Innovative Medicines Initiative

Introduction:

IMI moves personalized medicine forward

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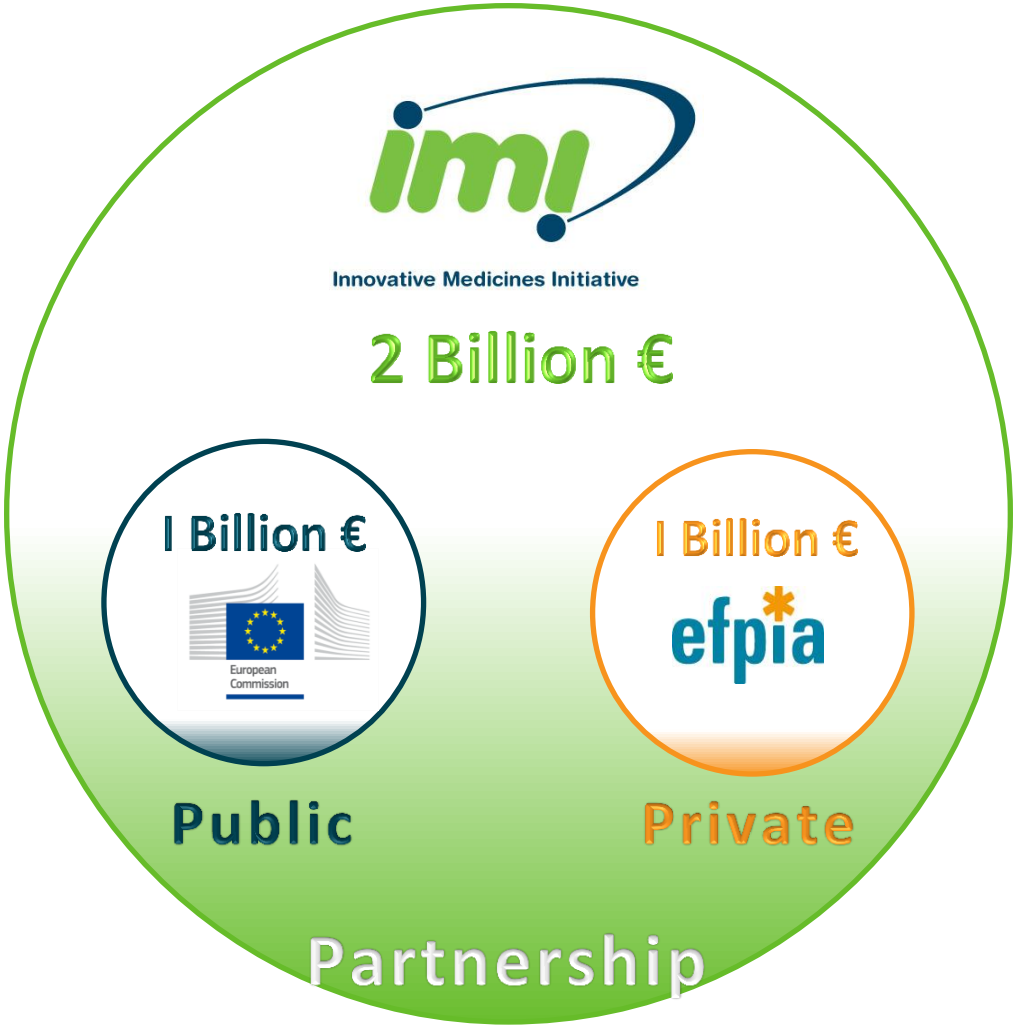
Executive Director

Innovative Medicines Initiative:

Joining forces in the healthcare sector



Key challenges addressed

- Disease heterogeneity
- Lack of **predictive** biomarkers
- Outdated clinical designs and regulatory processes
- Insufficient incentives for pharma industry and biotech companies
- Need for mindset shift in stakeholder communities

Key concepts underlying IMI

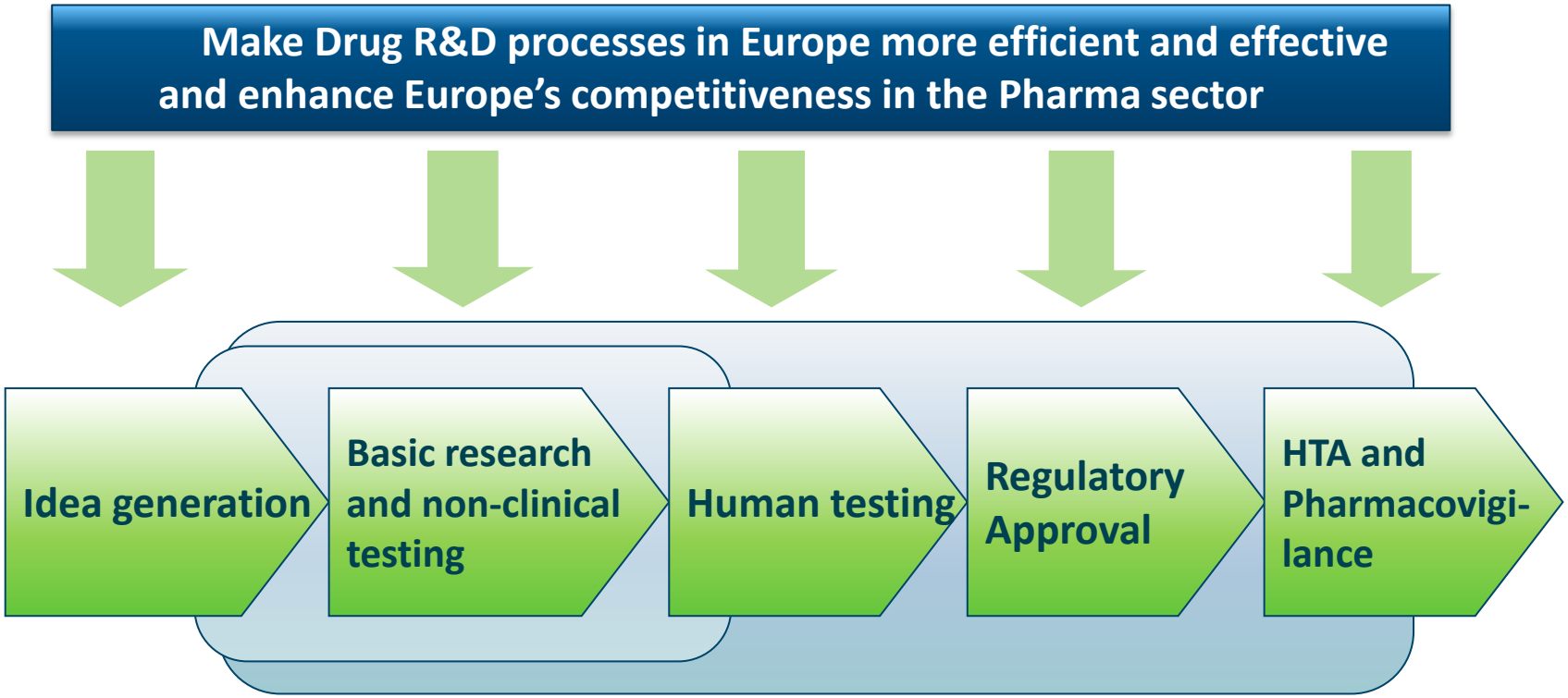
"Non-competitive" collaborative research for EFPIA companies

Competitive calls to select partners of EFPIA companies (IMI beneficiaries)

Open collaboration in public-private consortia (data sharing, wide dissemination of results)

The Evolution of IMI

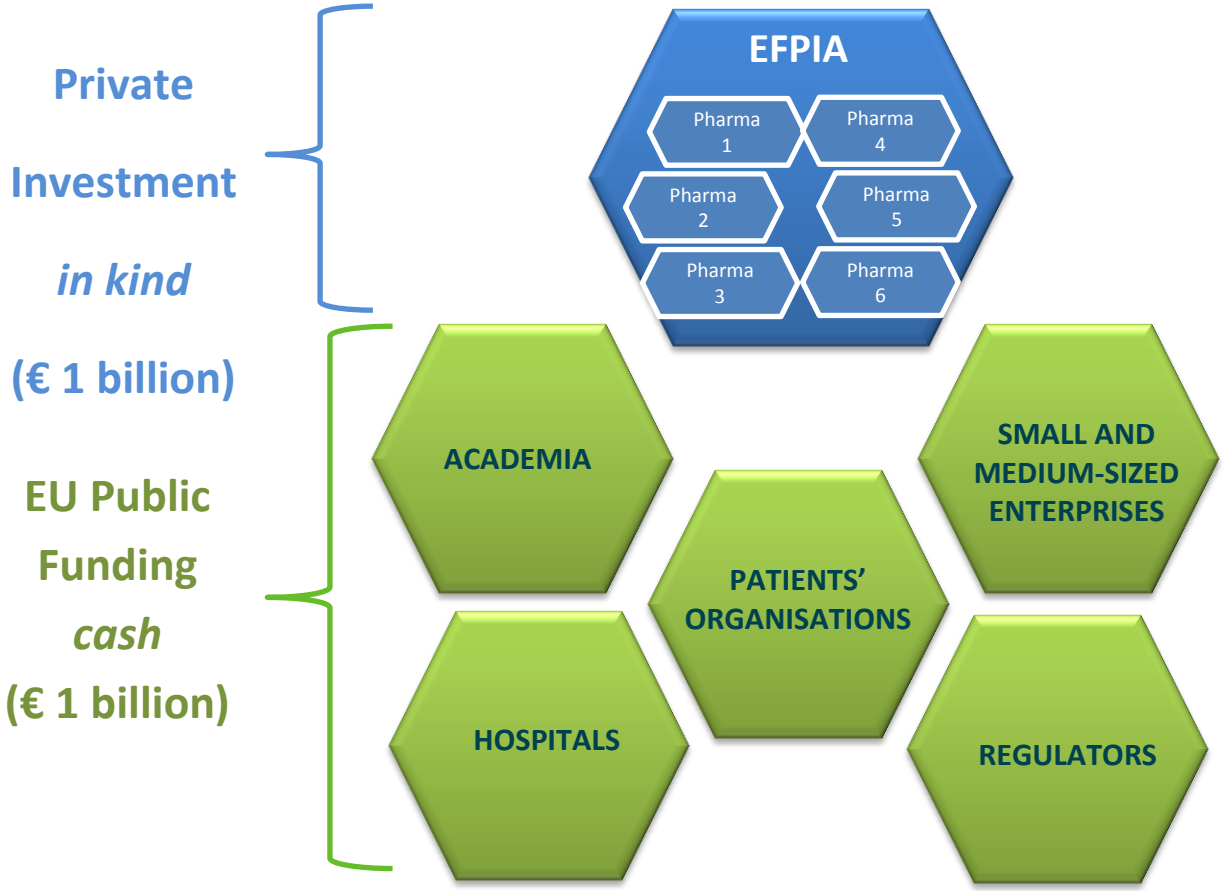
From bottlenecks in industry to bottlenecks in society



SRA – Strategic Research Agenda

How IMI works – Project architecture

A Typical IMI Consortium



IMI as a neutral platform

Fosters large scale industry collaboration and engagement with scientific community

Catalyses open innovation

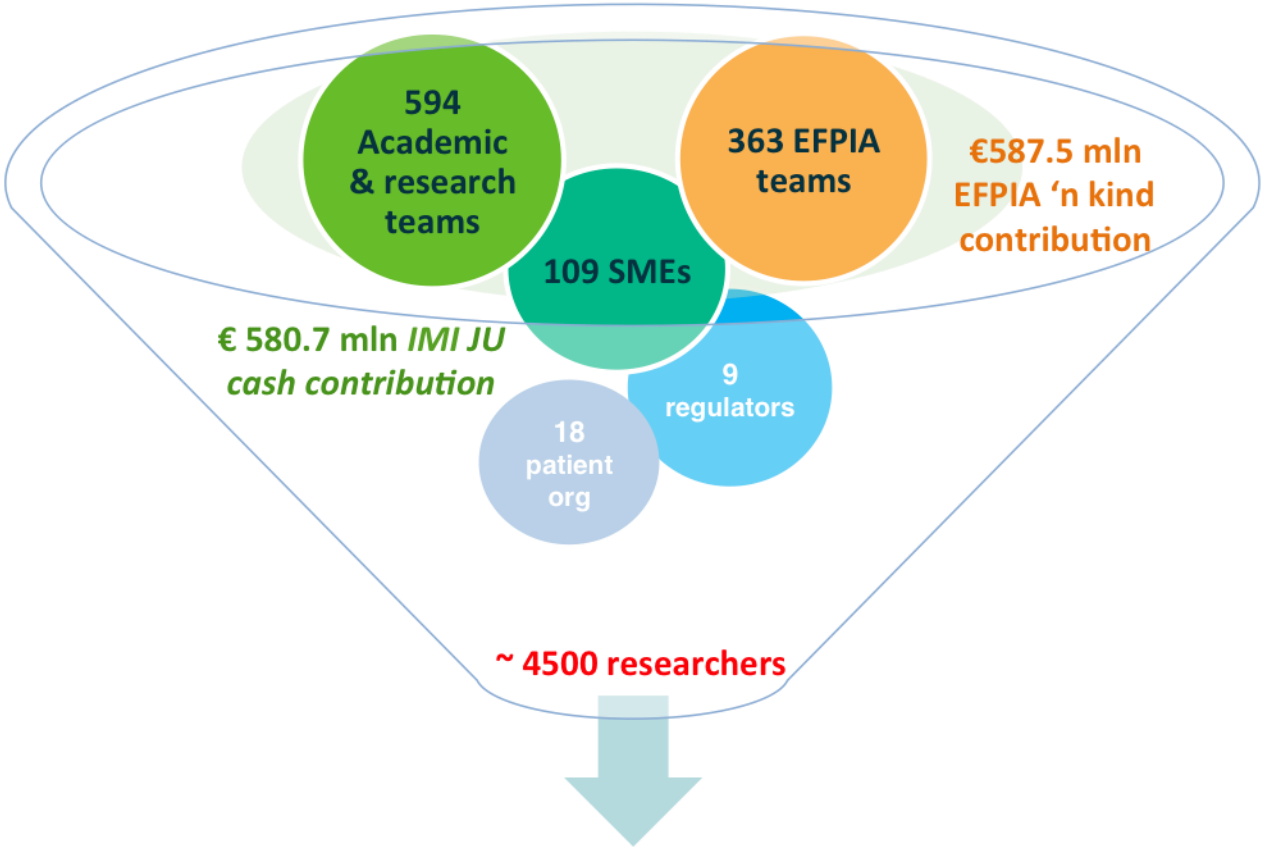
Facilitates Intellectual Property agreements

Ensures excellence of partnerships and projects

Promotes active involvement of patients, regulators and payers

Ongoing IMI Projects

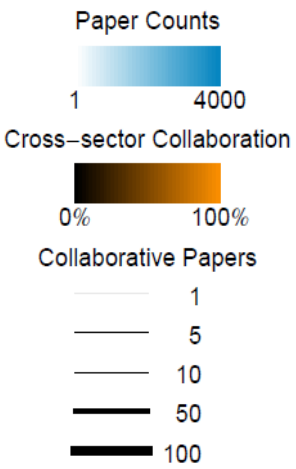
Key figures of ongoing IMI Projects



Increased probability of success
Earlier patient access

Mapping Collaborative Networks

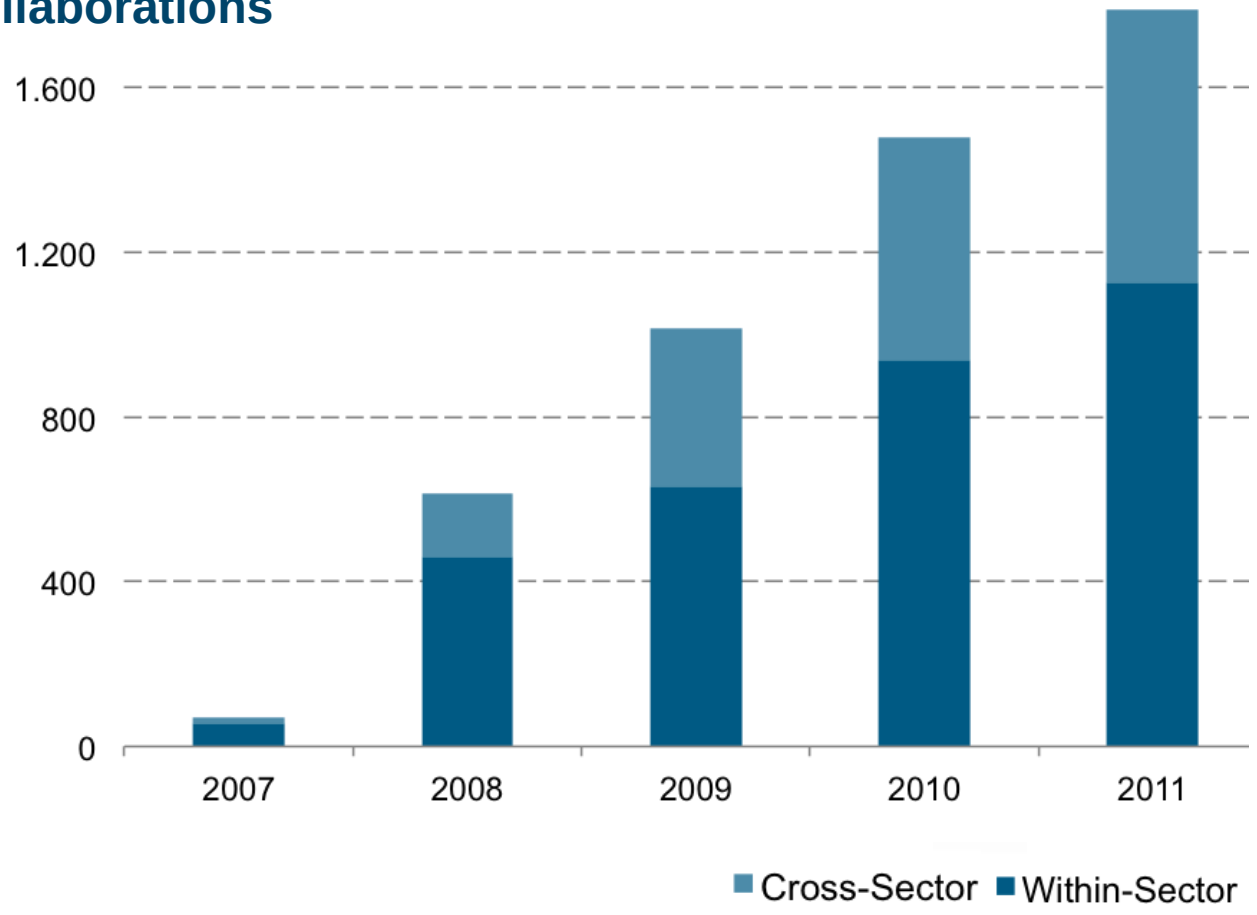
Collaborative publications among IMI researchers



Thomson Reuters Custom Analytics & IP Solutions, 2013

Collaborative activities in IMI Projects

N Collaborations

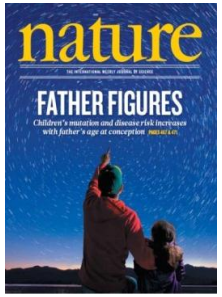


Data & analysis: *Thomson Reuters Custom Analytics & IP Solutions, 2013*

EU-AIMS
Autism Research in Europe

imi

Advances in autism research



Based on sequencing 78 Icelandic **parent–offspring trios**, a total of 219 distinct individuals (44 autistic, 21 schizophrenic offspring) the consortium has identified 4933 de novo mutations.

The consortium has found that as a **man ages**, the number of de novo mutations increases in his sperm, increasing the chance for his child to carry a deleterious mutation that could lead to autism or schizophrenia.

Science
AAAS

A new animal model that replicates a **nonsyndromic autism** was developed. A demonstration of the reversal of the condition with specific therapy in mice presents an opportunity clinical development of **new treatments for autism.**

"**Synapse dysfunction** in autism: a **molecular medicine approach** to drug discovery in neurodevelopmental disorders" – a review of the opportunities and challenges in drug development for autism and the insight into the neurobiology of ASDs.

efpia

EU-AIMS
Autism Research in Europe

imi

A unique partnership

Roche

Lilly
Answers That Matter.

Johnson & Johnson
PHARMACEUTICAL RESEARCH & DEVELOPMENT

SERVIER

Pfizer

Vifor Pharma

KING'S College LONDON

UMC St Radboud

UNIVERSITY OF CAMBRIDGE

UMC
Universitair Medisch Centrum
Utrecht

UNI BASEL

Institut Pasteur

MAX-PLANCK-GESELLSCHAFT

EMBL

Karolinska Institutet

Birkbeck
UNIVERSITY OF LONDON

UNIVERSITÀ CAMPUS BIO-MEDICO DI ROMA

ulm university universität
ulm

cea

deCODE genetics

GABOmi
A MILESTONE IN PROCESS MANAGEMENT

efpia


newEDS


PharmaCog


Pfizer


Abbott
A Promise for Life


ORION


zsi


Karolinska Institutet


UNIVERSITY OF CAMBRIDGE


Psynova
neurotech


MANCHESTER
1824
The University of Manchester


KING'S College LONDON


Bar-Ilan University
Tradition of Excellence


CSIC
Consejo Superior de Investigaciones Científicas


GABOmi
A MILESTONE IN PROCESS MANAGEMENT


deCODE genetics


Lundbeck


NOVARTIS


Lilly


Roche


SERVIER


AstraZeneca


janssen


gsk
GlaxoSmithKline


Eisai


Boehringer
Ingelheim


MARIO NEGRI
ISTITUTO DI RICERCHE FARMACOLOGICHE


ucb


MERCK


Inserm
Institut national
de la santé et de la recherche médicale


Alzheimer
Europe


cnrs
dépasser les frontières


Université Lille 2
Droit et Santé


IDIBAPS
Institut d'Investigacions Biomèdiques August Pi i Sunyer


UNIVERSIDAD DE MURCIA


UNIVERSITÄT LEIPZIG


Universitätsklinikum Essen


UNIVERSITÉ DE LA MEDITERRANÉE
AIX-MARSEILLE II


UNIVERSITÀ DEGLI STUDI DI VERONA


ICDD
Innovative Concepts in Drug Development

Qualissima

UNIVERSITÀ DEGLI STUDI DI FOGGIA

IHD
Innovative Health Diagnostics

expnhit

AlzProtect
Neuroprotectants for Alzheimer

efpia

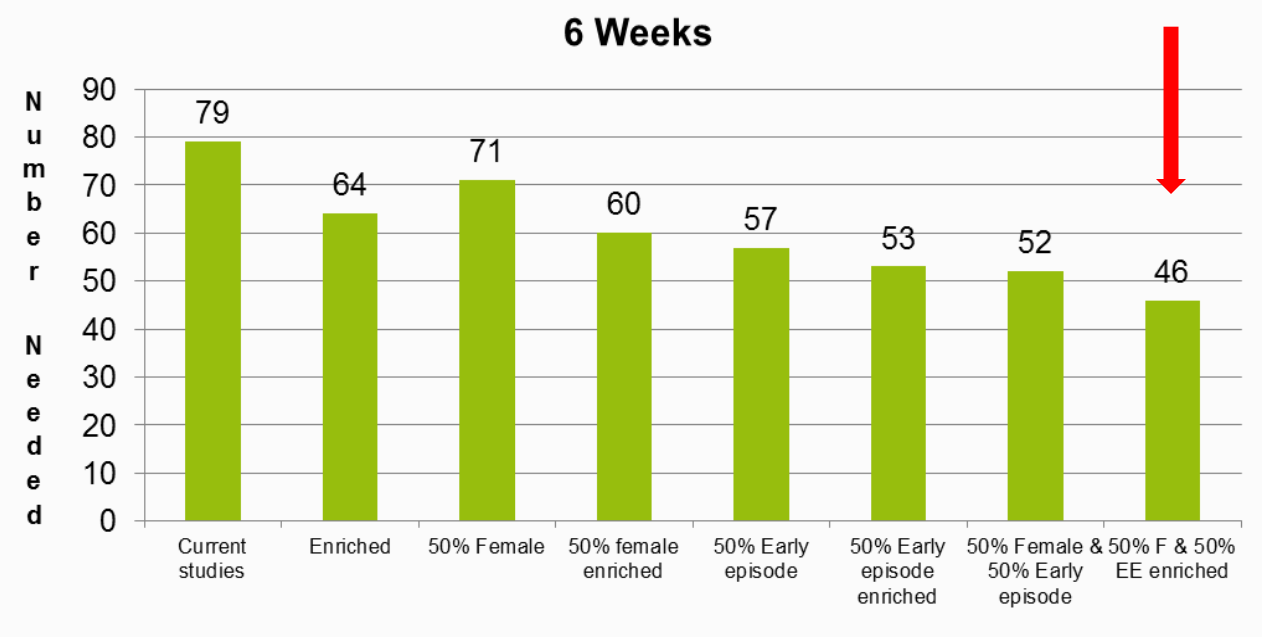
Optimizing trials for schizophrenia treatment

Proposed ways to reduce required numbers of patients needed for antipsychotic trials
while preserving 90% power ($p<.05$)

Based on resampling of data from **34 such trials** (**n=11,670 patients**) data from Astra Zeneca, Janssen, Lilly, Lundbeck, Pfizer

Samples can be reduced from 79 to 46 patients per arm by targeting trials

The trial duration can be reduced from 6 to 4 weeks



Current mix =70% female; 20% early episode; 40% enriched

Enriched=prominent positive and negative symptoms

Early episode=under 3 with 4 or more years of illness

Note: Per patient cost 6wk study $70,000-$100,000

'Think Big'

Research on human diseases at an *unprecedented scale*

- ✓ Access to information on **40 million patients** through EHR
- ✓ **Alzheimer'** disease: research on **10-times more subjects than ADNI** (Alzheimer's Disease Neuroimaging Initiative)
- ✓ Metabolics research on **> 20,000 obese & Type 2 diabetes subjects**
- ✓ Linkage of clinical and "omics" data
- ✓ Development of a secure (privacy, legal) modular platform
- ✓ Continue to build a network of data sources and relevant research

58 partners (3 consortia + Efpia)
>200 scientists involved
14 European countries represented
Total budget €56.4m
"3 projects in one"

Exploiting Electronic Health Records

Academic perspective

- Provide tools and services to better plan and conduct academic trials
- Facilitate comparative effectiveness research

Pharmaceutical perspective

- Improve patient recruitment process and study design
- Better understanding of real patient populations
- Support observational and outcomes research studies in real-world settings
- Enable more cost effective research and clinical trials

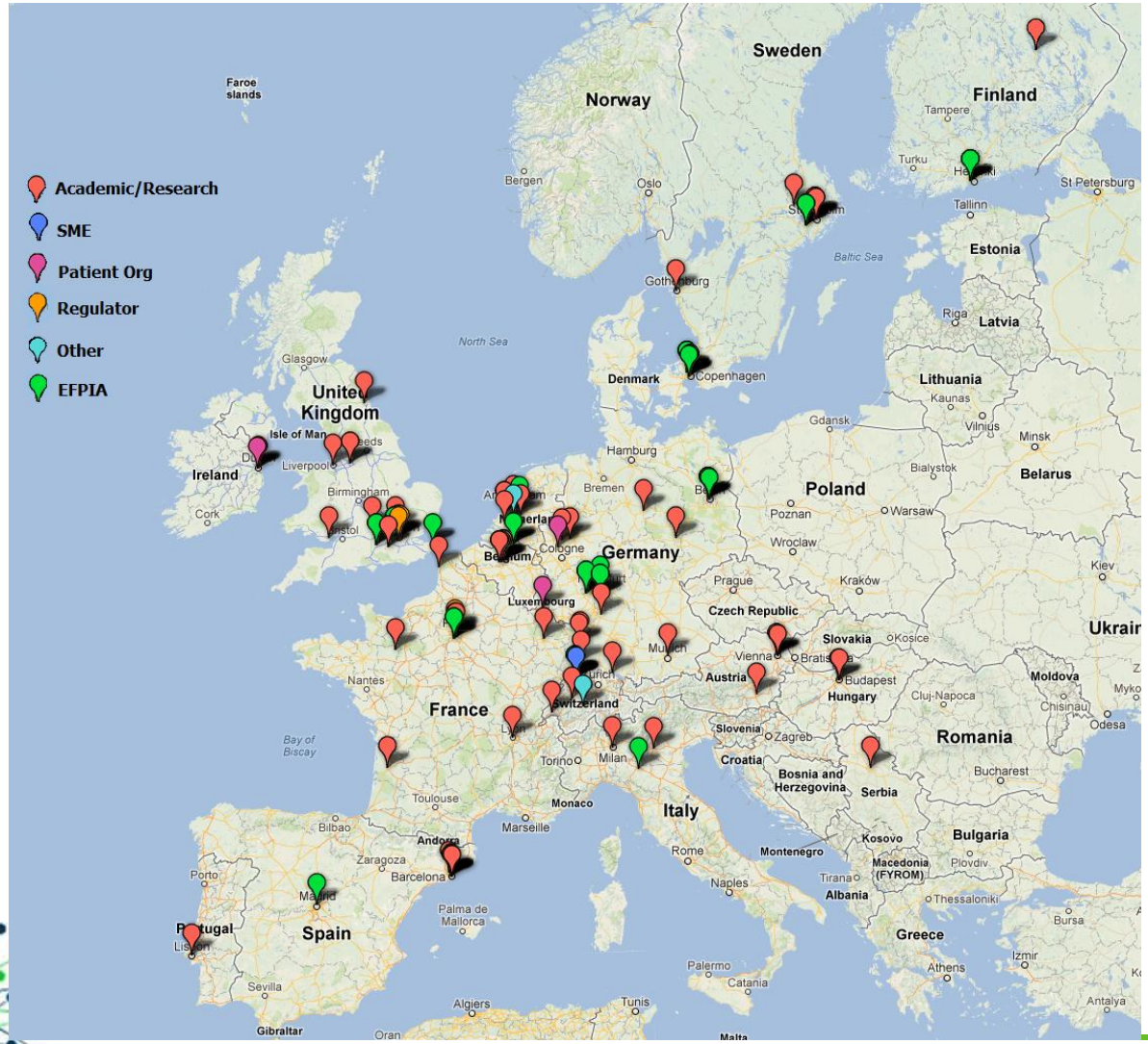
General Healthcare perspective

- Facilitate the re-use of EHR data to more efficiently manage public health issues
- Enabling safer and more evidence-based diagnosis and treatment

A new of taxonomy diseases to foster personalized medicine

- Cancer
- Asthma
- Diabetes
- Rheumatic diseases
- Alzheimer
- Parkinson
- Chronic obstructive pulmonary disease

The IMI Education and Training projects



EMTRAIN

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

EU2P
EUROPEAN PROGRAMME IN
PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

SafeSciMET

efpia

A patients' academy on therapeutic innovation

- **develop and disseminate** accessible, well-structured and user-friendly information and education on medicines R&D
- **build competencies** among well informed patients and the public about pharmaceutical R&D
- **build expert capacity** in patient advocates
- **create the leading public library** on patient information in six most common languages under public licensing
- **establish a widely used, sustainable infrastructure** for objective, credible, correct and up-to-date knowledge
- **facilitate patient involvement in R&D** to support industry, academia, authorities and ethics committees

Objective of the workshop

To demonstrate that public-private partnerships move personalized medicine forward by:

- addressing key scientific challenges
- developing tools to translate scientific advances into regulatory guidelines
- considering new pathways to accelerate patient access to innovative therapies
- providing a neutral platform that fosters collaboration between stakeholders

Innovative Medicines Initiative

THANK YOU !

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