



**Innovative Medicines Initiative**

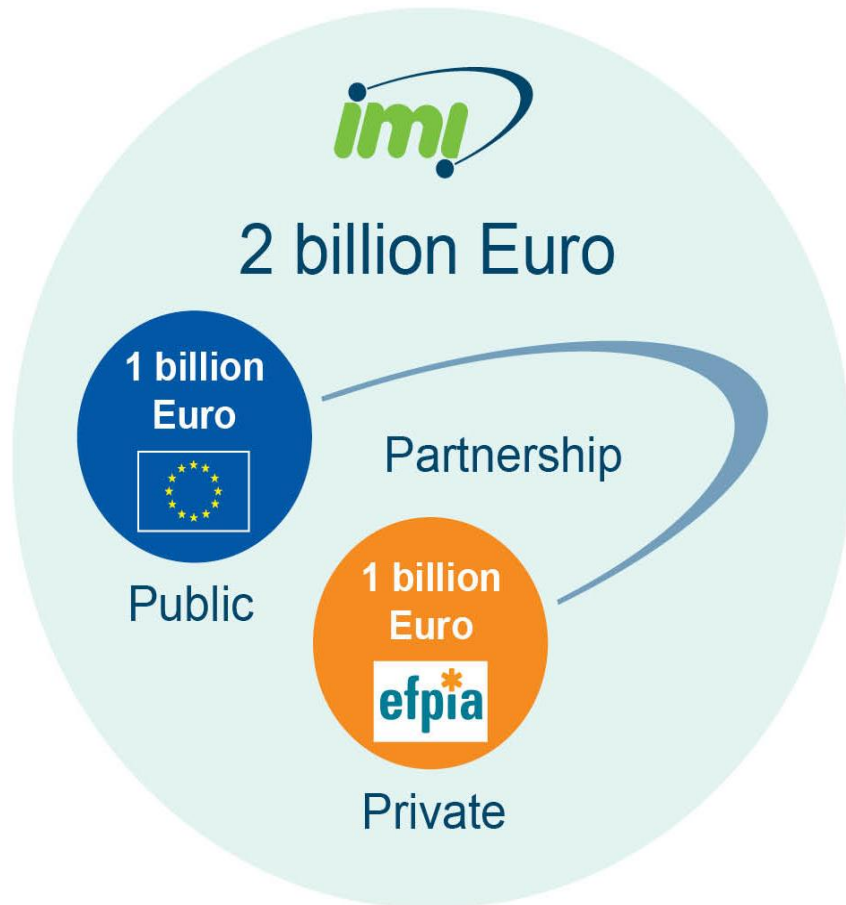
# **Innovative Medicines Initiative**

## **Magda Gunn**

**6th Workshop of the Council of European Federations**  
**30 October 2013**

# Innovative Medicines Initiative:

*Joining forces in the healthcare sector*



The European Union and the pharmaceutical industry have joined forces to make drug R&D processes in Europe more **innovative** and **efficient**, enhance Europe's **competitiveness** & address key **societal challenges** by forming **the biggest PPP in Life Science**

# Public-Private Partnerships: Why ?

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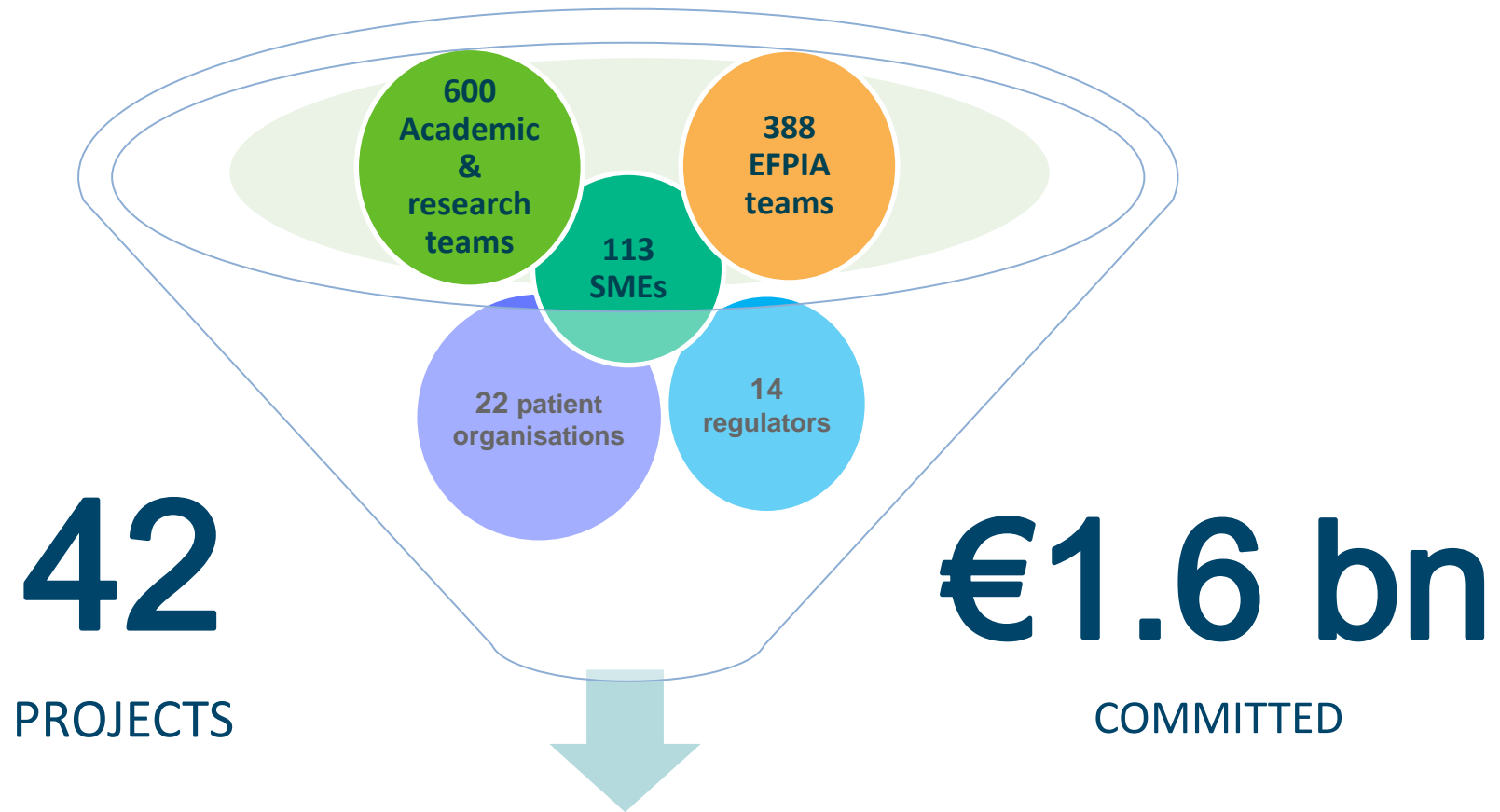
Pooling expertise, knowledge and resources

Developing incentives to address major unmet medical needs

Providing a neutral trusted platform to align public and private interests

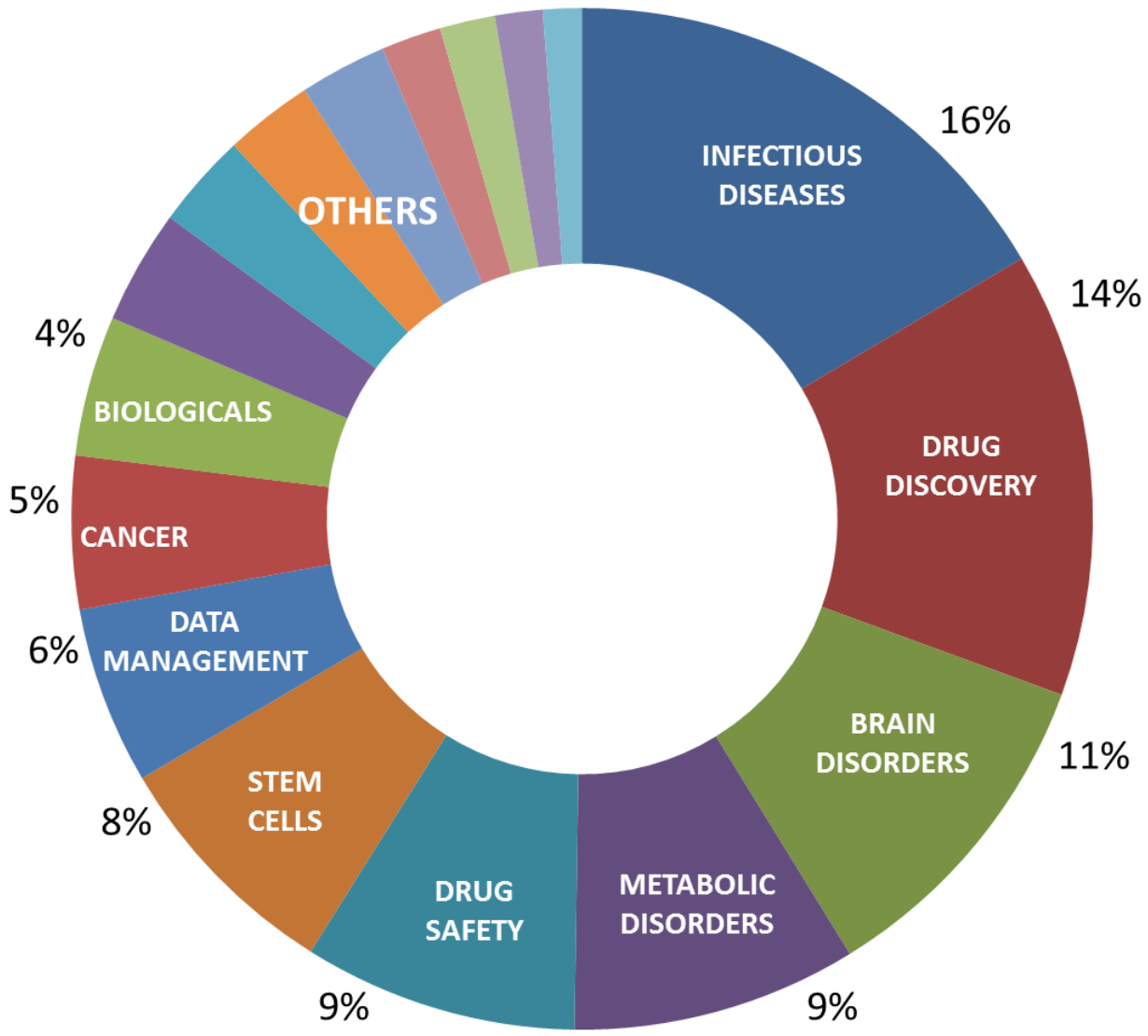


# The diverse IMI community

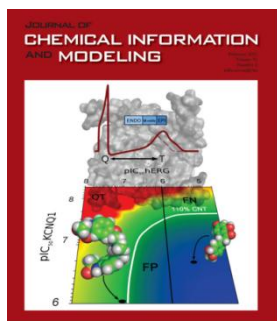
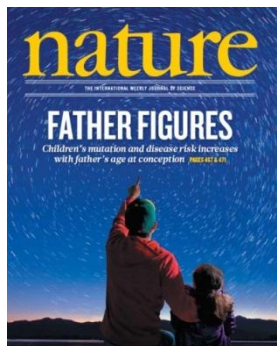


**Collective intelligence networks**  
**Improved R&D productivity of pharma industries**  
**Innovative approaches for unmet public health needs**

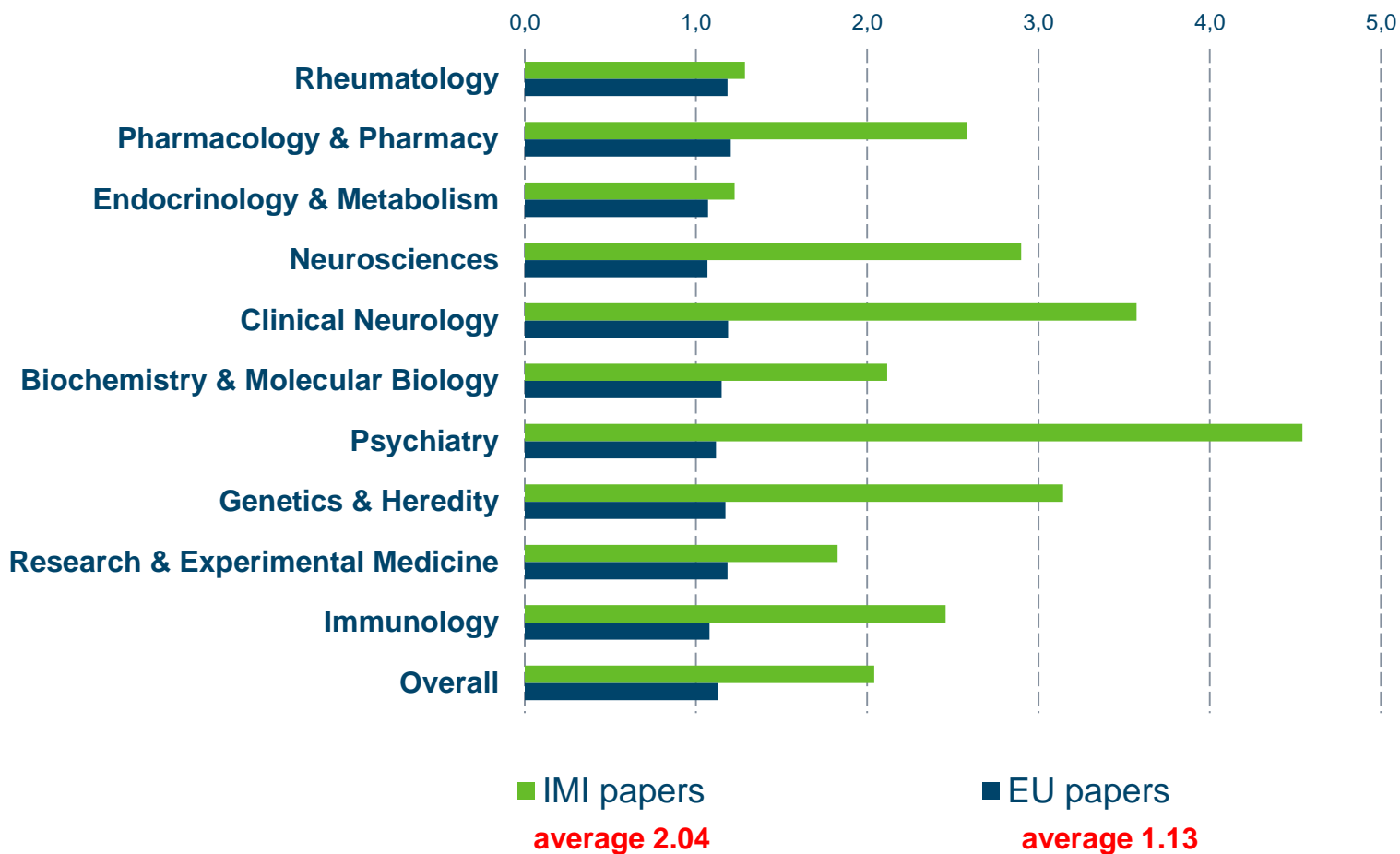
# IMI tackles diverse research areas



# Delivering high quality research



## Citation Impact by research area



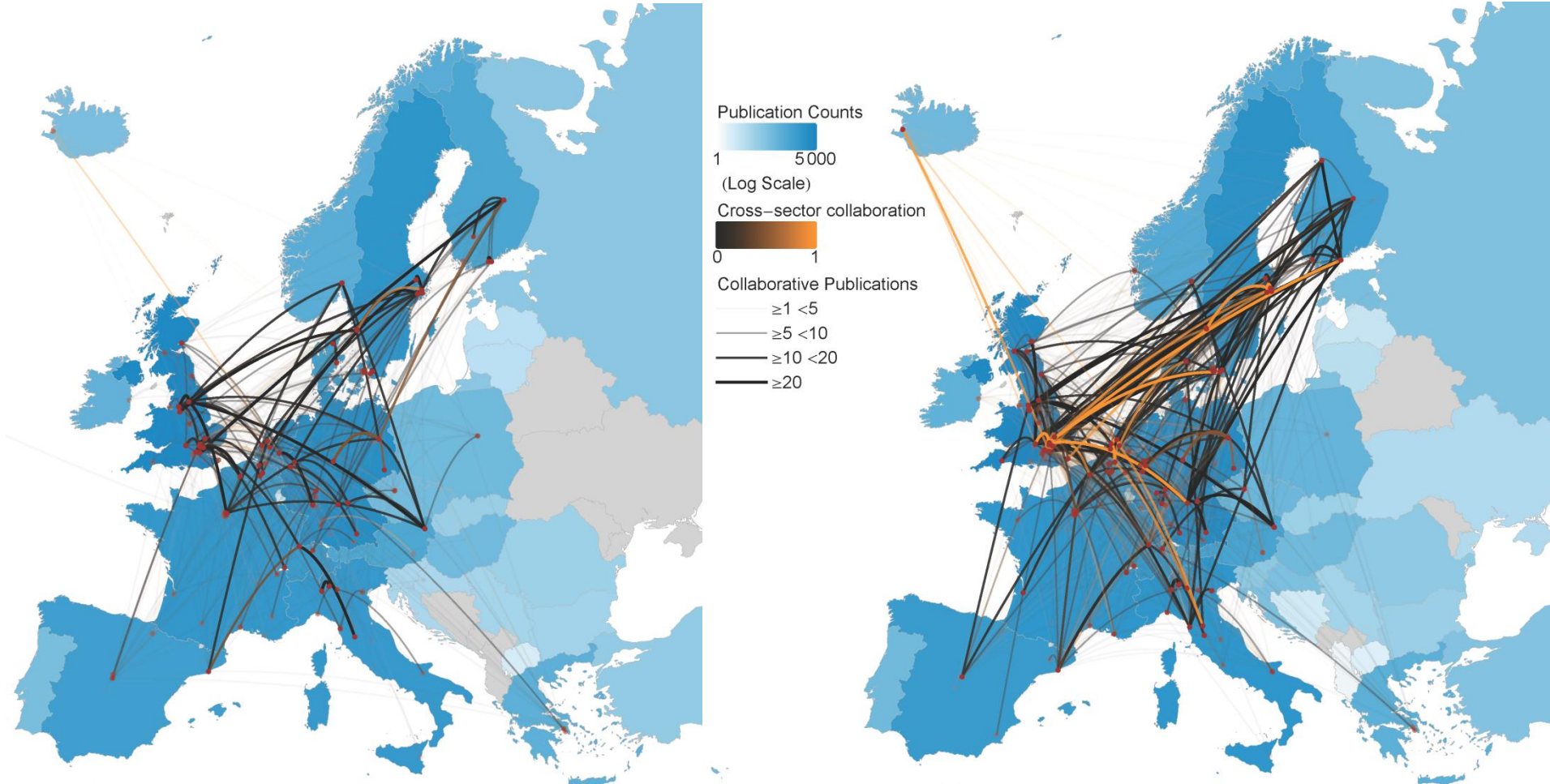
# IMI stimulates collaboration across EU

*Co-authorship between IMI-supported researchers*



Pre IMI funding award

Post IMI funding award



Data & analysis: Thomson Reuters (*Custom Analytics & Engineered Solutions*)





# 1 in 3

Europeans affected

# €798 bn

costs to economy / year



Developing new drugs

**takes longer &**

**costs more**

than for other diseases



# Sharing data to improve clinical trials for schizophrenia

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**23 000** patients

**67** studies

**25** countries



**1**  **newmeds**  
database

## Redesigning clinical trials could:

- ✓ make them **shorter** (6 weeks → 4 weeks)
- ✓ require **fewer people** (79 → 46 patients per arm)
- ✓ **cut costs** (savings of €2.8 million)
- ✓ gain **insights** into effects of treatment on negative symptoms (e.g. lack of emotion)

# Autism – a common disorder

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Affects **1 in 110** children

Lifelong condition

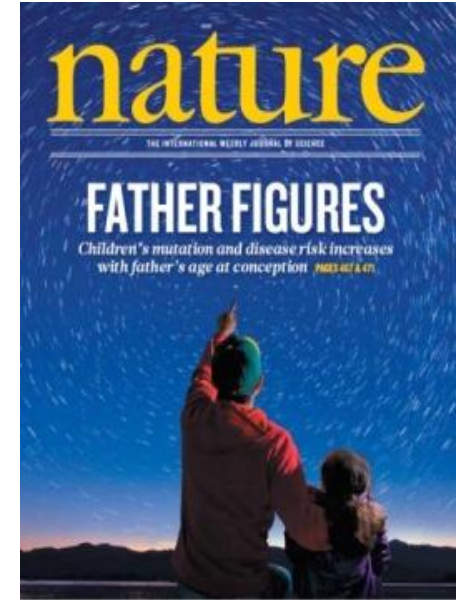
Difficulties in **social interaction**  
& **communication**, unusual  
**repetitive behaviours**

Major impact on **families &**  
**carers**

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Treatments designed  
specifically for autism

- ✓ New insights into underlying causes
- ✓ Could the brain changes be reversed?
- ✓ 2 major clinical trials for early detection and monitoring of ASD in children
- ✓ Working with regulators on treatment guidelines



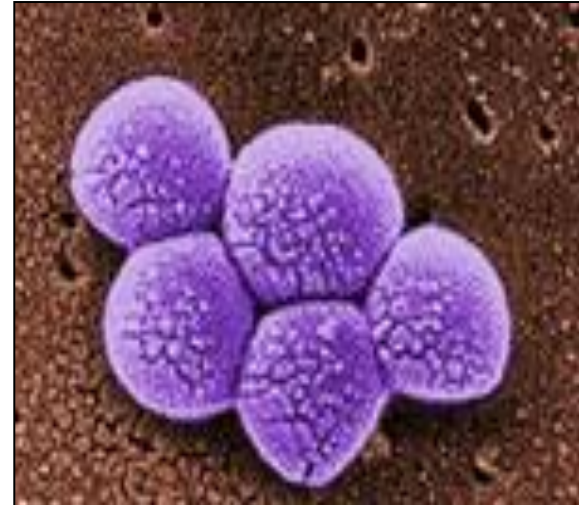
# Antimicrobial resistance – a growing threat

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**25 000**

Europeans killed / year



**€1.5 bn**

costs to economy / year

**2**

new classes of antibiotics  
in the last 30 years

# IMI – New Drugs for Bad Bugs

- €229 million budget
- **Addressing scientific challenges**
- **New models of collaboration**
- **Clinical trials network - 261 clinical sites in 32 countries**
- **Regulatory** environment
- Incentives for **industry to reinvest** in the area



# How IMI facilitates the development of new diabetes therapies

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Invested **€125 million** in 3 projects aiming at:

- Solving **scientific challenges**
- Developing reliable **measures of diabetes activity and complications**
- Developing **treatments tailored** to the different needs of individual patients

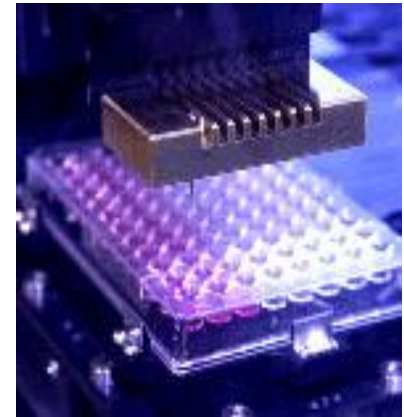


# IMI contributes to drug safety

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## SAFE-T project

- **153 potential biomarker candidates** for drug-induced injury of kidney, liver and vascular system evaluated
- **17 exploratory clinical studies** started or completed
- Dialogue with **regulatory agencies**





# IMI – joining forces for drug discovery



EUROPEAN LEAD FACTORY  
Game changing for innovative medicine

- An industry-like lead discovery platform available for public projects
- Joint European Compound Collection (Scotland)
  - 300 000 compounds from industry partners - in place ✓
  - 200 000 compounds from public partners
- European Screening Centre (the Netherlands)
  - 1st screen completed successfully ✓
- Sustainable model to establish independent business entity



efpia

# Patients in IMI → PPP+P

# Promoting Patient Involvements

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- ✓ IMI makes efforts to enhance **patient centric approach**
  - **Patient dedicated workshops**
  - Involving **patients at all levels**
  - Providing **forum for discussion**
  
- ✓ IMI best practice examples:

**EUPATI**

**U-BIOPRED**

**PROactive**

# For patient-centric R&D more trained patients are needed



**Competent authorities**



**Policy makers**



**Public**

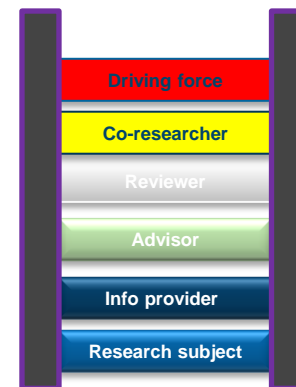
Trial protocol design, informed consent, ethical review, marketing authorization, value assessment, health policy



**Research Ethics Committees**



**HTA agencies & committees**



**Clinical Research**



# Paradigm shift in empowering patients on medicines R&D



Key European initiative to provide **objective, credible, correct and up-to-date public knowledge about medical research**

Will **build competencies & expert capacity** among patients & public

Will **facilitate patient involvement in R&D** to collaborate in academic research, industry research, authorities and ethics committees



- Towards personalised medicine for severe asthma
- The challenge – to recruit 1 025 people
- **Patients involved in project as partners**
  - Patient Advisory Board (driving force)
  - Internal Ethics Board (advisory)
  - Steering Committees (advisory & co-decision)
  - Meetings with project partners (based on equality)
- Offered **patients' perspective** on recruitment, study design, and project communication



## Framework

- Digital forum
- F2F meetings
- Training
- Charters & Protocols
- Evaluation criteria

## Input

- Study protocols
- Information leaflets
- Study progress monitoring
- Evaluation of results
- Questionnaire on experiences

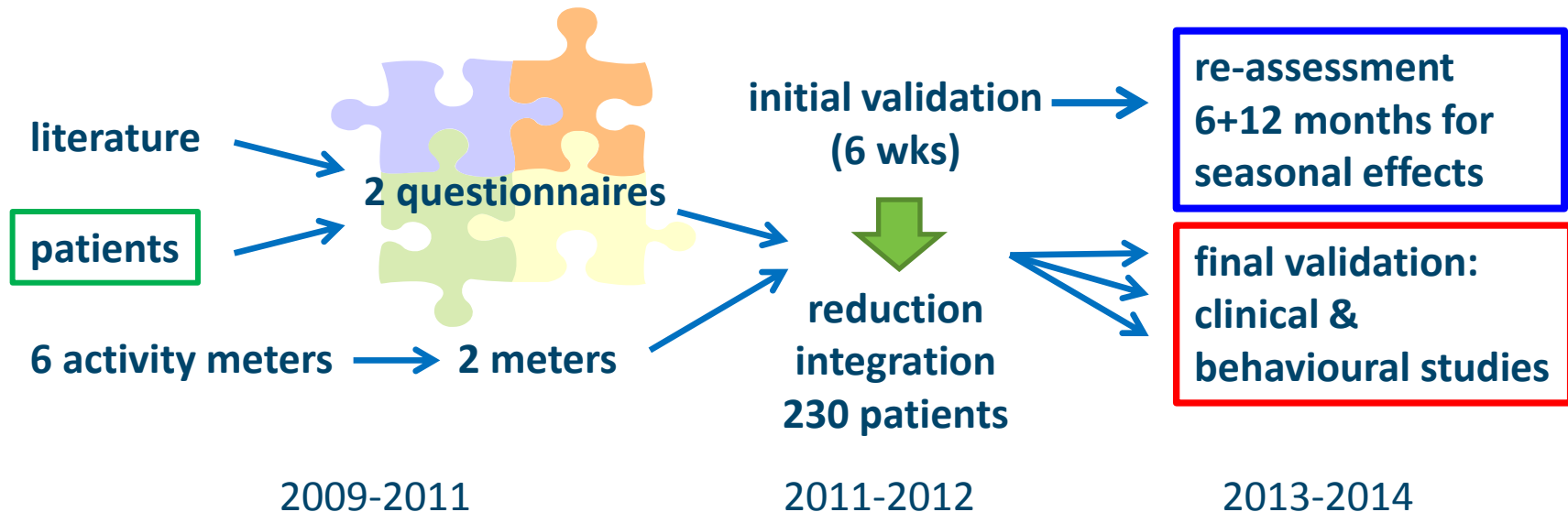
## Results

- Adaptation of research proposal
- Helping recruitment
- Communication materials
  - Plain language use
  - Website content



**Aim: development of Patient Reported Outcomes that**

- measure aspects of physical activity relevant to patients and
- are sensitive to changes due to treatment.



# How can patient organisations participate in a research consortium?

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- As a partner
- Via Advisory Board
- Via Ethics Board
- Feedback on research protocols
- Feedback on research
- Provide patient perspective
- Contribute to dissemination

# What's next for IMI ?

## Call 9 – stage 1 evaluation Nov 12 – 15

- Physical Frailty and sarcopenia
- Leveraging emerging technologies for pharmacovigilance
- Driving re-investment in R&D and responsible use of antibiotics
- Clinical development of antibacterial agents for Gram-negative antibiotic resistant pathogens

## Call 10 – launched Oct 29th

- Immunological Assay Standardisation and Development for Use in Assessments of Correlates of Protection for Influenza Vaccines

## Call 11 – Currently under discussion



European  
Commission

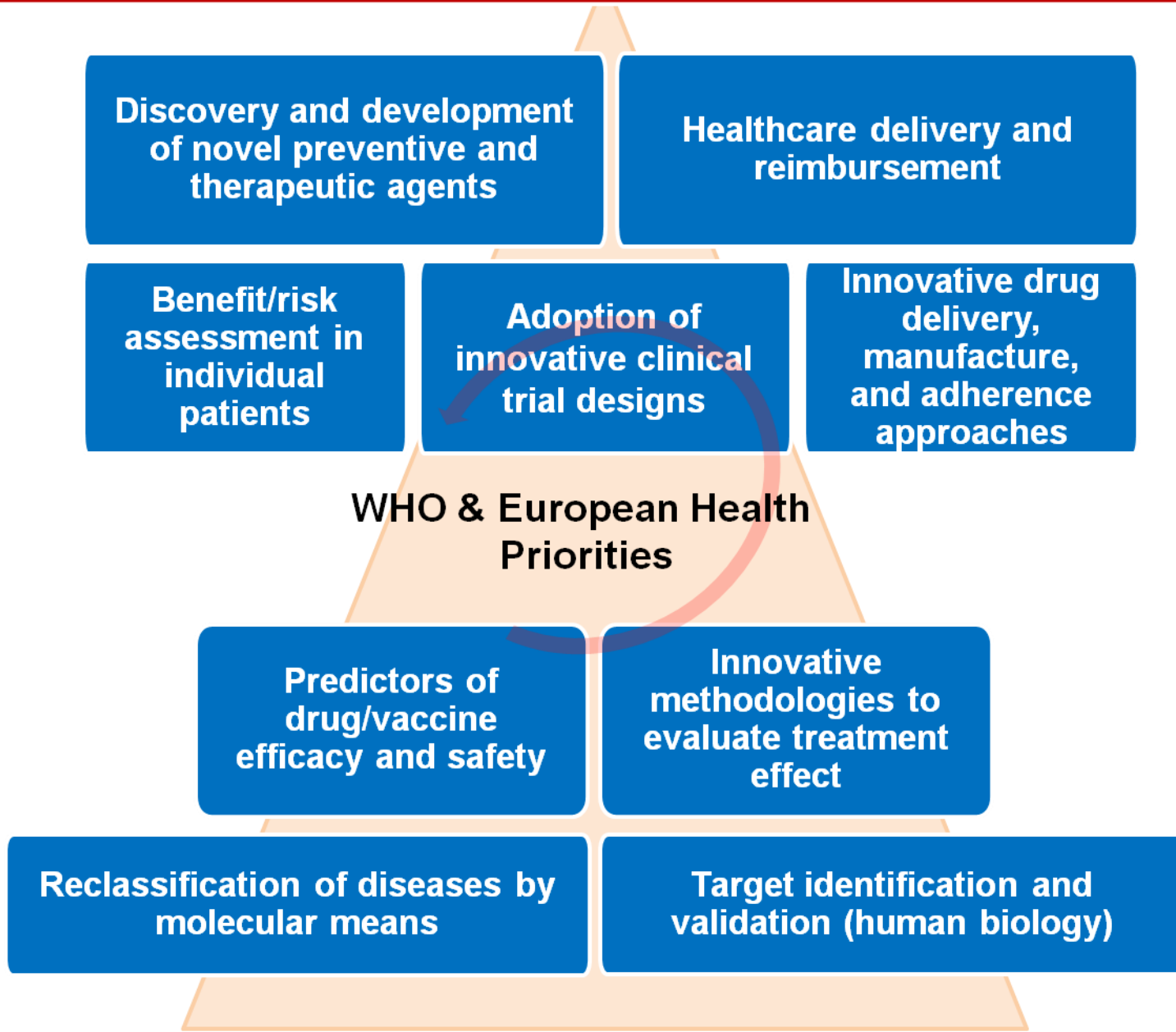
## Innovative Medicines Initiative 2: Europe's fast track to better medicines

- Next generation vaccines, medicines and treatments, e.g. new antibiotics;
- Faster roll-out of effective and sustainable healthcare;
- Leveraging public and private research funding to lower investment barriers;
- Supporting the global competitiveness of Europe's pharmaceutical industry.



# Healthcare Solutions: Effective delivery of the right prevention and treatment, to the right patients, at the right time

## IMI2 Strategic Research Agenda



# Strategic Research Agenda for IMI2:

The right prevention and treatment  
for the right patient at the right time

Draft available at  
<http://bit.ly/1axl076>

Comments and suggestions are welcome:  
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Thank you  
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