Innovative Medicines Initiative

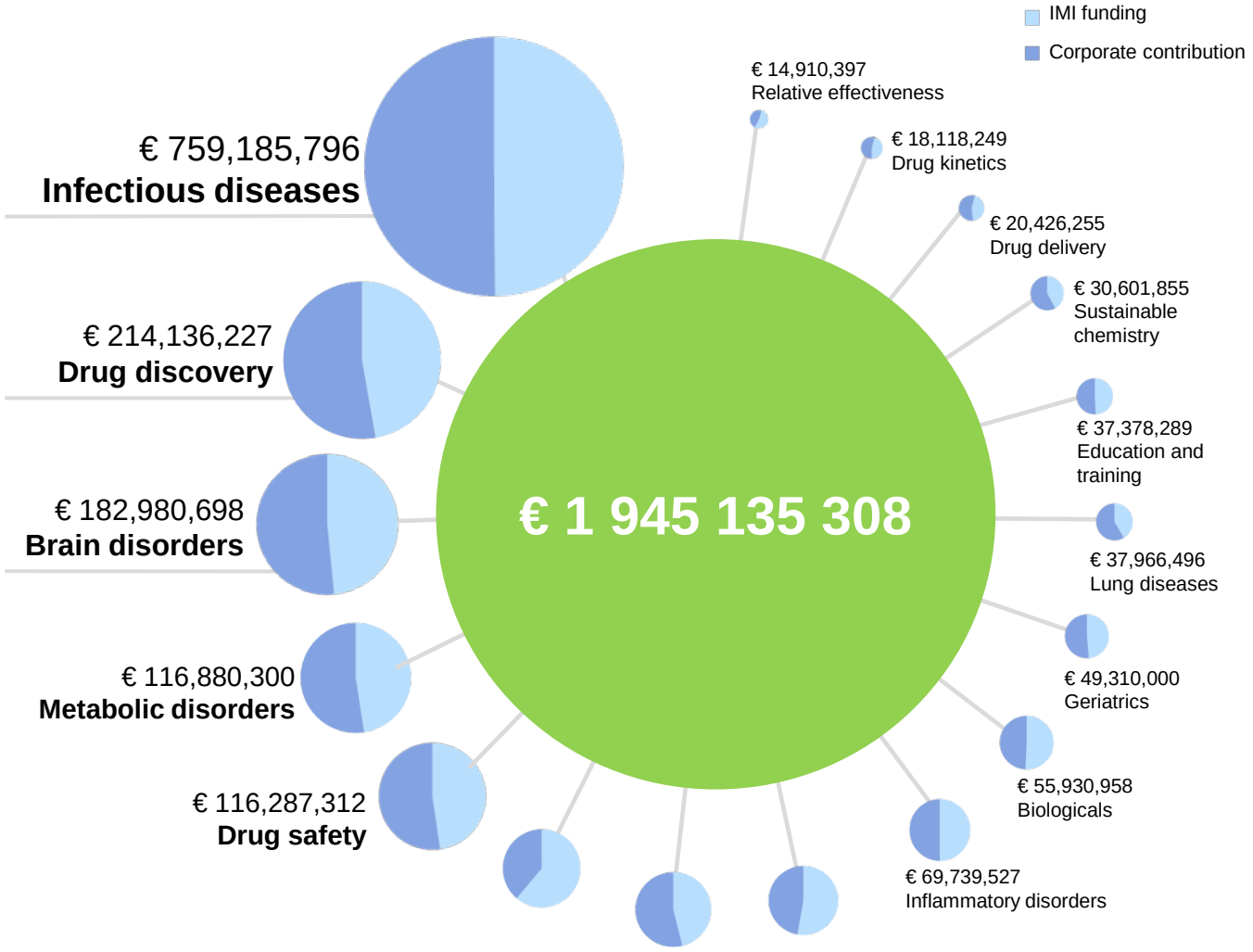
IMI 2:
The New European Engine for Therapeutic Innovation

Michel Goldman
Executive Director

Joining forces from public and private bodies

* IMI 1+2
2008-2020

IMI1: budget breakdown

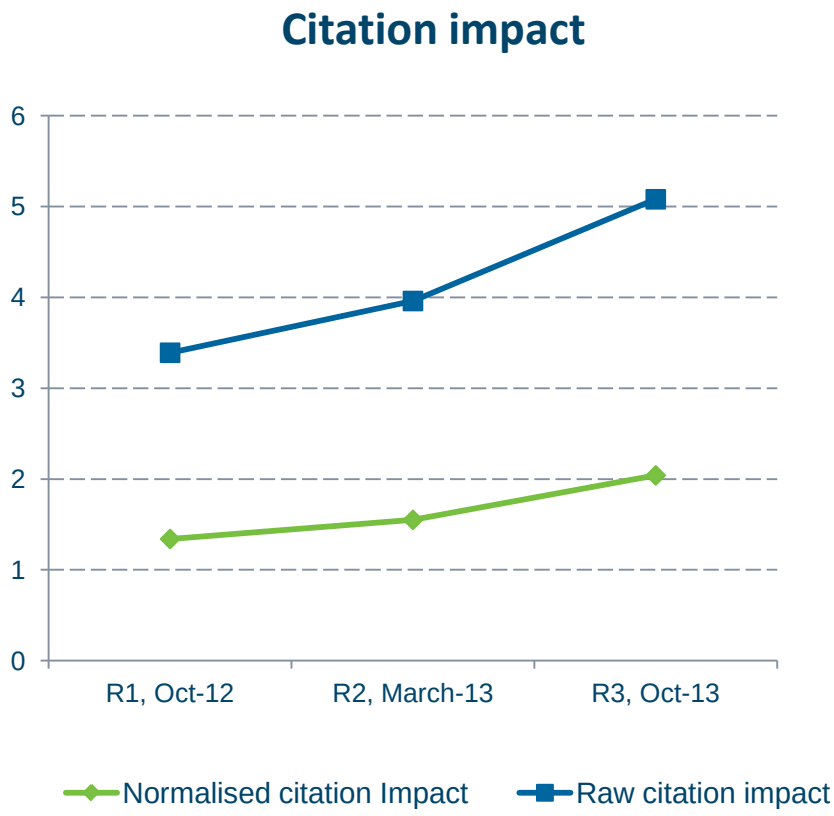


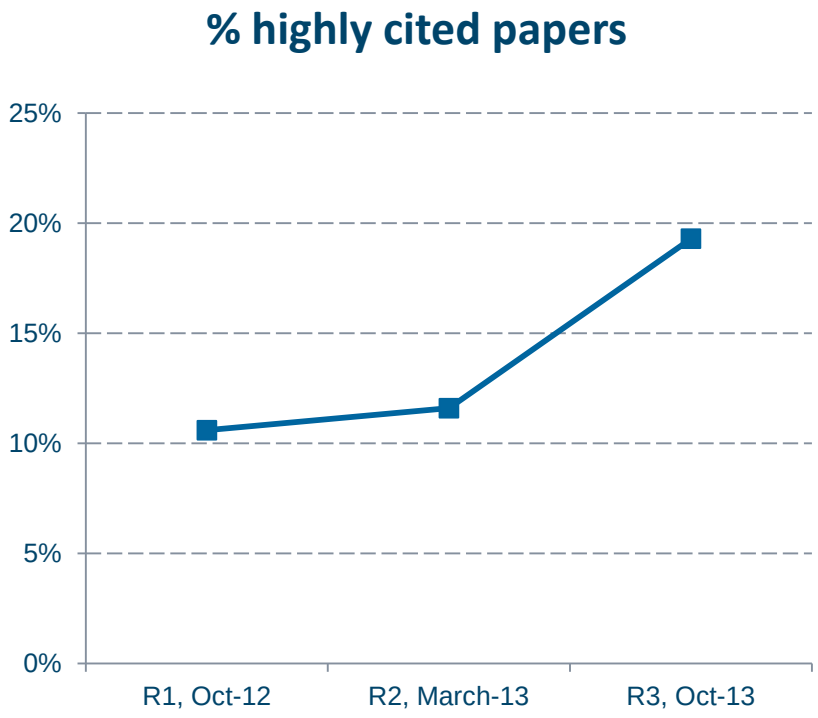
Working for

- Collective intelligence networks
- Improved R&D productivity
- Innovative approaches for unmet medical needs

Quality increases over time

Bibliometric indicators trend analysis

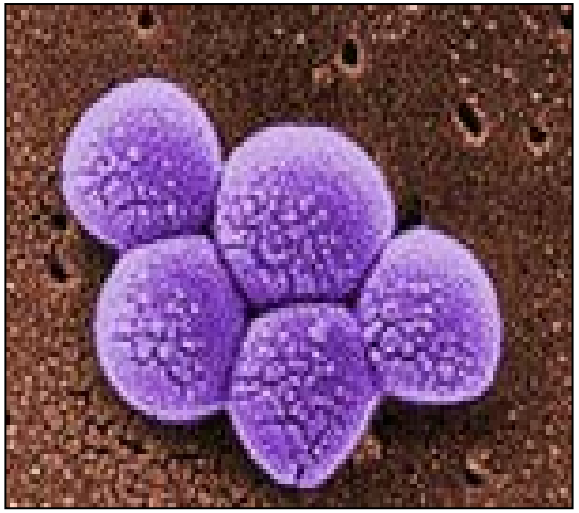




Antimicrobial resistance – a growing threat

25 000

Europeans killed / year



€1.5 bn

costs to economy / year

2 new classes of antibiotics in the last 30 years

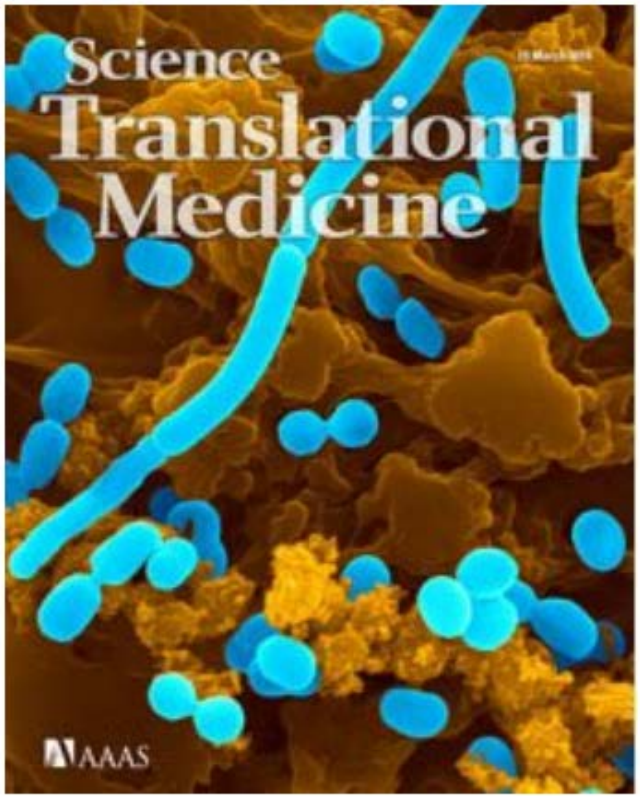
19 MARCH 2014, VOL. 6, #228

COVER STORY | EDITORIAL

How to Get Good Drugs into Bad Bugs

Robert A. Stavenger, Mathias Winterhalter

The TRANSLOCATION project deciphers how to help antibiotics penetrate the surface of Gram-negative bacteria.



ALZHEIMER'S DISEASE:

An urgent need for new therapeutic strategies

Major Public Health Need	Recent failures	Hurdles to drug development
- **10m** Europeans affected, will reach **14m by 2040** - Annual cost in EU: **€180b,** will reach **250b by 2030**	**Inconclusive results of 3 large clinical trials:** - solanezumab - bapineuzumab - human immunoglobulins	**Complexity of brain pathology** **Patients' heterogeneity** **Lack of validated markers for disease activity**

How IMI addresses Alzheimer's disease

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

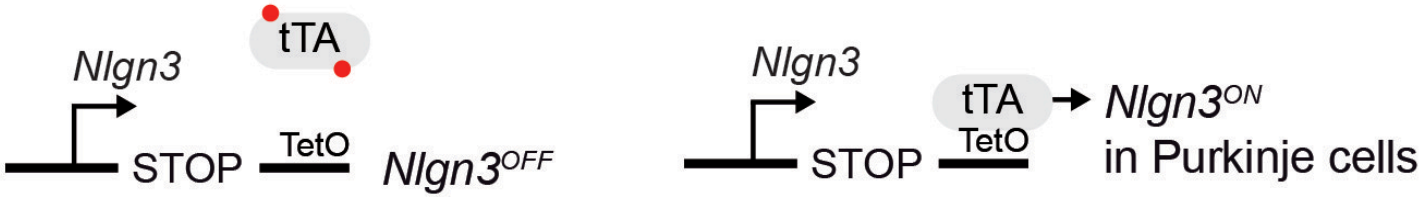
- Developing models to predict the efficacy of drug candidates in patients
- Connecting data on 40 millions of individuals to decipher links between genetic background, biological abnormalities, brain imaging changes, mental symptoms and disease progression
- Identifying subgroups of the disease allowing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

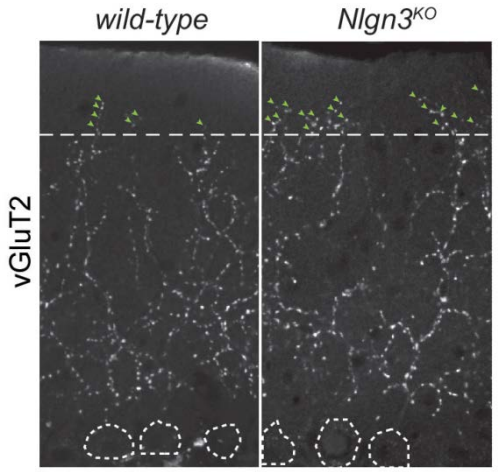
AUTISM SPECTRUM DISORDERS:
A paradigm for non-competitive Public-Private Partnership

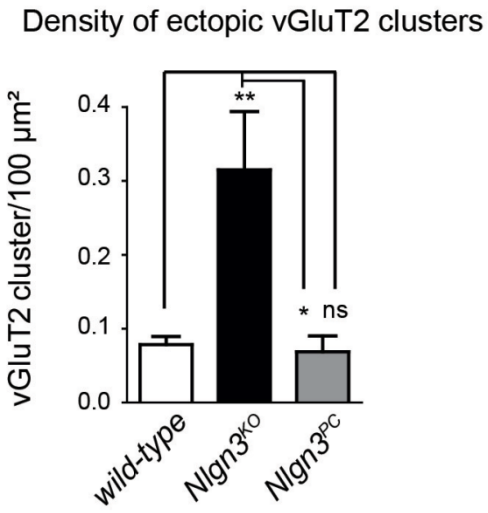
Major Public Health Need	Distrust in past-research	Hurdles to drug development
1% children affected **High societal burden** - Lifetime cost: €3mi/patient - UK annual cost: €40 billion	**MMR vaccine allegation** **Psychoanalytic theories (France)**	**Complexity of brain circuitry** **Patients heterogeneity** **Lack of validated markers for disease activity**

Neuronal Alterations are Reversible

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







Baudouin et al., *Science*, 2012

EU-AIMS
Autism Research in Europe

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

imi

1 21 March 2013
2 EMA/CHMP/40896/2013
3 Committee for Medicinal Products for Human Use (CHMP)

4 Concept paper on the development of Medicinal 5 products for the treatment of Autism Spectrum 6 Disorder

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Agreed by CNS Working Party	February 2013
Adopted by CHMP for release for consultation	21 March 2013
Start of public consultation	4 April 2013
End of consultation (deadline for comments)	4 July 2013

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Comments should be provided using this template. The completed comments form should be sent to CNSWPSecretariat@ema.europa.eu

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Keywords	Autism, Paediatric population, Asperger's Disorder, Rett's disorder, Childhood disintegrative disorder and Pervasive Developmental Disorder – not otherwise specified

Optimizing trials for schizophrenia treatment

Shared data set of patient-level data from:

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

Drug-placebo differences already significant:

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

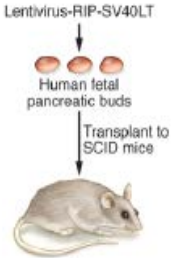
when appropriate gender balance, symptoms and disease duration are selected

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

DIABETES:
Fighting the epidemic through Public-Private Partnership

Major Public Health Need	Distrust in past-research	Hurdles to drug development
Diabetes will affect 43 million Europeans in 2030 €89 million spent on 2011 on treating diabetes and its complications	Cardiovascular complications of rosiglitazone and benfluorex	Patients' heterogeneity Lack of reliable markers for disease activity and complications

IMIDIA



Related Commentary, page 3395 Technical advance

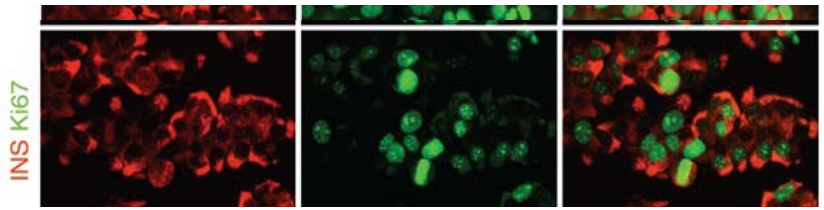
A genetically engineered human pancreatic β cell line exhibiting glucose-inducible insulin secretion

Philippe Ravassard,[1,2,3] Yasmine Hazhouz,[2,4] Séverine Pechberty,[4,5] Emilie Bricout-Neveu,[2,4]

Finally! A human pancreatic β cell line

Gordon C. Weir and Susan Bonner-Weir

Section on Islet Cell Biology and Regenerative Medicine, Research Division, Joslin Diabetes Center, and Department of Medicine, Harvard Medical School, Boston, Massachusetts, USA.



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

Advancing benefit-risk assessment methods

EUROPEAN MEDICINES AGENCY

+

4 other regulatory agencies

12 EFPIA companies

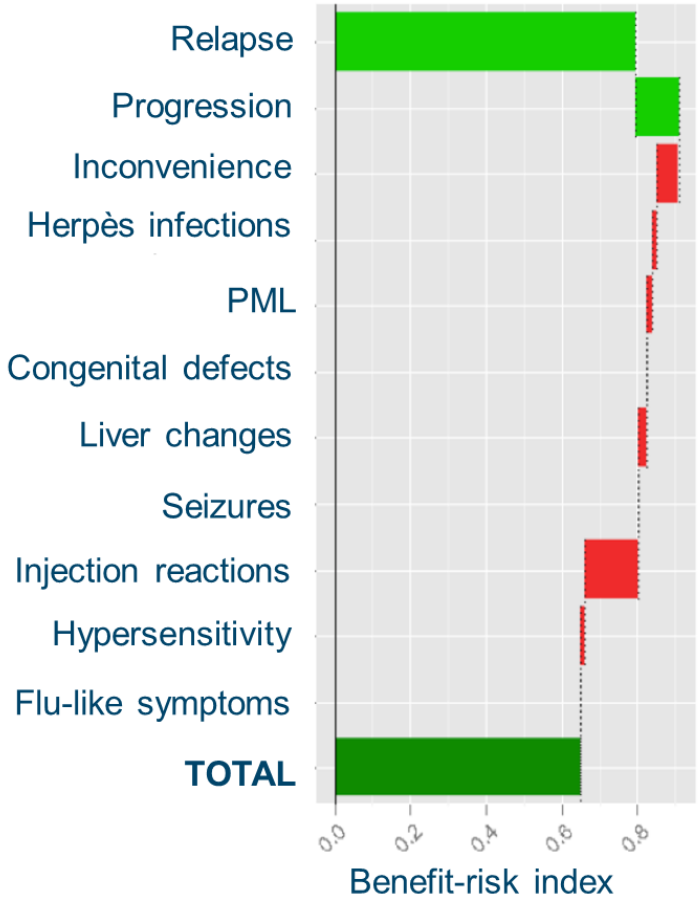
11 Academic institutions

1 Patient coalition

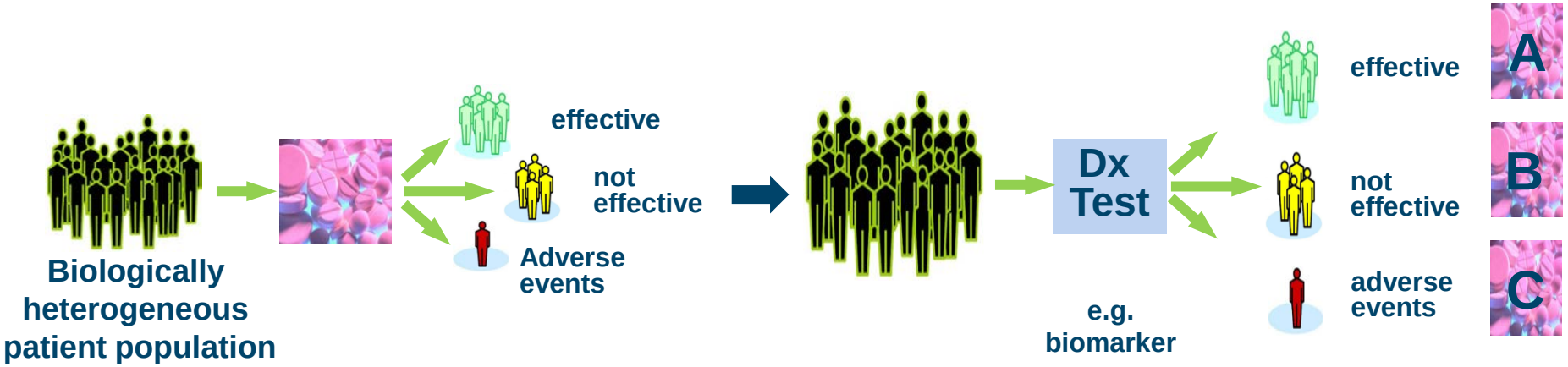
2 SMEs

Budget: 29.8 Mi €

Case study: Natalizumab



The Vision for IMI2 – The right prevention and treatment for the right patient at the right time



Trial and Error vs **Information based treatment decisions**

Graphic adapted from C. Carini, C. Fratazzi, Eur. Pharm. Rev. 2008, 2, 39-45

IMI2 Strategic Research Agenda

Priority Themes

1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

Support Technologies

1. Imaging
2. ICT
3. Medical devices….

Enablers

Patient access to innovative solutions (MAPPs):

- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation and interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access

IMI2 - Broad participation to be able to set ambitious goals

Innovative Medicines Initiative

IMI is evolving, with a stronger focus on the needs of patients and society and with simpler rules and procedures

Evolution in scientific focus

- Stronger focus on needs of patients and society, including unmet needs
- Increased emphasis on improving patient access to innovative medicines (in addition to medicines development)
- **The right treatment for the right patient at the right time**

efpia

efpia

IMI2 - Broad Participation to achieve ambitious goals:

Bigger budget: 3,45 Billion Euro, equally shared by EU and industry

- **Not limited to EFPIA members**
- **Open for other industries / companies, which can contribute to the PPP goals (Healthcare IT, medical devices,…) giving them the opportunity to establish their own projects**

  Specified Budget: 225 million Euros reserved (to be matched by in kind/cash contributions)

First IMI2 Call for Proposals

➢ 2 Topics:

1. Discovery & validation of novel endpoints for retinal diseases

- ✓ **Technical**, **medical** and **health economic appropriateness** of new methods including **imaging methods** and **patient-reported outcomes;**
- ✓ **Bridging pre-clinical and clinical studies**.

For more information: nathalie.seigneuret@imi.europa.eu

2. Translational approaches to modifying therapy of type 1 diabetes

- ✓ **In-depth characterization** of type 1 diabetic patients using **"omics", electronic records, databases, biobanks…;**
- ✓ **Bridging pre-clinical and clinical studies.**

For more information: magda.gunn@imi.europa.eu

IMI2 Calls in 2014

- All relevant Call materials is available on IMI's website: http://www.imi.europa.eu/content/

- Launch of first call: 9th July 2014

  EoI submission: 12 November 2014

- 2nd Call: mid-December 2014

Thank you

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