The Innovative Medicines Initiative:

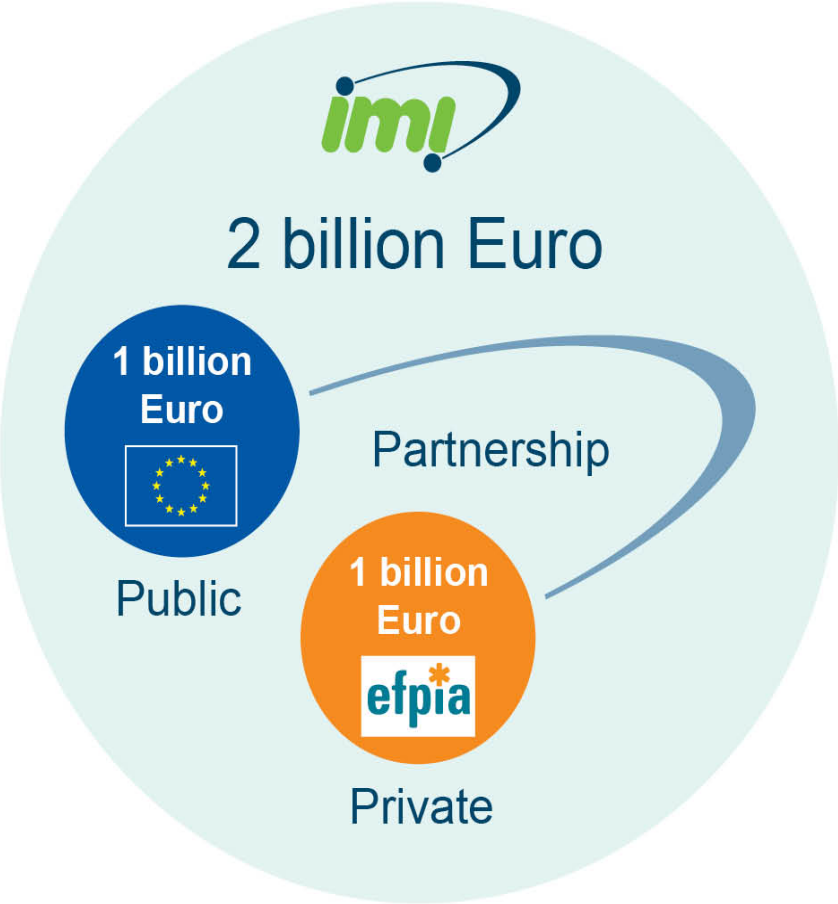
Building New Models of Collaborative Research across Europe

Magda Gunn, IMI Scientific Officer

efpia

What is IMI?
How does it work?

Innovative Medicines Initiative:
Joining Forces in the Healthcare Sector



The biggest public/private partnership in Life Science aiming to:

- Make drug R&D processes in Europe more **innovative** and **efficient**
- Enhance Europe's **competitiveness**
- Address key **societal challenges**

Features:

- 1:1 funding, joint decision making
- All EU funds go to SMEs, academia, patient organisations and regulatory agencies
- Large pharmaceutical industry, represented by EFPIA, contributes in-kind

Key Concepts

- "Non-competitive" collaborative research for EFPIA pharma companies
- Competitive calls to select partners of EFPIA companies (IMI beneficiaries)
- Open collaboration in public-private consortia (data sharing, dissemination of results)

IMI focus - Hurdles to better healthcare

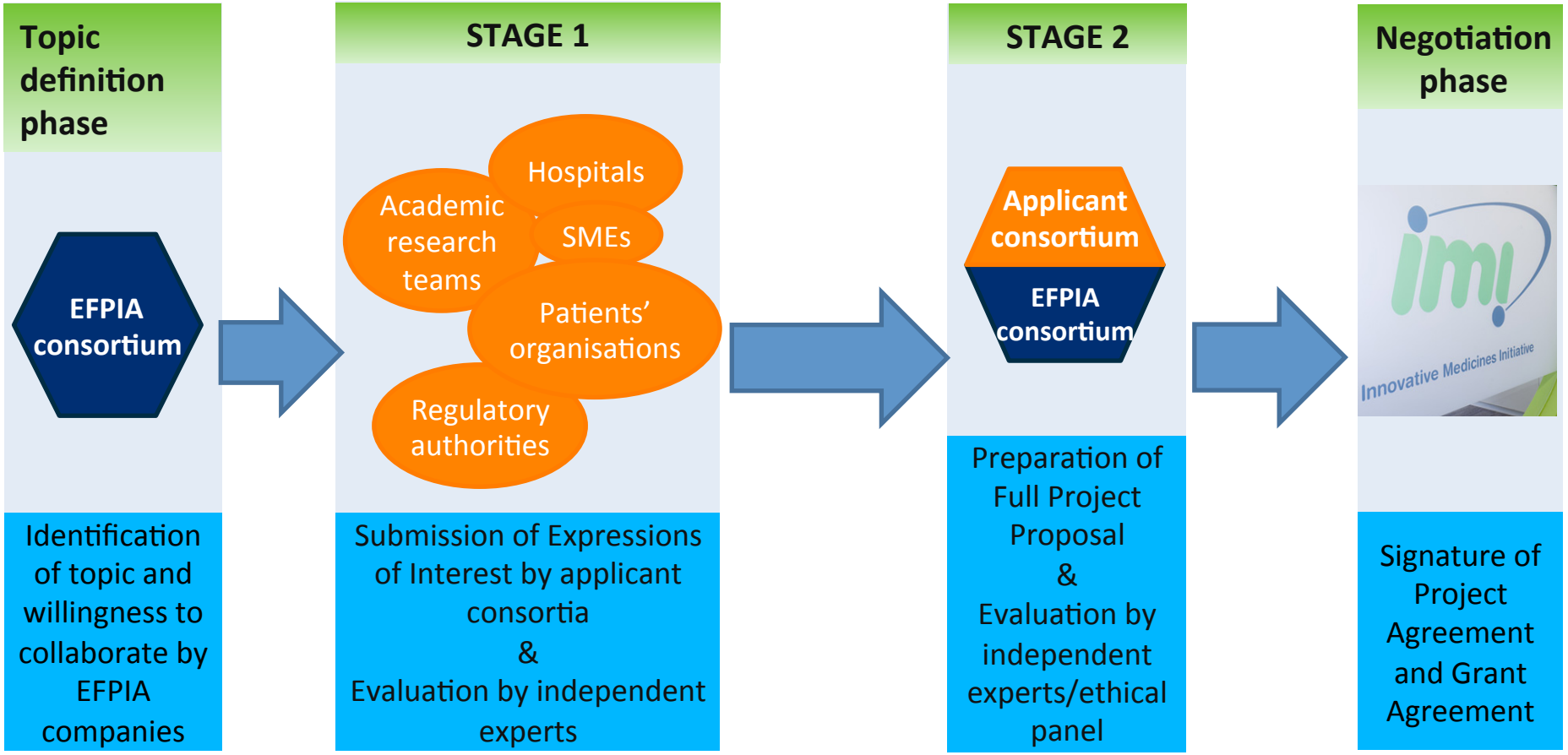
- Disease heterogeneity
- Lack of efficacy and safety predictive biomarkers
- Insufficient pharmacovigilance tools
- Outdated clinical designs
- Socio-economic approaches not adapted to tailored therapies
- Insufficient incentives to develop drugs for rare or complex diseases
- Lack of training programmes focusing on collaborative approaches

A Typical IMI Consortium

Private Investment *in kind* (€ 1 billion)

EU Public Funding *cash* (€ 1 billion)

From topic definition to project start



Call Launch → **Invitation to selected team to merge with EFPIA team** → **Start of the negotiation phase** →

Achievements so far…

NATURE MEDICINE I NEWS Published online 07 January 2014

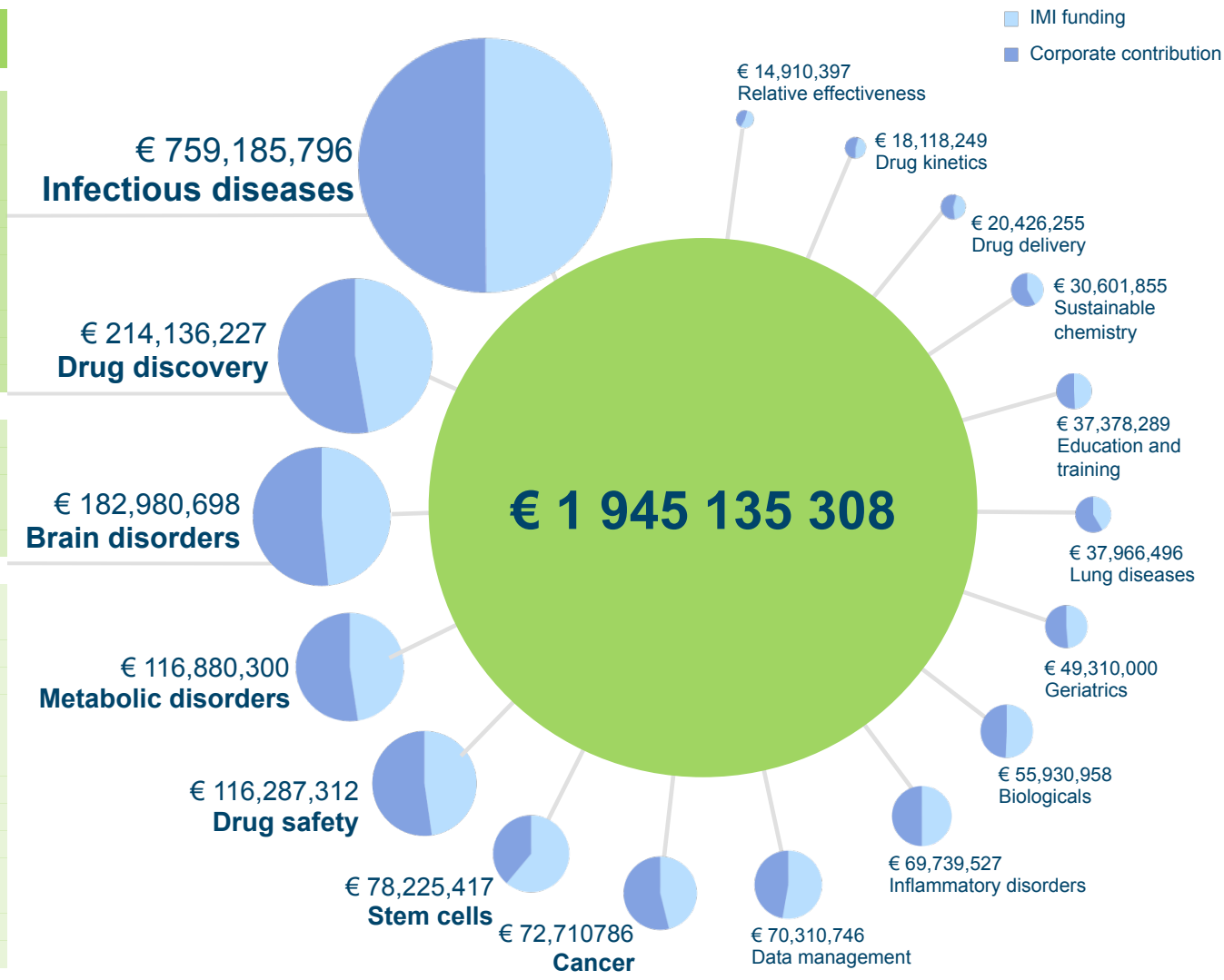
Infectious disease leads in first phase of Europe's IMI effort

Partners

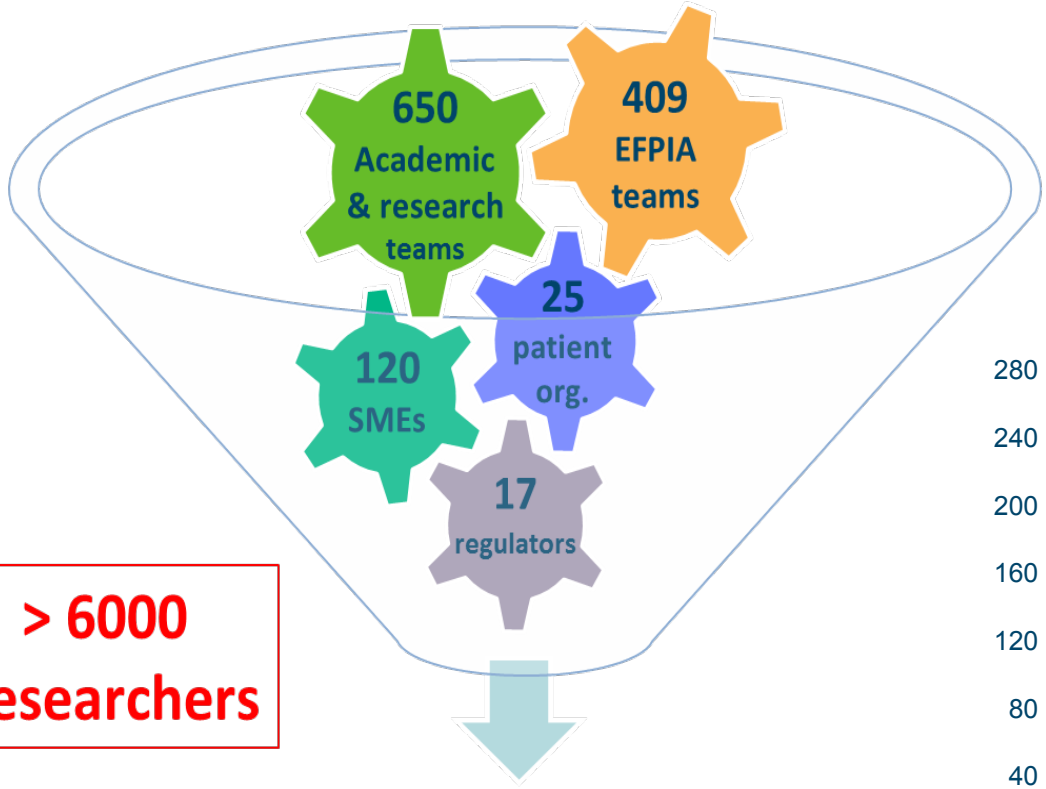
AiCuris	**Johnson&Johnson**
Animal Health	Medimmune
Division of Sanofi	**Merck**
Astellas	Merck Sharp
AstraZeneca	& Dohme Corp
Basilea	**Merial**
Boehringer Ingelheim	Novartis
Cubist	**Pfizer**
GSK	Rempex
Janssen	**Sanofi**

AstraZeneca	**Novartis**
Bayer	Pfizer
Janssen	**Sanofi**
Lundbeck	UCB
Merck	

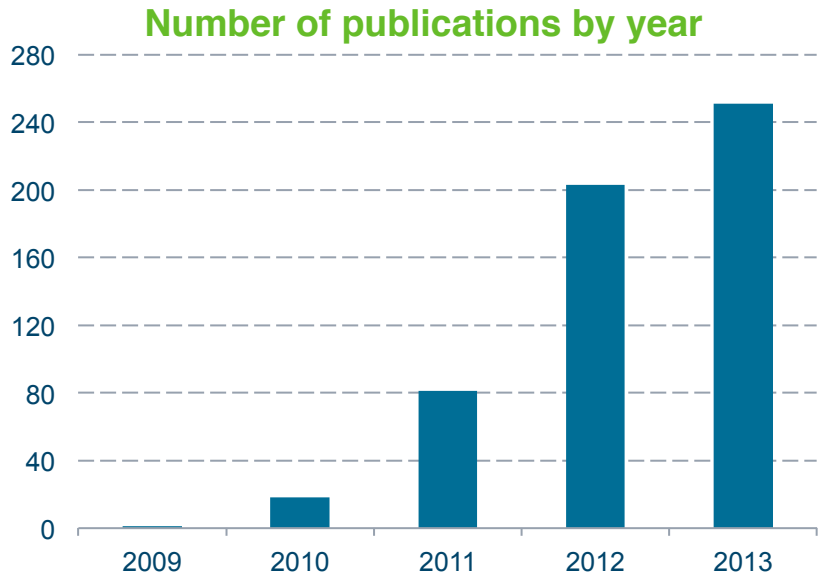
Abbott	Janssen
AbbVie	**Lundbeck**
AC IMMUNE	Merck
Amgen	**Novartis**
Astellas	NOVO NORDISK
AstraZeneca	**Orion Corporation**
BIOGEN IDEC	Pfizer
Boehringer Ingelheim	**Roche**
Eisai	Sanofi
Eli Lilly	**SERVIER**
ESTEVE	UCB
Grunenthal	**Vifor**
GSK	



Key Figures IMI Projects up to call 9



> 6000 researchers

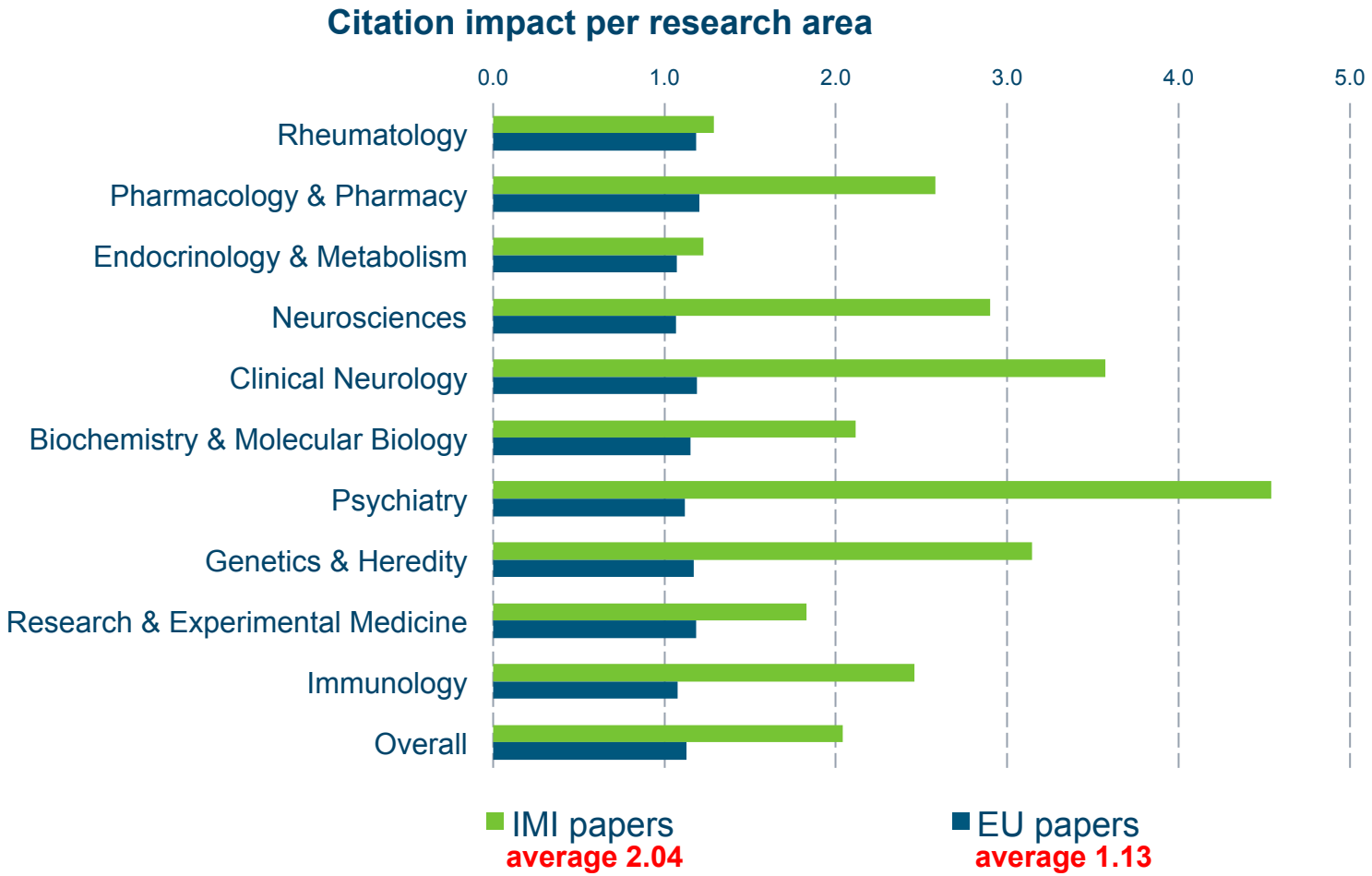


Collective intelligence networks
Improved R&D productivity of pharma industries
Innovative approaches for unmet public health needs

Research quality and dissemination of knowledge

~ 600 publications

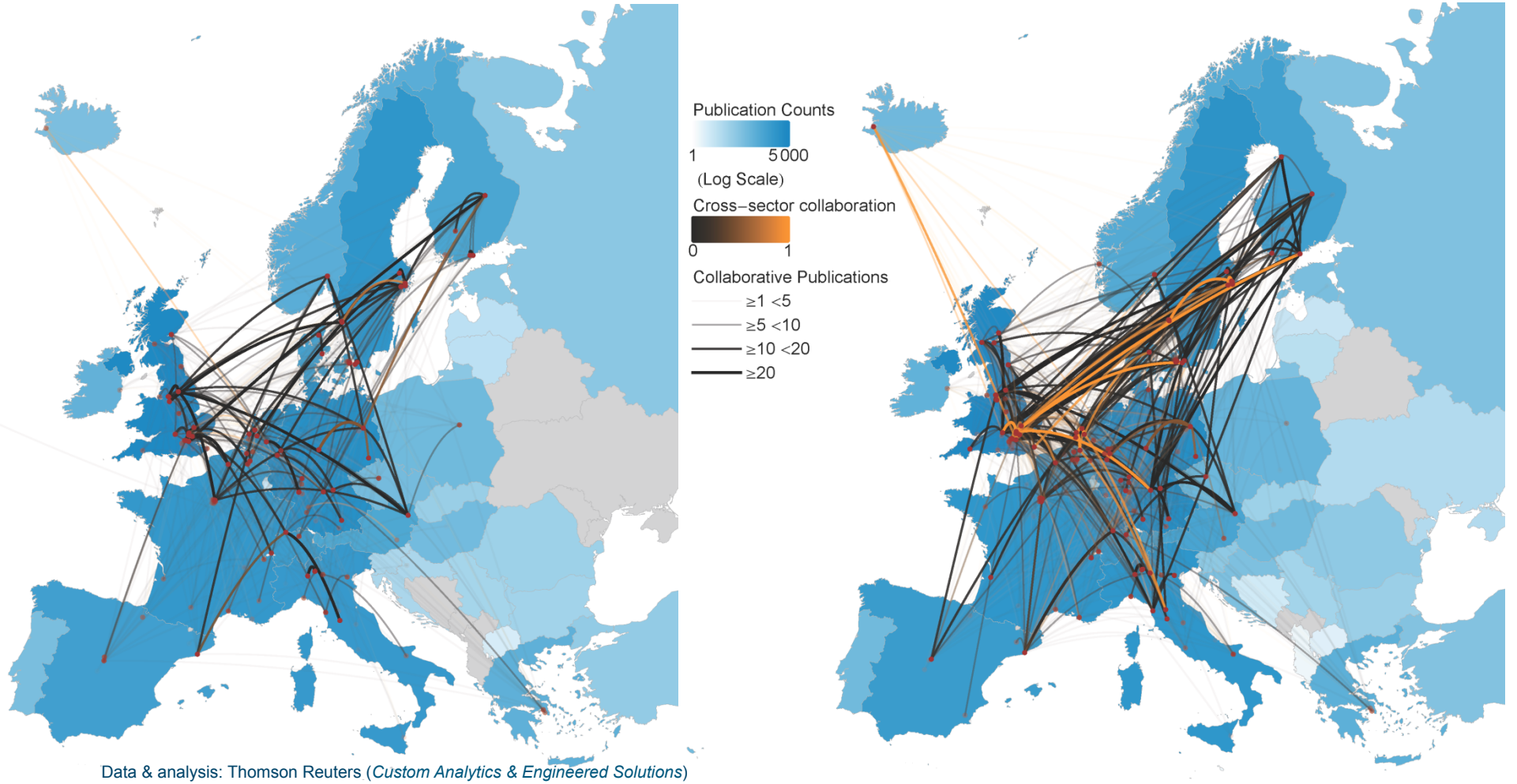
~ 25000 citations



IMI stimulates collaboration across EU

Co-authorship between IMI-supported researchers Calls 1-4

Pre IMI funding award

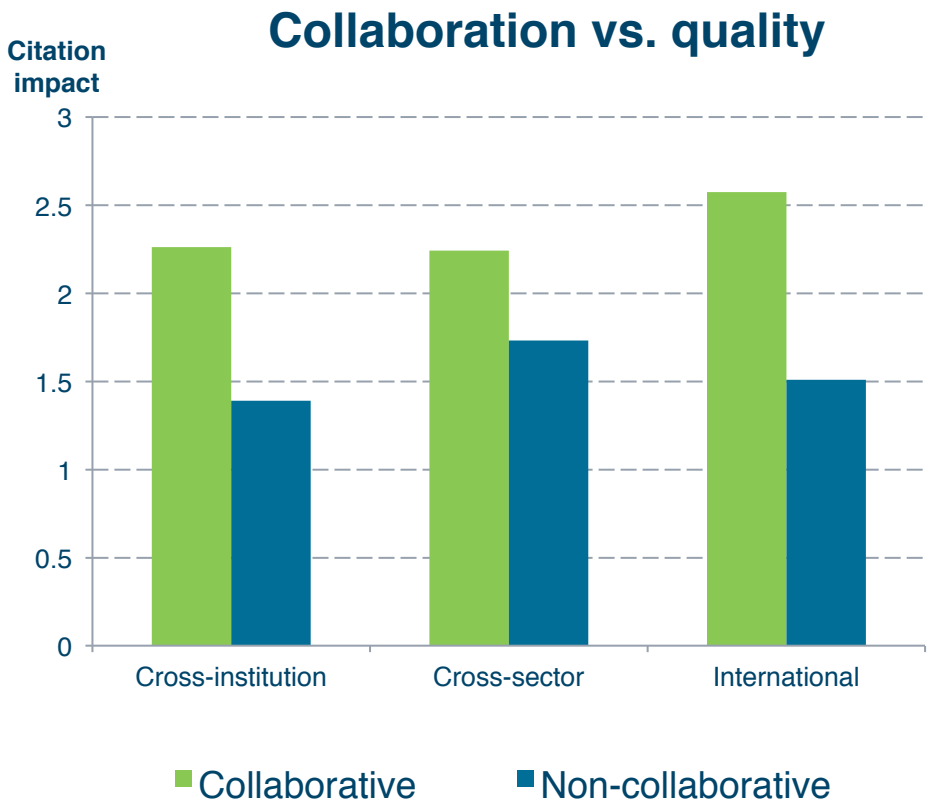


Post IMI funding award

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

Collaboration is key!

Type of collaboration	Percentage of publications
Cross-institution	61%
Cross-sector	75%
International	50%



IMI accelerates the development of new therapies for major yet unmet public health needs

Antimicrobial resistance – a growing threat

25 000

Europeans killed / year

€1.5 bn

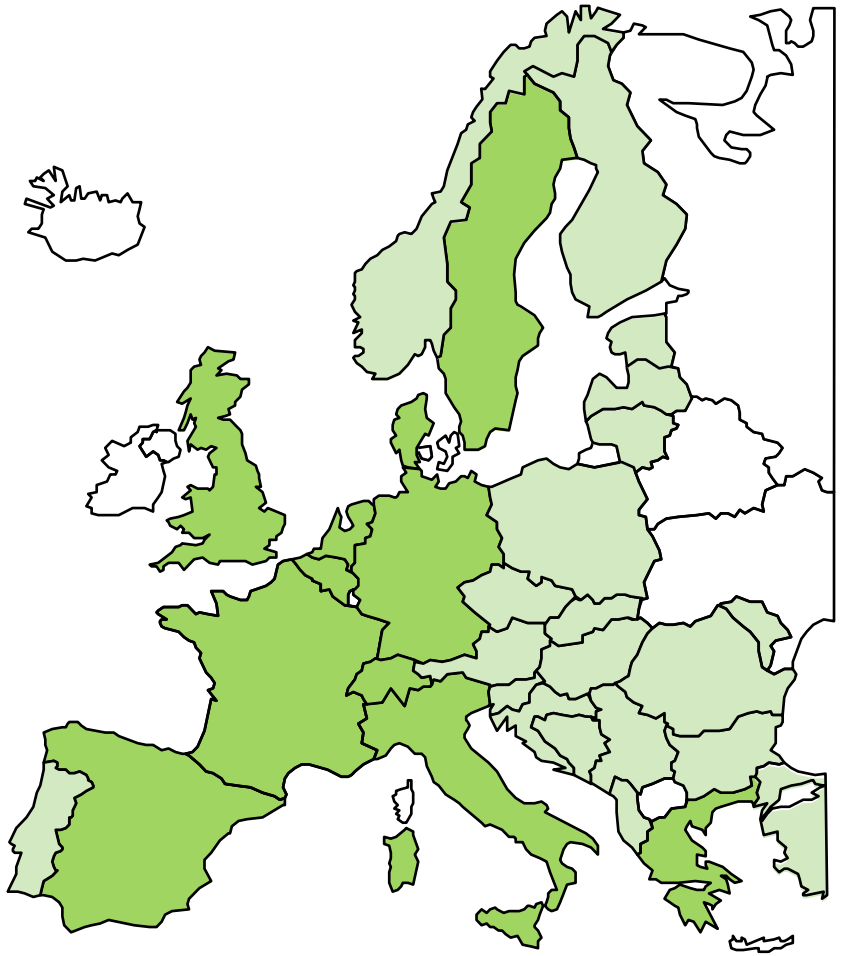
costs to economy / year

2 new classes of antibiotics in the last 30 years

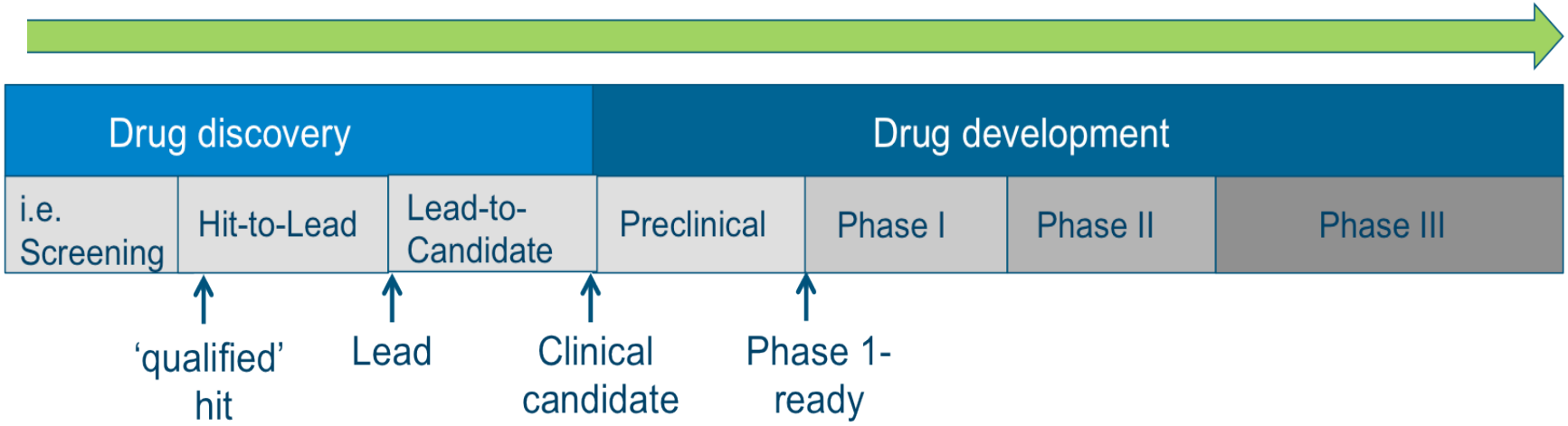
How IMI addresses Anti-Microbial Resistance: the ND4BB programme

IMI already invested **€712 million in:**

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



Discovery Centre of Excellence for Antibiotic Resistance



- Focuses on **Gram-negative infections**:
  E. coli, K. pneumoniae, A. baumannii, P. aeruginosa
- Invites **public** and **private** partners with antibacterial drug discovery experience and assets to collaborate
- Aims to combine expertise, knowledge and resources

Budget:
€58 M: European Union
€26 M: EFPIA industries

How IMI addresses brain disorders

Invested €183 million in projects aiming at:

- Shedding new light on the underlying **causes of autism** (EU-AIMS)
- Combining data to pave the way for **new treatments for schizophrenia & depression** (NEWMEDS)
- Identifying new targets for drugs for **chronic pain** (Europain)
- Developing models to **predict the efficacy** of drug candidates in Alzheimer's patients (PHARMACOG)
- Revisiting **regulatory environment** for drug development
- Providing necessary **incentives** for industry to reinvest in brain disorders

2 Largest Clinical Trials for Early Detection and Monitoring of ASD

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

Preclinical Alzheimer's disease

THE LANCET Neurology

Preclinical Alzheimer's disease and its outcome: a longitudinal cohort study

Stephanie J B Vos, Chengjie Xiong, Pieter Jelle Visser, Mateusz S Jasielec, Jason Hassenstab, Elizabeth A Grant, Nigel J Cairns, John C Morris, David M Holtzman, Anne M Fagan

Findings in preclinical Alzheimer's disease:

- ✓ common in cognitively normal elderly people
- ✓ can be diagnosed by cerebrospinal fluid markers
- ✓ associated with future cognitive decline and mortality – therapeutic target

How IMI facilitates the development of new diabetes therapies

IMI already invested **€117 million** in 3 projects aiming at:

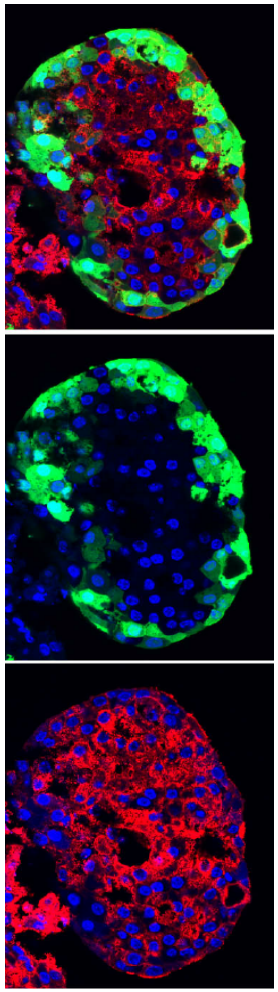
- Solving **scientific challenges**
- Developing reliable **measures of diabetes activity and complications**
- Developing **treatments tailored** to the different needs of individual patients

Biomarkers of Diabetic Complications

- ✓ Generated **the largest ever made database of GWAS** samples in diabetic nephropathy (DN) from patients with T1D & T2D - discovery of potential biomarkers
- ✓ Identified multiple **biomarker candidates** for diabetic related kidney damage, retina damage and coronary vascular disease
- ✓ Developed an ultrasound/radiofrequency-based virtual histology for non-invasive assessment of plaque structure
- ✓ **3 patents** in preparation

imidia
European combined excellence in diabetes research

Advances in Diabetes



- ✓ Discovered a lipid signature in the serum of mice fed with high fat diet that correlates with physiological readouts – **potential biomarker for diabetes**
- ✓ Generated the **1st human ß-cell line** (EndoCBeta H1) and its beta cell phenotype maintenance has been confirmed by 3 pharma partners
- ✓ Working on the 2nd generation human ß-cell lines with excisable immortality genes - more suitable for drug discovery purposes
- ✓ Generated the **world largest bio repository of human islets** for diabetes research, with a bioinformatical analysis of the genome, transcriptome, lipidome and morphological and physiological characteristics - 138 islets

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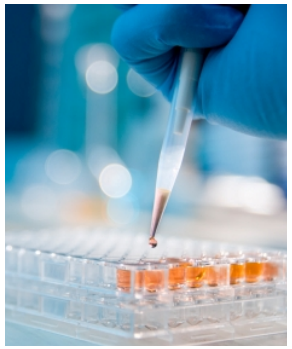
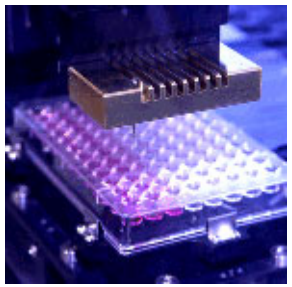
Safety and risk-benefit assessment of existing and future medicines

Safer and Faster Evidence Based Translation





Evaluated 153 potential biomarker candidates for drug-induced injury of the kidney, liver and vascular system

17 exploratory clinical studies started or completed

> 6500 retrospective samples collected

Dialogue with Regulatory Agencies established

- providing access to a huge amount of most relevant clinical safety data across all pharmaceutical companies and all major drug classes
- A drug safety signal detection system across global regulatory data is being set up initially with EMA data, driven by IMI and EFPIA

Development of reliable toxicity predictive systems

✓ 6th release of the **Vitic Nexus eTOX database**

831 substances (584confidential) linked to **1,703 study designs**

(Bayer, Boehringer, Esteve, GlaxoSmithKline, Lundbeck, Novartis, Pfizer, Roche, Sanofi, Servier and UCB)

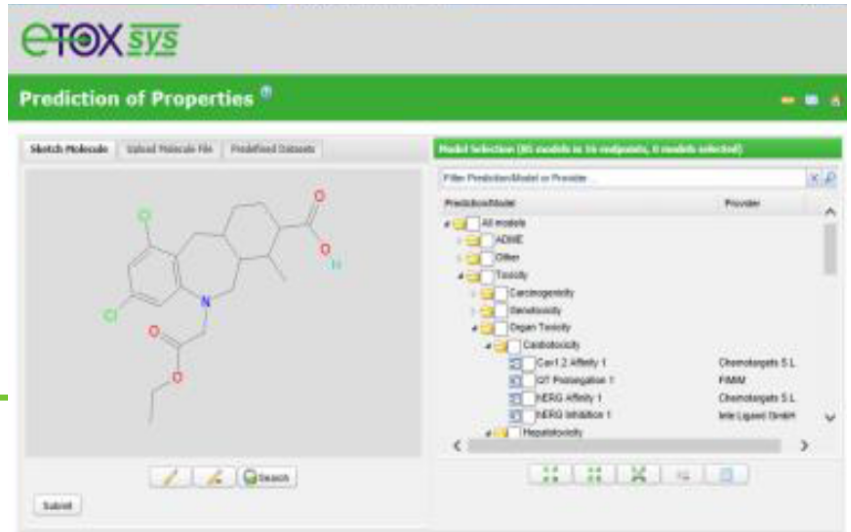
✓ 3rd release of the **ChOX database**

411 toxicology-linked targets; 162,287 distinct compounds and 701,181 activities

✓ Version 1 of the integration system, eTOXsys, was released to all partners

7 out of 10 companies already use the system

✓ **90 predictive models** developed



Advancing benefit-risk assessment methods

PROTECT

EUROPEAN MEDICINES AGENCY

+

4 other regulatory agencies

12 EFPIA companies

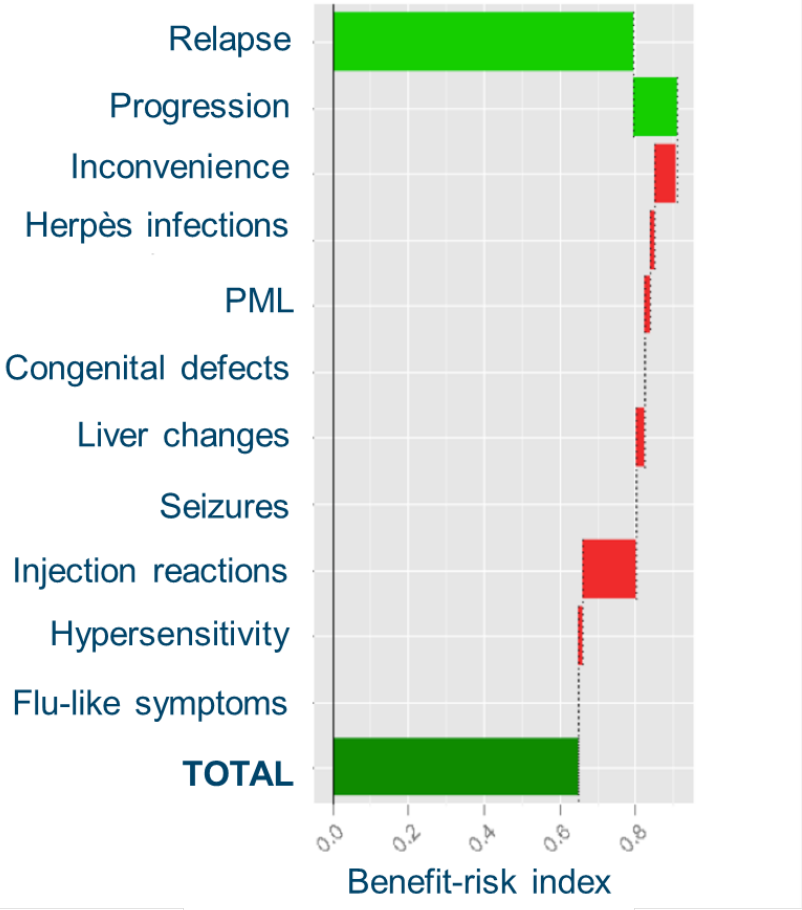
11 Academic institutions

1 Patient coalition

2 SMEs

Budget: 29.8 Mi €

Case study: Natalizumab



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IMI actively involves patients → PPP+P

Promoting Patient Involvements

- ✓ 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

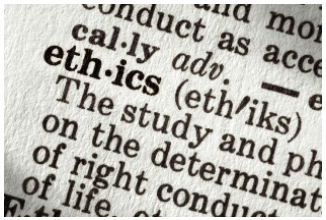
Public

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
BfArM
MHRA
swissmedic

Competent authorities

Policy makers

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



Research Ethics Committees

HTA agencies & committees

Clinical Research

EUPATI
European Patients' Academy
on Therapeutic Innovation

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

IMI 11th call for proposals
Opportunities to participate!

Application deadline - 8 April 2014 17:00

http://www.imi.europa.eu/content/11th-call-2013-8
http://www.imi.europa.eu/events/2013/12/03/imis-11th-call-webinars

IMI 11th Call - Topics

Call 11 Topic	Budget (€ million)	
	IMI JU	EFPIA
Identification and Validation of Innovative Clinical Endpoints for **Osteoarthritis**	7.50	7.50
European platform for proof of concept for prevention in **Alzheimer's disease**	25.00	28.19
Blood-based Biomarker assays for **personalised tumour therapy**: the value of circulating tumour cells, tumour DNA, and miRNA	6.62	7.36
Zoonoses Anticipation and Preparedness Initiative (ZAPI)	9.90	9.90
Generation of **research tools** to translate genomic discoveries into drug discovery projects	21.20	21.60
Clinical development of novel systemic **antibacterial molecules** against healthcare-associated infections (HAIs) caused by *Pseudomonas aeruginosa* and other Gram-negative bacterial pathogens	75.34	91.61
Development of novel **inhaled antibiotics treatment** regimen in patients with cystic fibrosis (CF) and patients with chronic obstructive pulmonary disease (COPD)	27.00	31.00
ECORISKPREDICTION (ERP)	3.00	3.88

Applied public-private research enabling osteoarthritis clinical headway (APPROACH)

Budget: €7,500,000 IMI; €7,500,000 EFPIA GlaxoSmithKline, Merck KgaA, Servier

Objectives:

1. Implement comprehensive and high quality **biomarker assessment** to characterise OA **patient subsets** and support future **regulatory qualification** and **endpoint validation**

2. Provide framework to identify **the "right patient" to treat** for a given drug
   - Link OA patient subsets to potential targets based on phenotypic biomarkers, highlight specific disease drivers and progression criteria

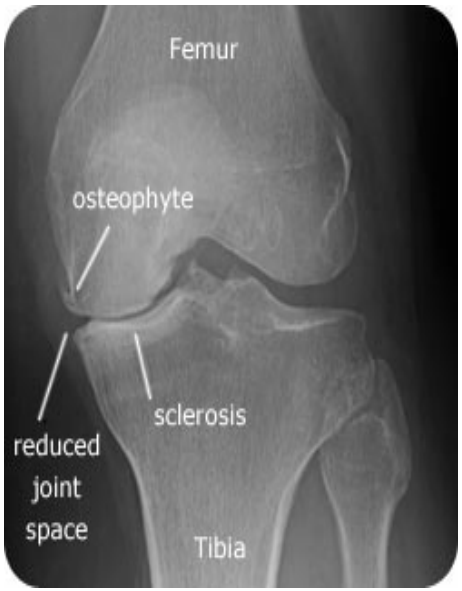
3. Build **stronger collaborations** within and among academic and industrial groups to enable future OA therapeutic development

Applied public-private research enabling osteoarthritis clinical headway (APPROACH)

Expected contributions of the applicants

- Workpackage co-leadership
- Statistical expertise
- Imaging and image analysis expertise
- Novel imaging modalities
- Biomarker discovery and Omics expertise
- Biochemical marker kits/reagents
- Existing biochemical marker data
- Access to OA patient cohorts
- Existing clinical samples
- Clinical centre with required infrastructure
- Sample processing/storage expertise
- Certified (CLIA) testing lab
- Strategic clinical/academic perspective
- Strategic patient perspective

Key stakeholders:
Academia
SME
Patient org.
Healthcare org.
Clinicians



European platform for proof of concept for prevention in Alzheimer's Disease (EPOC-AD)

Budget: €25,000,000 IMI; €28,193,000 EFPIA Janssen, Eisai, Roche, AbbVie, AC-IMMUNE, Amgen, Astellas, BIOGEN IDEC, BI, Lundbeck, Pfizer, UCB

Objectives

The overarching goal is to build an European Platform and a process to facilitate Proof of Concept Trials for prevention of Alzheimer's disease

- **EPOC Registry -** Build large primary care physician (PCP) networks and create **well characterised registry** of individuals at risk of developing AD dementia
- **A longitudinal natural history study** of at risk individuals to qualify and validate **biomarkers of disease subtype and/or progression** (genetic and imaging among others) and diagnostics critical to AD prevention, for selection and stratification of individuals to be enrolled in the trials. Novel diagnostics and/or endpoints might be included.
- Create a **novel adaptive clinical trial** approach for prevention of AD that will allow continuous testing and comparison of multiple different regimens as well as disease modelling, involving a shared and rotating placebo population to ensure that a greater percentage of participants receive investigational treatments

European platform for proof of concept for prevention in Alzheimer's Disease (EPOC-AD)

Expected contributions of the applicants

- Neurodegeneration & AD disease knowledge (epidemiology)
- Biomarker development expertise
- modelling and simulationCRO capabilities

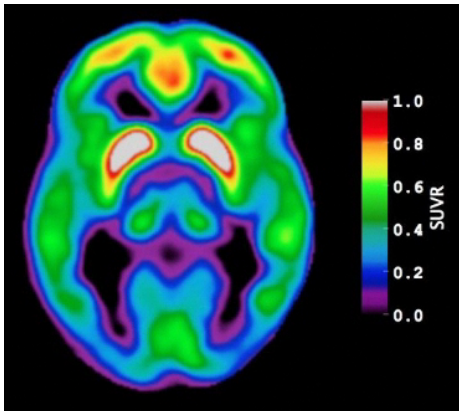
(biostatistics, clinical research and clinical trial including design, monitoring and GCP expertise, PK/PD, data and knowledge management, regulatory, ethics, patients, and relationship with patients, effectiveness/HTA)

- Project management

Valuable assets include:

- Relevant existing datasets and existing clinical studies
- Clinical cohorts of at risk individuals and registries
- Access to primary care physician networks
- Compounds that can be brought into the POC trial
- Involvement of patient organizations

Key stakeholders:
Academia
Hospitals
SMEs
Patients & patient org.
Public health org.
Regulators
HTA bodies



Blood-based biomarker assays for personalized tumour therapy: value of latest circulating biomarkers

Budget: **€6,620,000 IMI**; €7,360,000 EFPIA
Bayer, BI, Eli Lilly, Menarini, Orion, Servier

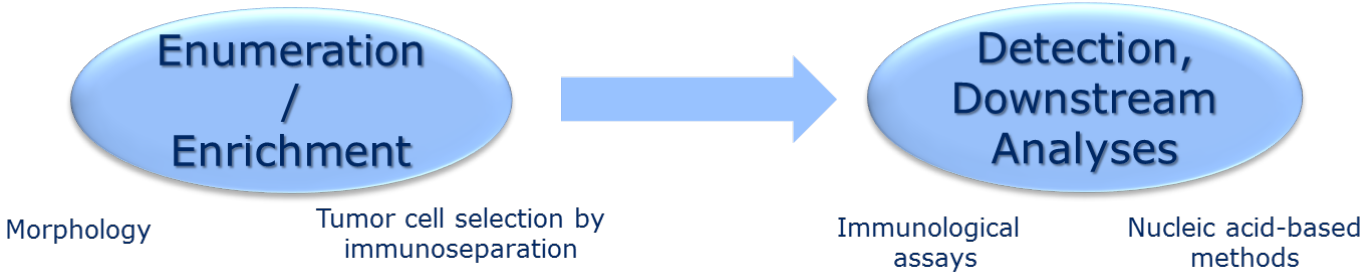
Objectives:

- Establishment, technical and clinical validation of methods for predictive blood-based biomarkers (***patient stratification/predictive biomarkers***), monitoring of treatment response (***surrogate biomarker***s and ***prognostic biomarkers***)
- Development of blood-based ***companion diagnostics*** (CDx)
- Validation of biomarker assays

Pre-evaluation phase - Selection of the most promising concrete technologies based on available data. Criteria for evaluation of key parameters need to be defined (e.g. what defines a circulating tumor cell?).

Technical evaluation phase - Selected technologies to be applied using the standards defined, preferentially head to head. Using in vitro and animal studies the technologies comparison e.g. with regard to sensitivity, reproducibility, predictivity etc.

Clinical validation phase – Selected technologies will be used to run analysis in retrospective samples from well-defined patients and in prospective clinical studies.

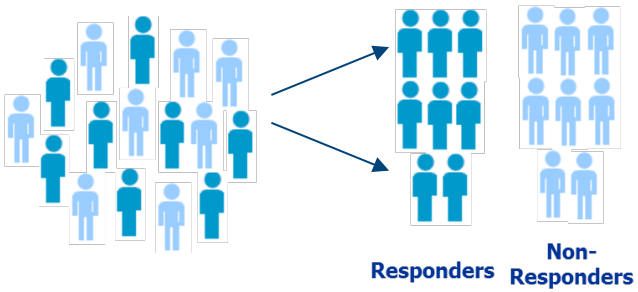


Blood-based biomarker assays for personalized tumour therapy: value of latest circulating biomarkers

Expected contributions of the applicants

- Applicant Consortium should address all research objectives outlined above
  - clinicians with expertise in the field and having access to clinical samples
  - academic research groups with a track record in the molecular analysis of CTCs or ctDNA
  - SMEs with established close-to-the-market technologies for CTC isolation and analysis
  - Additional required expertise includes:
    - bioinformatics,
    - *in vivo* and *in vitro* models for CTCs.
- The EFPIA Participants would highly welcome the involvement of regulatory authorities (EMA, FDA) early on in the project either as official partners or as member of the Advisory Board.

Key stakeholders:
Academia
SME
Clinicians
Regulators



Zoonoses anticipation and preparedness initiative (ZAPI)

Budget: **€9,900,000 IMI**; €9,900,000 EFPIA
Merial, Sanofi, Boehringer Ingelheim, Medimmune

Objectives:

Definition of fast-track manufacturing processes for providing biological control tools (**vaccines** and/or **antibodies**) against (re-) emerging **viral diseases with pandemic potential**

Specific objectives:

- **Ultra-fast screening processes** for identifying key protective immunogen(s) and corresponding neutralizing proteins (antibodies or antibody-like proteins)
- **Validated GMP processes for:**
  - Manufacturing system(s) enabling surge capacity and short QC release for neutralizing reagent (antibody or antibody-like proteins)
  - Vaccine manufacturing system(s) enabling surge capacity and short / immediate, fully *in vitro*, QC batch release assays
- **Pre-approved regulatory process:** allowing fast track review for vaccines, antibodies, (and antivirals) in the context of a new zoonosis (based on current model developed for human influenza vaccine).

Zoonoses anticipation and preparedness initiative (ZAPI)

Expected contributions of the applicants

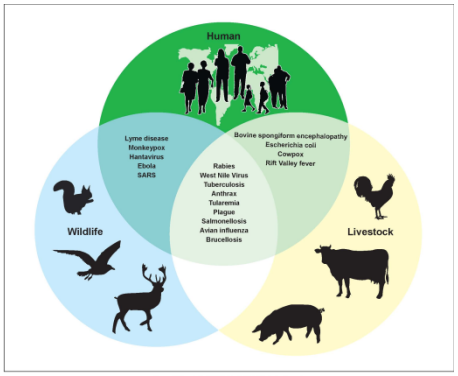
State-of-the-art scientific and technical expertise for zoonotic diseases

- Immunology, microbiology, antibody neutralization and immunoprofiling assay technologies
- *in silico* immunogen design, interactive database development innovative expression systems able to support the objectives of the project

Key stakeholders:
Academia
SME
Public health org.
Animal health org.
Regulators

Capability and capacity to design new universal tools:

- *In silico* design of candidate immunogens for expression as subunits or VLPs in recombinant systems
- Design universal libraries for antibody molecules from multi-species origin
- Design HTS techniques for neutralization assays
- Provide basic knowledge for immunoprofiling assays



Generation of research tools to translate genomic discoveries into drug discovery projects

Budget: **€21,200,000 IMI**; €14,800,000 EFPIA
Novartis, Bayer, Janssen, Pfizer

Objectives:

Expand the range of drug targets required to address unmet medical need

- Translate genomic discoveries into **enabling research tools** for proteins linked to disease
- Exploit these tools systematically in relevant models of human disease (derived from human tissue) for **target identification & validation** and **lead discovery**
- Initial focus should be on targets related to inflammatory mechanisms and diseases with an emphasis on epigenetic regulators as well as ion channels & solute transporters.

Generation of research tools to translate genomic discoveries into drug discovery projects

Expected contributions of the applicants

The Applicant Consortium is expected to demonstrate excellence and track record in:

1. **Expertise and leadership in protein science & assays**

   Human protein structures, cell-based assays of inflammatory mechanisms

2. **Established wide and continuously evolving network of thought leaders in all sectors**

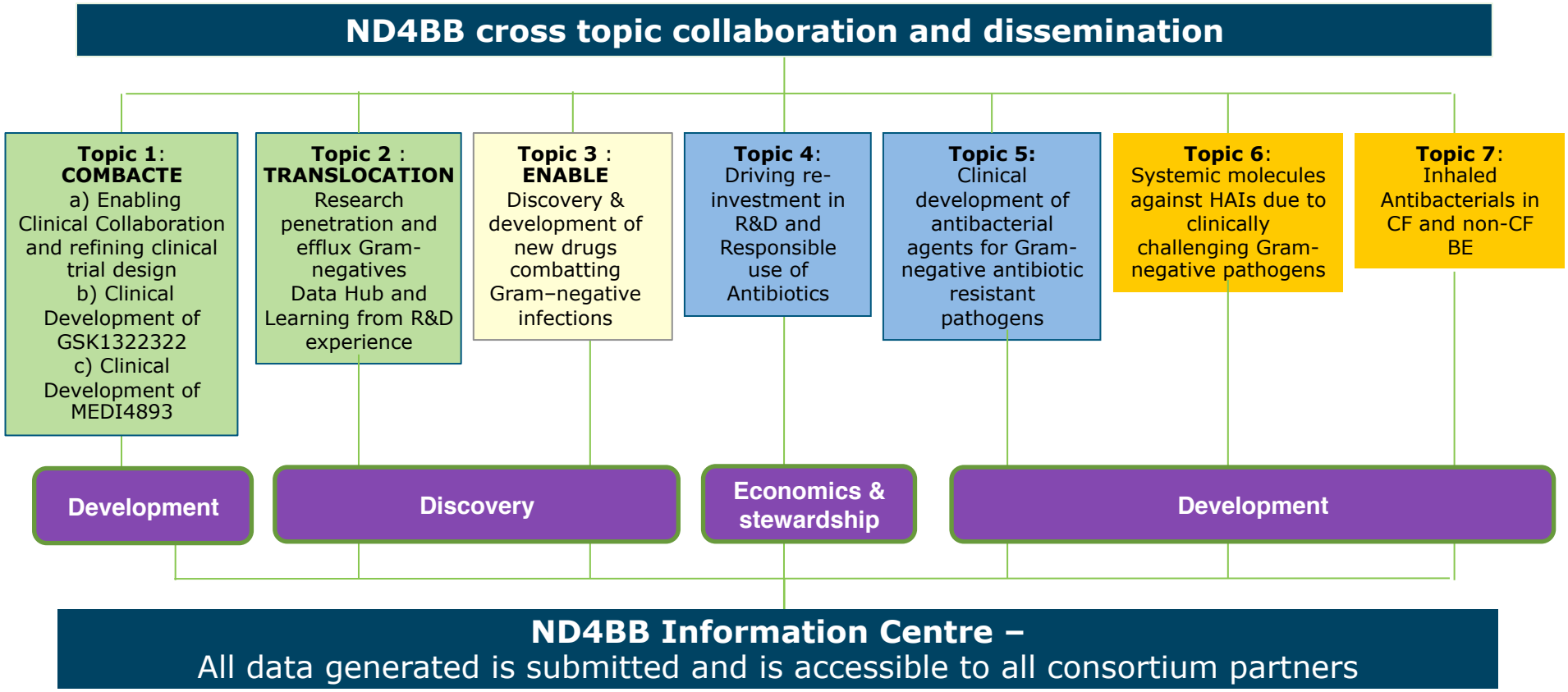
   Chemistry, biological assays, human biology, genetics and the clinic

3. **Track record of successfully collaborating with industry**

   Impact on internal drug discovery projects

Key stakeholders:
Academia
SME

New Drugs For Bad Bugs (ND4BB) programme



ND4BB Topic 6: Development of novel systemic molecules against healthcare associated infections caused by Clinically Challenging Gram-negative bacterial pathogens

Budget: **€75,340,200 IMI**; €91,610,000 EFPIA AstraZeneca/MedImmune, AiCuris, GSK, Basilea, Sanofi, Novartis

Objectives:

- To develop a coherent **epidemiology strategy** and organise pertinent expertise and available data sources in Europe and across ND4BB in support of public health and drug development priorities related to antimicrobials
- Describe epidemiology of HAIs due to P. aeruginosa and other Gram-negative pathogens to help support the development of novel molecules against these infections
- Estimate the impact of preventive or therapeutic interventions against serious P. aeruginosa disease, and any impact on antimicrobial resistance of P. aeruginosa
- Clinical development of BiS4aPa, a novel anti-pseudomonal antibody for the prevention of P. aeruginosa ICU pneumonia
- Clinical development of a novel resistance-breaking beta-lactam antibiotic, AIC499, in combination with a beta-lactamase inhibitor (BLI) for the treatment of severe bacterial infections due to Gram-negative pathogens, including complicated urinary tract infections (cUTIs) and complicated intra-abdominal infections (cIAIs)

ND4BB Topic 6: Development of novel systemic molecules against hospital associated infections caused by Clinically Challenging Gram-negative bacterial pathogens

Expected contributions of the applicants

- Experts in active-surveillance, observational epidemiology, and clinical studies in ICU bacterial infections to participate in pan-European consortium
- Expertise in immunointervention or prophylaxis for infectious diseases in the ICU populations
- Expertise in paediatric PK studies
- Project leadership and coordination infrastructure
- Data storage, processing, and analysis capabilities
- Hospital and healthcare institutions to join a clinical trial network with capability to run Phase 1, 2 & 3 clinical trials and epidemiology surveillance studies
- Experts in diagnostics suitable for use in clinical trials, and in novel biomarker research
- Coordination & conduct of microbiology surveillance programs
- Clinical research organisation with relevant global experience

Key stakeholders:
Academia
Research centers
SMEs
CROs
Hospitals

ND4BB Topic 7: Development of novel inhaled antibiotic regimens in patients with cystic fibrosis (CF) and patients with non-CF bronchiectasis (BE)

Budget: **€27,000,000 IMI**; €31,000,200 EFPIA
Novartis, Basilea

Objectives (CF):

To improve care in CF patients, there is an increasing need in gaining experience with inhaled antibiotic combination regimens, in particular in identifying combinations with additive or synergistic effects.

- Determine compound X with synergistic antibacterial effects against Pa and other difficult to treat Gram-negative bacteria when combined with tobramycin.
- Inhaled formulation and preclinical development of BAL30072 and compound X.
- Clinical PoC study to explore alternating monthly or simultaneous combination therapies of inhaled compound X and tobramycin dry powder (TIP) for long-term suppressive antimicrobial therapy
- Clinical development (ph1 and ph2 studies) of inhaled BAL30072 against respiratory infections with Gram-negative (including multidrug-resistant) pathogens in patients with CF.
- Explore novel endpoints such as lung clearance index and imaging.
- Build on LAB-net (COMBACTE) by defining and adding laboratories with a track record in the field of sputum microbiology and lung microbiomes.
- Build capability for storage of non-fermenter strain samples for future research.

ND4BB Topic 7: Development of novel inhaled antibiotic regimens in patients with cystic fibrosis (CF) and patients with non-CF bronchiectasis (BE)

Objectives (BE):

In non-CF BE, infection with P. aeruginosa is linked with more rapid disease progression and a higher risk of morbidity and mortality. No inhaled antibiotics are approved for this indication and there is a high need for controlled studies with clinically relevant endpoints.

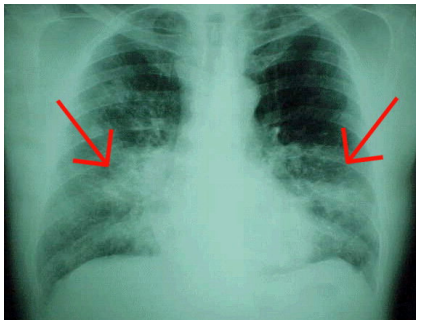
- Clinical development (ph2 and ph3 registration studies) of tobramycin powder for inhalation (TIP) against Pseudomonas aeruginosa (Pa) respiratory infections in patients with non-CF BE.
- Clinical development (ph1 study) of inhaled BAL30072 against respiratory infections with Gram-negative (including multidrug-resistant) pathogens in patients with non-CF BE
- Support alignment and coordination between current local or pan- European initiatives that have or are in the process of setting up registries for non-CF bronchiectasis with the goal to arrive at a EU-wide registry with information on frequency of the disease, use of medication, microbiology, co-morbidities, prognosis etc.

ND4BB Topic 7: Development of novel inhaled antibiotic regimens in patients with cystic fibrosis (CF) and patients with non-CF bronchiectasis (BE)

Expected contributions of the applicants

- Proposal for and **execution** of a plan for the **management** of all aspects of the **clinical studies**, e.g. clinical sites selection/ management, monitoring, collection and analysis for microbiology and PK, central evaluation of CT-scans
- Expertise in the design and conduct of CF and non-CF BE clinical studies including alternative study designs and endpoints (e.g. Imaging, LCI)
- Laboratories with a track record in sputum microbiology
- Involvement with data-registries of non-CF BE
- Proposal for and execution of plans for microbiology and pharmacology studies to determine compound X
- Non-clinical data package BAL30072 and compound X
- Proposal for and execution of plans for inhalation formulation development of BAL30072

Key stakeholders:
Academia
Research centers
SMEs
CROs
Hospitals



Ecorisk prediction (ERP)

Budget: **€3,000,000 IMI**; €3,884,200 EFPIA
Bayer Pharma, Novartis, AstraZeneca, Roche, Johnson and Johnson, Merck, Pfizer, Sanofi

Objectives:

- Develop experimentally validated methodology based on scientific information on specific properties of pharmaceutical compounds in order to predict a response in environmental organisms
- Establish an **ecotoxicological database** for pharmaceuticals to identify predictive elements for ecotoxicological hazards in close collaboration with other EU (co-)funded projects
- Develop **recommendations** for the use of the results of the project for prioritizing legacy products for experimental testing and in early development programmes for new compounds
- Develop recommendations for closing knowledge gaps and evaluating the questions about **risks of pharmaceuticals in the environment**

Ecorisk prediction (ERP)

Expected contributions of the applicants

- **SMEs**: Support the development of in vivo, in vitro and in silico tools for ecotox hazard identification, prioritisation and risk assessment , identify and extract public data and populate a ecotoxicological data base
- **Academia**: Elaborate theoretical and experimental testing programmes, development of in vivo, in vitro and in silico tools for ecotox hazard identification
- **Regulatory Institutions**: Contribute with available information on registered APIs and the existence of ERAs
- Advisory committee with key stakeholders from industry, academia and regulators: Evaluate and discuss appropriate assessment strategies to address the issue of pharmaceuticals in the environment

Key stakeholders:
Academia
SME
Regulators

Innovative Medicines Initiative

Questions?

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