



Innovative Medicines Initiative

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## *Role and Mission of IMI*

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**iMed.**  
**ULisboa** Instituto de  
Investigação do  
Medicamento

***Budapest, September 2014***



**efpia**  
1

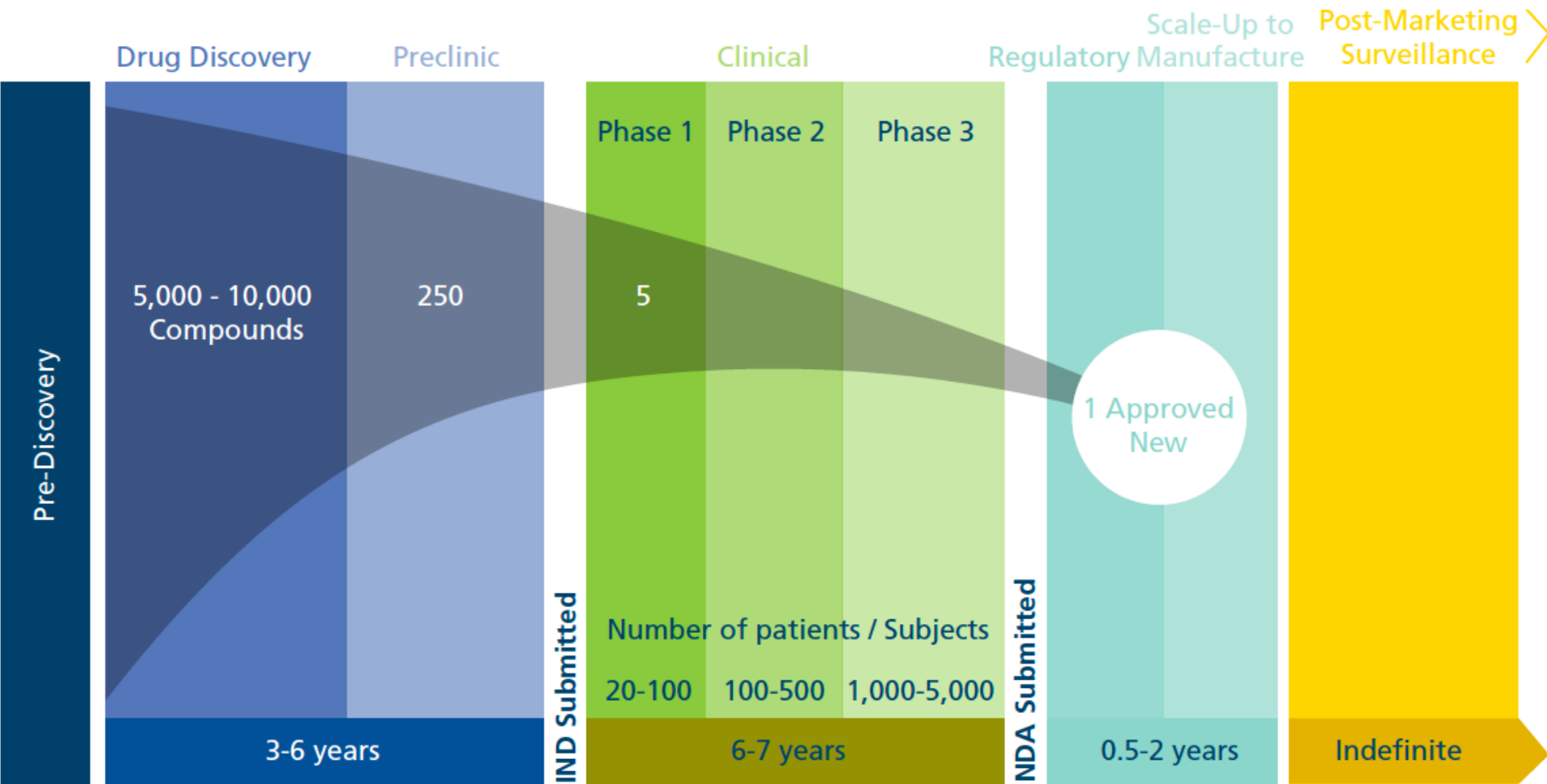
# Why ?

## The Research Agenda 2008

- Inefficiency of systems in place to provide “Safe Medicines Fast” to the patients!!
- The decreased Industry investment in European medicines R&D (into US)
- Insufficient coverage of multiple diseases

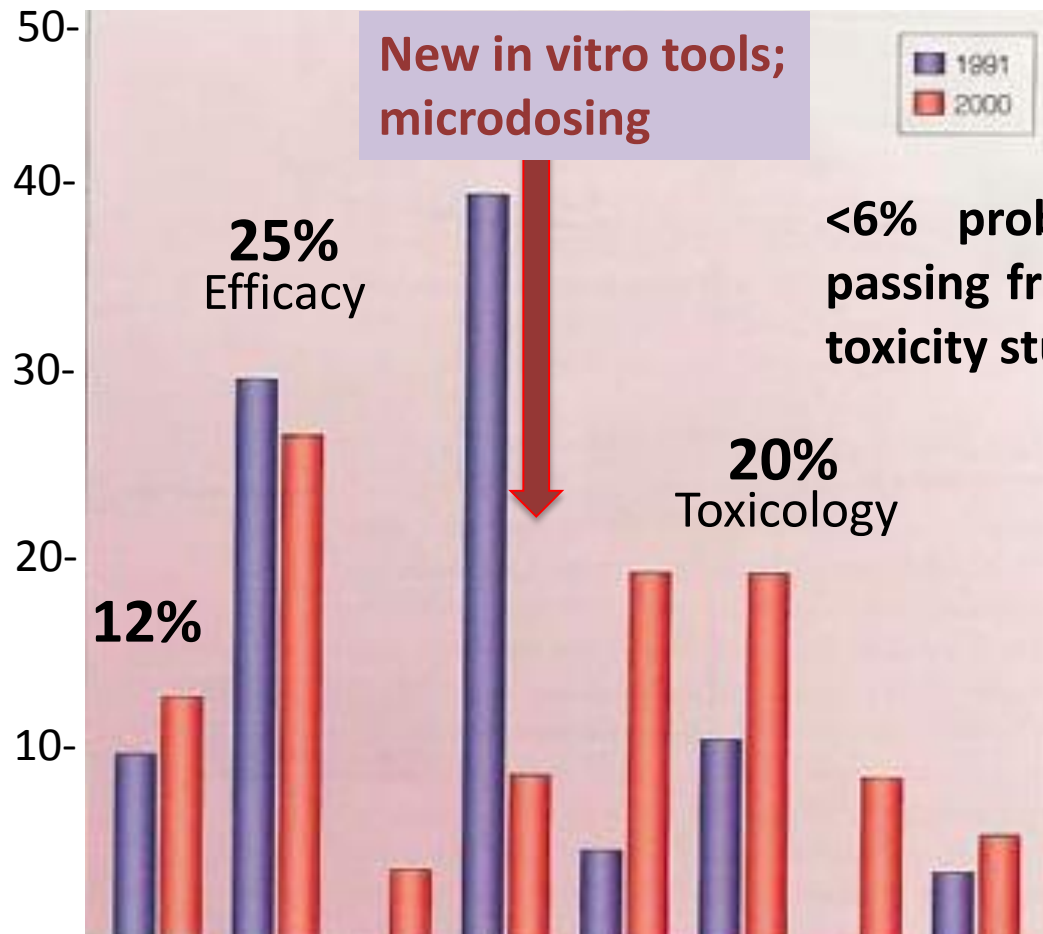


# The Pharmaceuticals Development Success Rate



# Reasons for Attrition During Clinical Development

% NCEs



<6% probability of a drug candidate passing from pre-clinical stages (first GLP toxicity study) to market (>94% failure!!!)

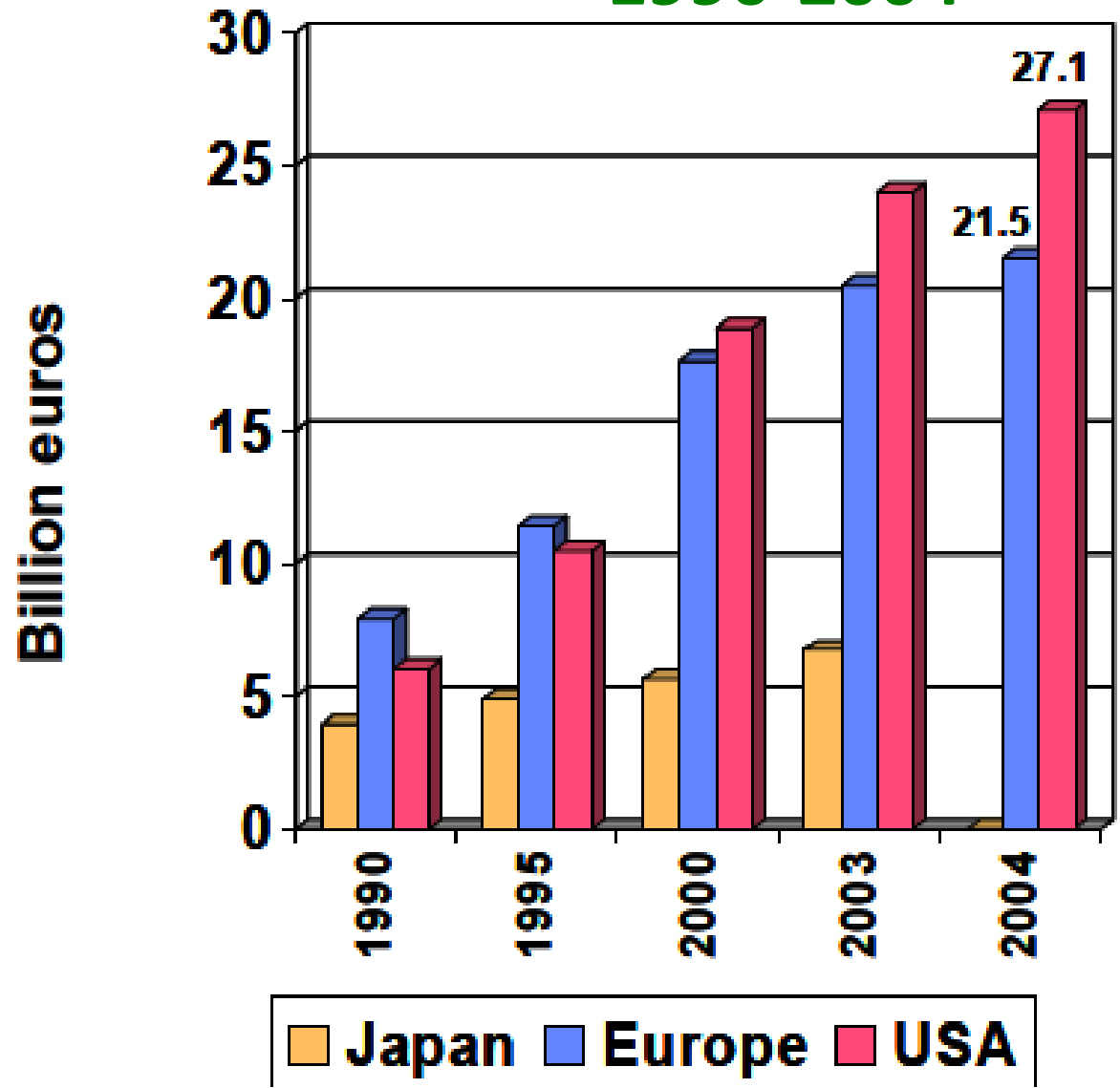
Clinical Safety

PK

Kola and Landis (2004).. *Nature Reviews Drug Discovery*; Vol 3: 711




# Pharmaceutical R&D Expenditure in EU, US, Japan 1990-2004



Growth:  
2.6 fold in EU  
vs  
4 fold in US

# EUROPE TOWARDS INOVATION in Pharmaceuticals R&D

- 1999- Identification of the problem :  
**SAFE MEDICINES FASTER**
- 2005- Action : **RESEARCH AGENDA**
- 2008- Implementation  1st call



# Innovative Medicines Initiative

## AIM:

- Address the complex issues associated with the future of biomedical research within the EU
- Address ways of achieving accelerated development of new, safe and more effective medicines
- Help to revitalize the European biopharmaceutical research environment.

## Expected Final Outcome

- Help speed up the process for drug development
- Revolutionize and completely change the process by which drugs are developed.



# Innovative Medicines Initiative: *Joining Forces in the Healthcare Sector*

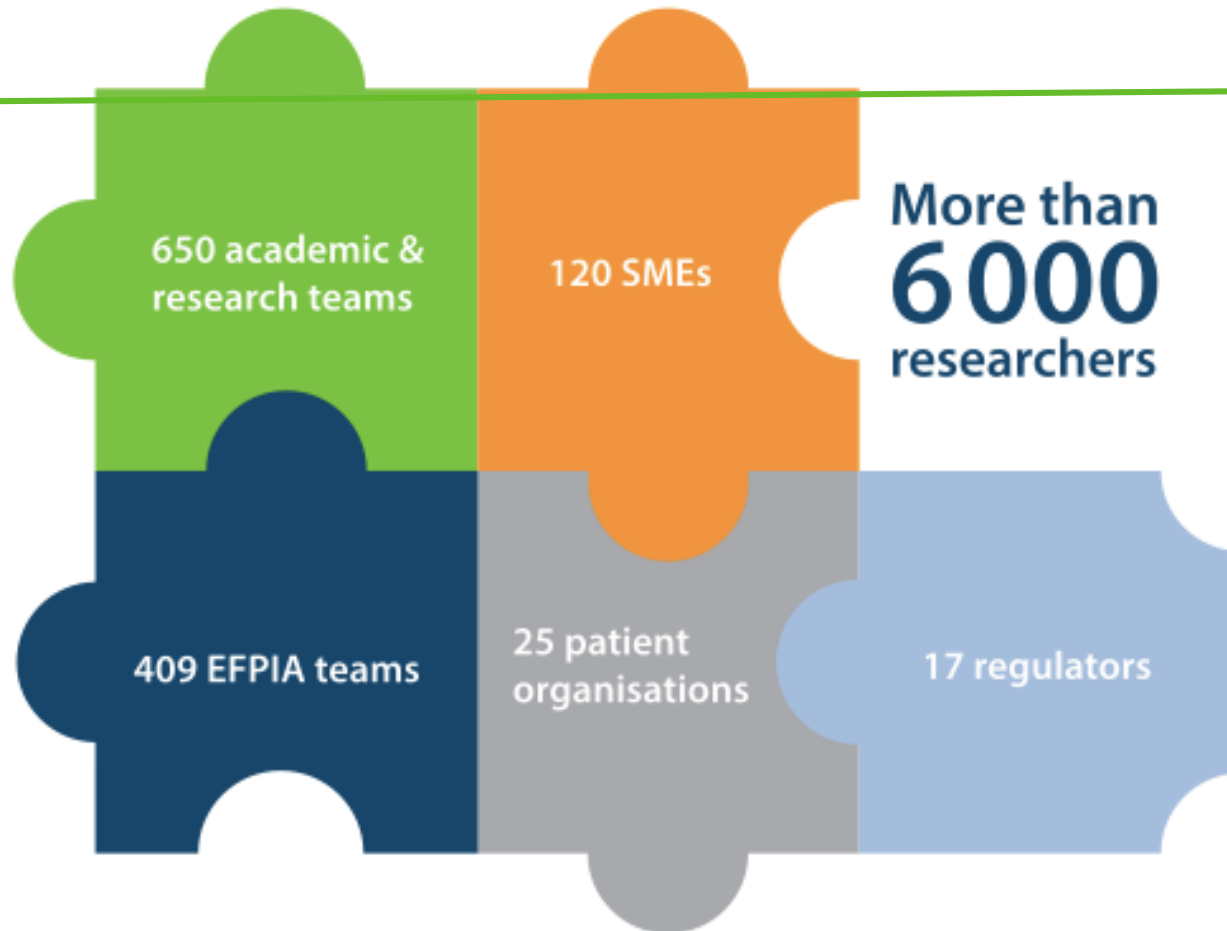




# The 4 IMI Pillars from 2008 Strategic Research Agenda



# Joining Forces in the Healthcare Sector

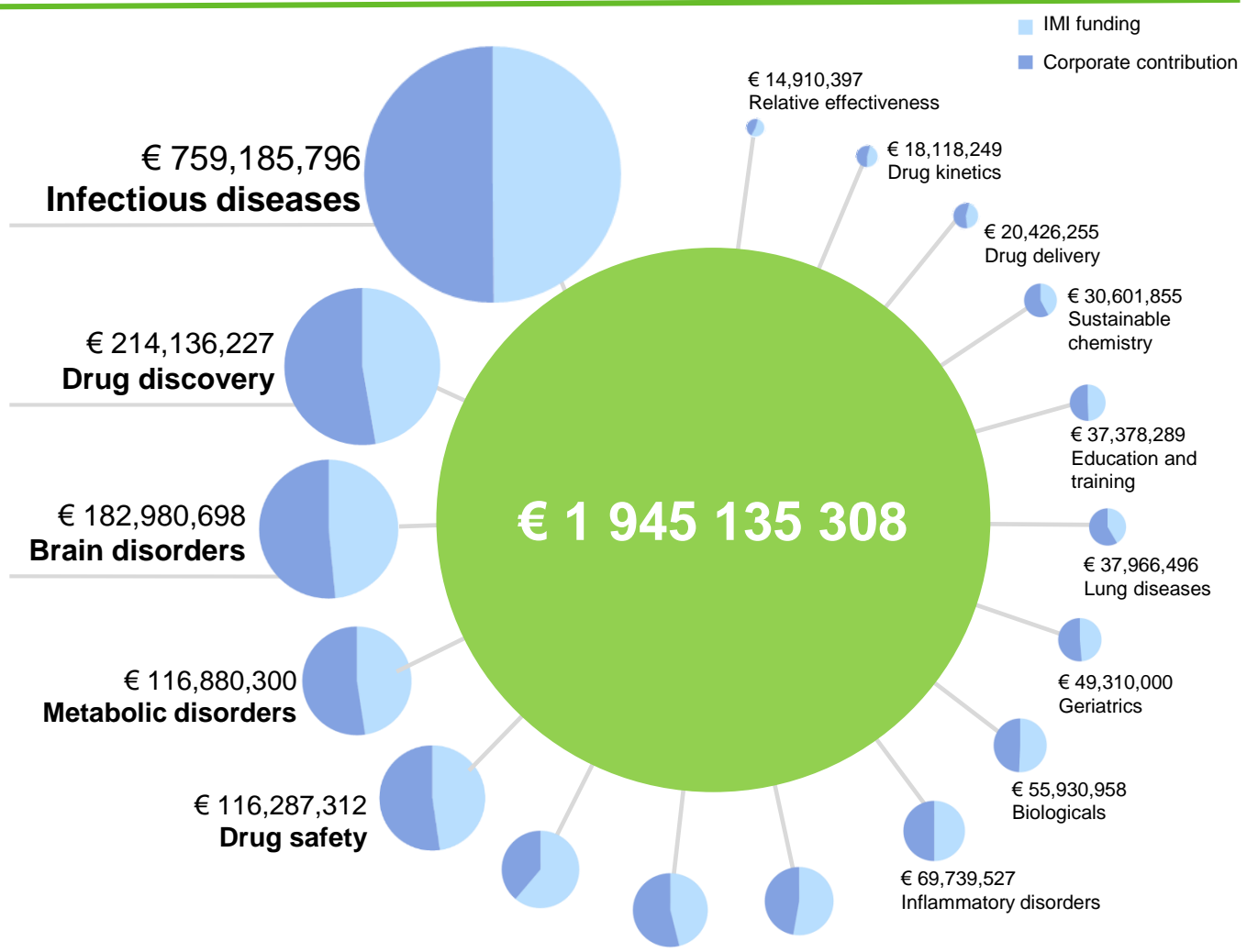


More than  
**6000**  
researchers

## Working for

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

# IMI 1: Budget Breakdown



# % Expenditure in R&D Expenditur in EU and USA

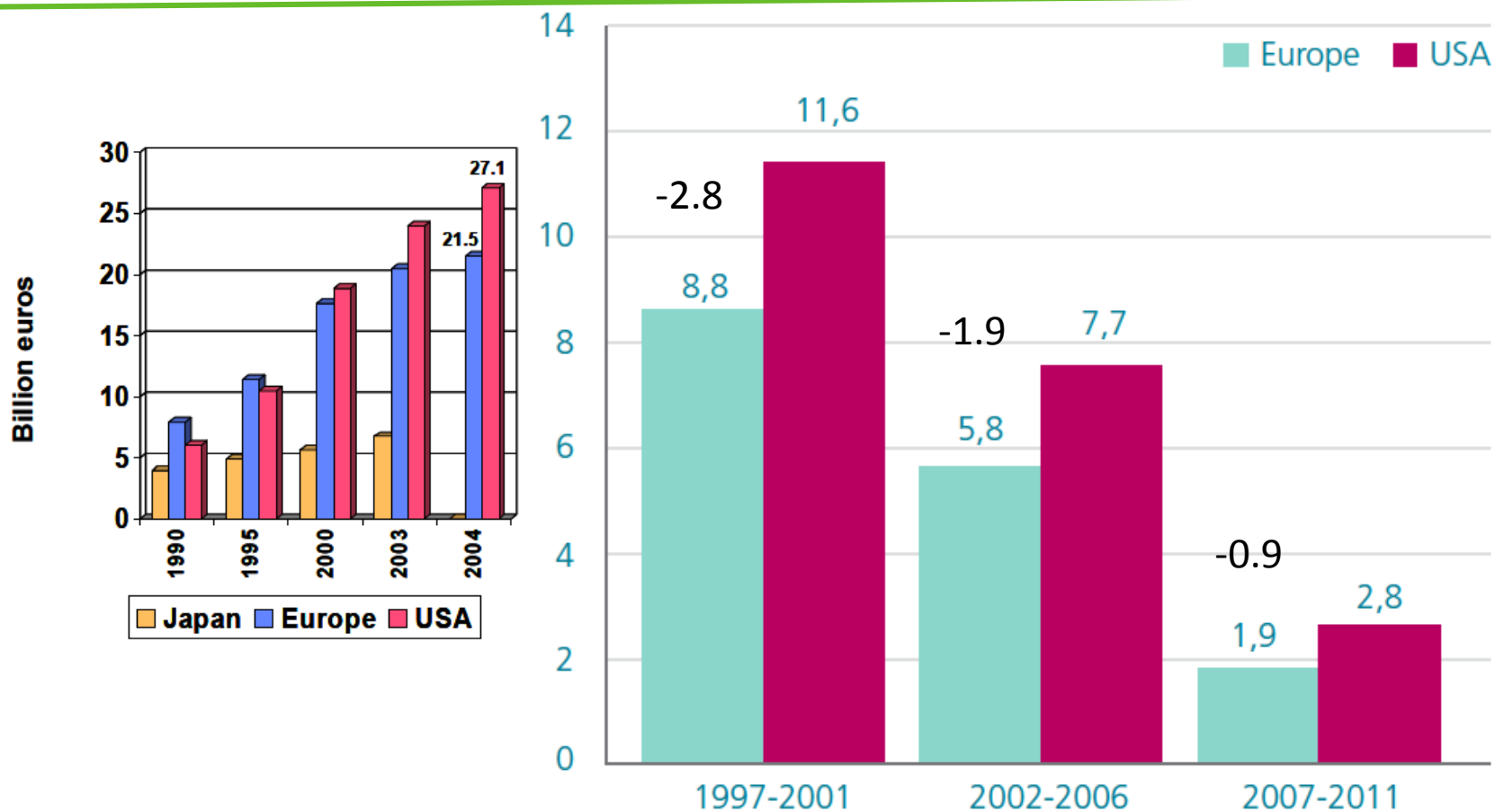


Figure 4: Growth in R&D has slowed in both Europe and the US.  
Source: EFPIA/PhRMA

# IMI-1 Deliveries 2008-2014

## Expected Final Outcome

- Help speed up the process for drug development
- *Revolutionise and completely change the process by which drugs are developed.*

## Is the Road being Paved??



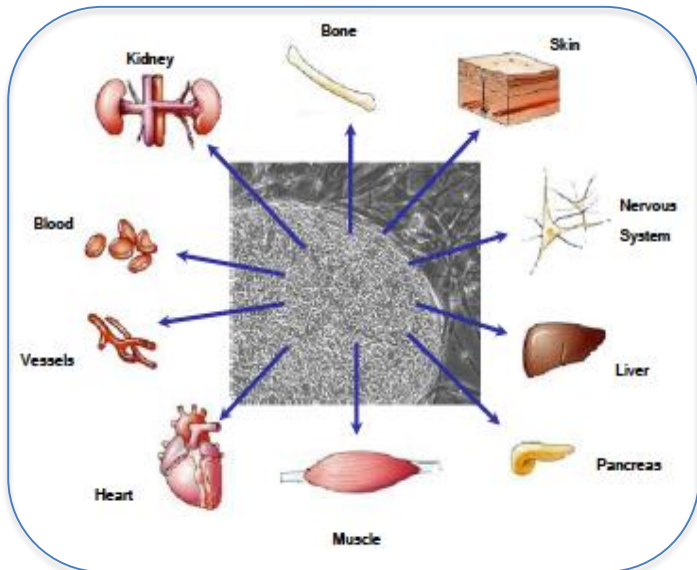
# IMI-1 Deliveries; 47 projects (2008-2014)

- Advances in Predictive Toxicology and Training
- New screening methodologies, pre-clinical & clinical e.g., in diabetes and Alzheimer's disease;
- More rapid identification of new therapeutic targets in areas of high unmet need e.g. autism, schizophrenia;
- Biomarker identification, qualification and validation in several medical conditions;
- Enhanced clinical trial design;
- Building effective platforms for data storage, integration and interrogation;



# Example: Preclinical Safety

StemBancc/ EBISK  
iPScells / Bank



Cancer Biomarkers  
MARCAR

eTOX

Chemo/bioinformatics  
(all toxicities?)

PredTOX

Omics / models / systems tox  
(liver / kidney)

MIP-DILI

Human Hepatocytes

Safe-T

DILI/DIKI/DVI  
(Humans)

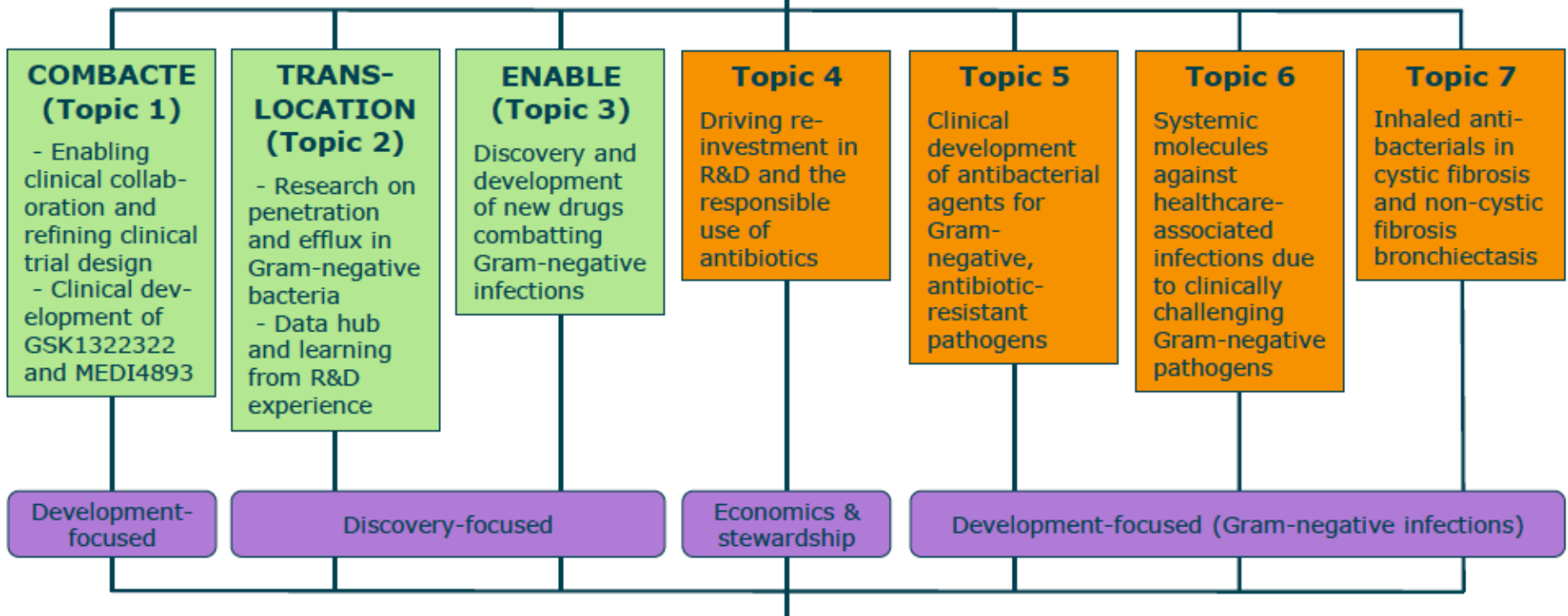


# New Drugs 4 Bad Bugs (ND4BB)



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## Cross-project communication & collaboration



## ND4BB Information Centre

All data generated is submitted and made accessible to all partners

Ongoing projects

Projects under development

[RAPP-ID, point-of-care tests for infectious diseases,](#)







# For Diabetes

- **DIRECT**- Diabetes research on patient stratification
- **IMIDIA**-Improving  $\beta$ -cell function & identification diagnostic biomarkers for treatment monitoring
- **SUMMIT**- surrogate markers for micro and micro vascular endpoints for innovative diabetes tools
- **PROTECT** – Pharmacoepidemiological research for outcome of therapeutics
- **EHRMCR**-Electronic Health Record systems for clinical research



# Education and Training

- Reducing the “silos” organization of Universities
- Building links between basic and clinical scientists
- Creation of a pan-European platform for research, research training and technology development supporting the entire medicines development and approval process,
- Proposal on how to facilitate exchange programs for scientists between Academia and Industry



# The Future Safety Scientists

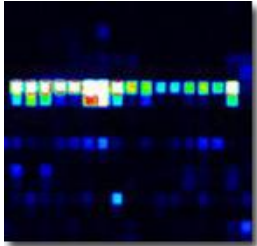
Analysis + Modeling = Context and Relevance



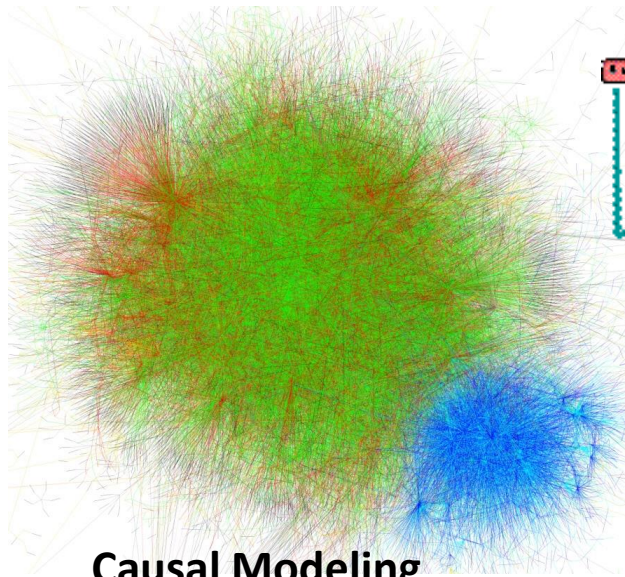
Biologists +

Computer Scientists

Safety Scientists



Data Analysis



Causal Modeling



Mechanism Discovery



# Training A New Generation of Scientists

safety/regulatory/PhV-PhE/Pharm.medicine

## **EMTRAIN:**

European Medicines Research Training Network

## **SafeSciMet:**

European Modular Education and Training Programme  
in Safety for Medicines

## **PharmaTrain**

Pharmaceutical Medicine Training Programme

## **EUPATI:**

European Patient's Academy on Therapeutic Innovation

## **Eu2P:**

European Program in Pharmacovigilance and  
Pharmacoepidemiology





# Cooperative European Medicines Development Course

Coordinated by Semmelweis University, Budapest

## Scientifically Accredited by PharmaTrain and IFAPP

Aim

- to train experts who understand the complex process of medicines development from molecule to health care.
- applying this knowledge working in large or small, innovative or generic pharmaceutical companies, enterprises, regulatory agencies in health care and health insurance management







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

Strategic Research Agenda for  
Innovative Medicines Initiative 2

IMI1 has shown the progress that is possible when we bring stakeholders from the public and private sectors together. With IMI2, we are looking to go even further. We want to not only progress research but also progress the delivery of research results - of innovative medicines - to patients.

”



Michel Goldman

Executive Director | IMI - Innovative Medicines Initiative



With IMI2, we have the opportunity to build on accomplishments of IMI1 and further align medical research programmes and public health priorities. This gains in importance day-by-day as society faces increasing challenges in difficult areas, such as age-related illnesses and chronic diseases.

”



Dr Ruxandra Draghia-Akli  
Director, Directorate Health, DG Research and Innovation





# IMI2 - Expanding IMI 1

## Major Axis of Research

Biomarker identification/validation  
(precision medicine)

Reclassification of disease  
by molecular means

Target Identification and  
validation (human biology)

Determinants of drug/vaccine  
Safety and efficacy

Innovative drug delivery  
methodologies

Manufacturing for  
personalised medicines

Discovery and Development  
of novel preventative and  
therapeutic agents



Innovative methodologies to  
evaluate treatment effect

Adoption of innovative clinical  
trial designs

Benefit/Risk Assessment

Healthcare delivery: focus on  
the treatment programmes not  
just the medicine

Innovative adherence  
programmes



DRIVE CHANGE IN DELIVERY OF MEDICAL PRACTICE

# IMI 2 - Ultimate Goal

- A 30% better success rate in clinical trials of priority medicines identified by the WHO;
- Clinical proof of concept in immunological, respiratory, neurological and neurodegenerative diseases in just five years;
- New and approved diagnostic markers for four of these diseases
- And at least two new medicines which could either be new antibiotics or new therapies for Alzheimer's disease.

# Joint Efforts and Cooperation NEEDED!!!





# THANK YOU!

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## The Operating Room of the Future

The way I see the future is the building of  
the next generation operating room,

