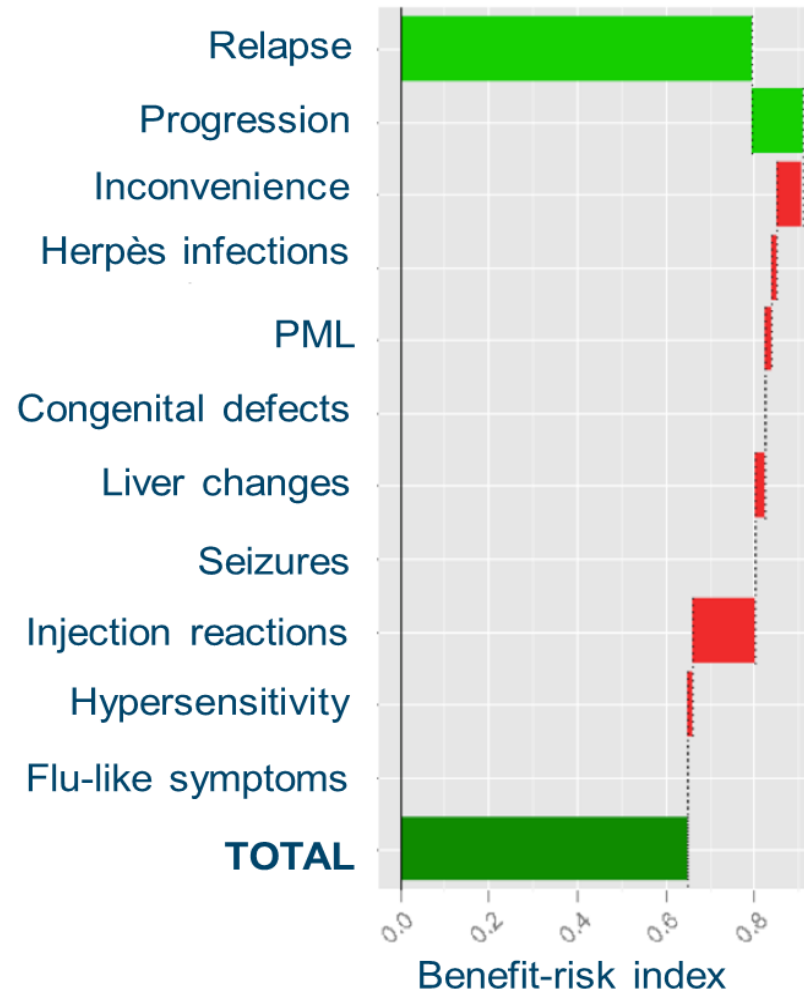


**eTOX**

**imi** | innovative  
medicines  
initiative

# Advancing benefit-risk assessment of medicines

## Case study: **Natalizumab**



# IMI 2: What's new?

- Projects developed by other industries active in healthcare  
(**ICT, Imaging, Medical Devices.....**)
- Greater focus on benefits for **patients** and **society**
- **Simplified** funding rates & reporting (aligned with **H2020**)
- **More types of organisations** eligible for funding (charities)

# A single set of rules



EU Financial  
Regulation

Specific rules  
for  
participation

- Covering all H2020 research and innovation actions
- Adaptability where needed:
  - Entities eligible for funding
  - IP

# The measures of success



**SUCCESS**

New models  
developed &  
published

Setting new  
standards

In house  
implementation  
by industry

Impact on  
regulatory  
guidelines

**Better Science = Better Decisions**

# Thank you

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

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