From IMI to IMI2 new models of collaborative research

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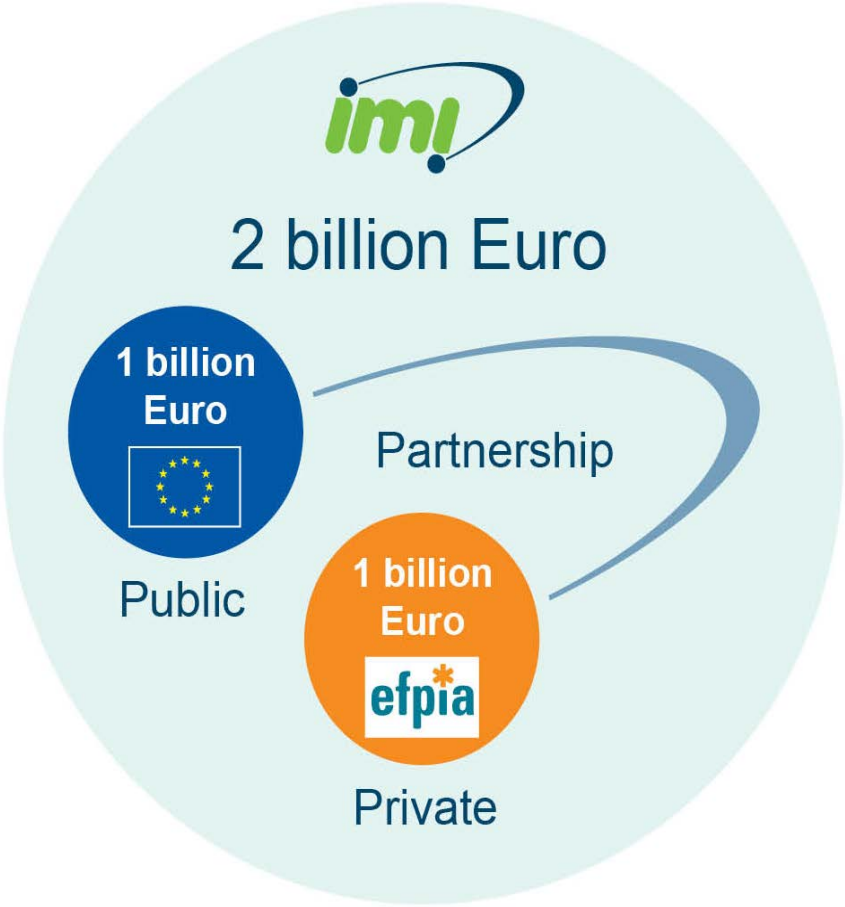
European Federation of Pharmaceutical Industries and Associations
www.efpia.eu

What is IMI and 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

The role of the IMI Executive Office

A neutral broker:

- To **implement** programmes and activities in the **common interest** of **all** stakeholders
- To **monitor** the use of public funds and industry investment
- To **guarantee** fair and reasonable conditions for optimal knowledge exploitation and dissemination
- To **facilitate** the interaction between stakeholders, including Intellectual Property agreements
- To actively **communicate** and promote IMI and its activities

From topic definition to project start

Topic definition phase

EFPIA consortium

Identification of topic and willingness to collaborate by EFPIA companies

STAGE 1

Hospitals
Academic research teams
SMEs
Patients' organisations
Regulatory authorities

Submission of Expressions of Interest by applicant consortia
&
Evaluation by independent experts

STAGE 2

Applicant consortium
EFPIA consortium

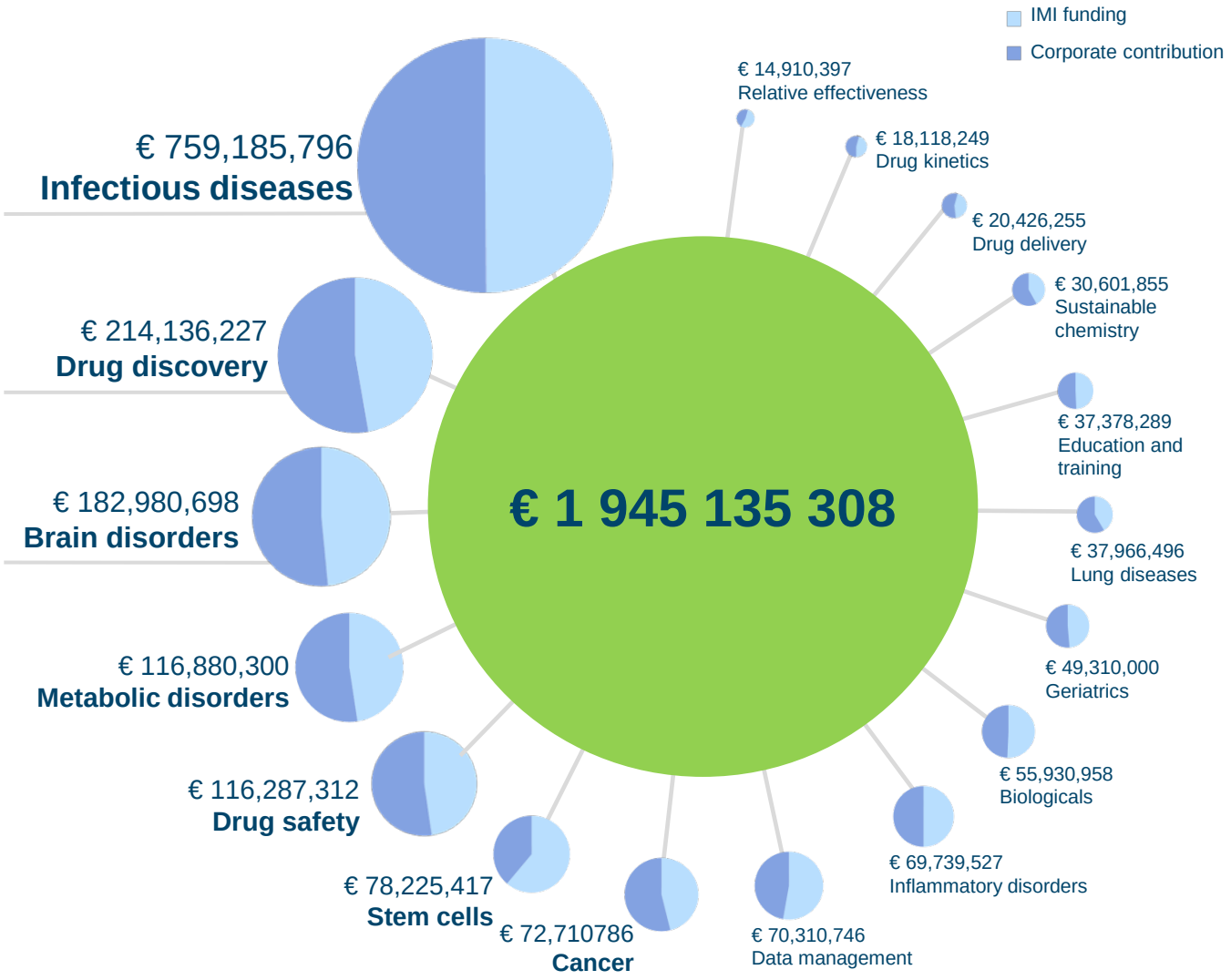
Preparation of Full Project Proposal
&
Evaluation by independent experts/ethical panel

Negotiation phase

Signature of Project Agreement and Grant Agreement

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

IMI delivers to patients, society and industry



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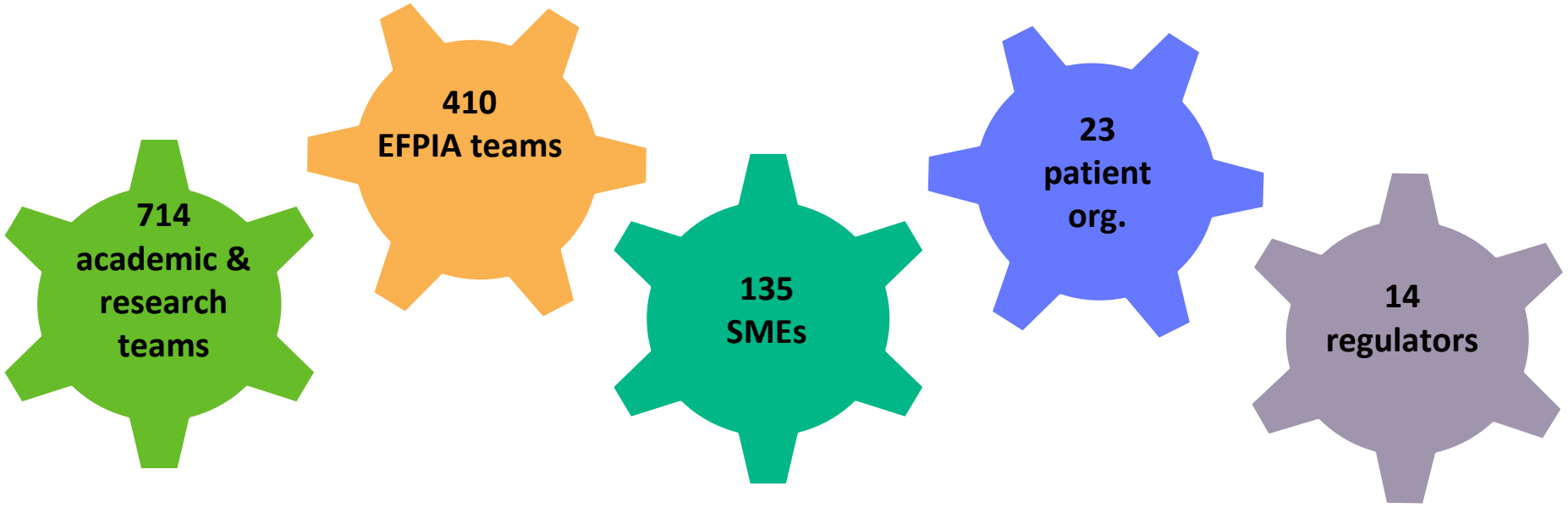
The IMI Community

Innovative Medicines Initiative

Calls 1-8 ➡ 46 projects ➡ > 6000 researchers



61% of projects reported some form of **PATIENT INVOLVEMENT**

REGULATORS ON BOARD OF **12** PROJECTS

50% of projects have **REGULATORY AUTHORITIES** representatives in Scientific Advisory Boards

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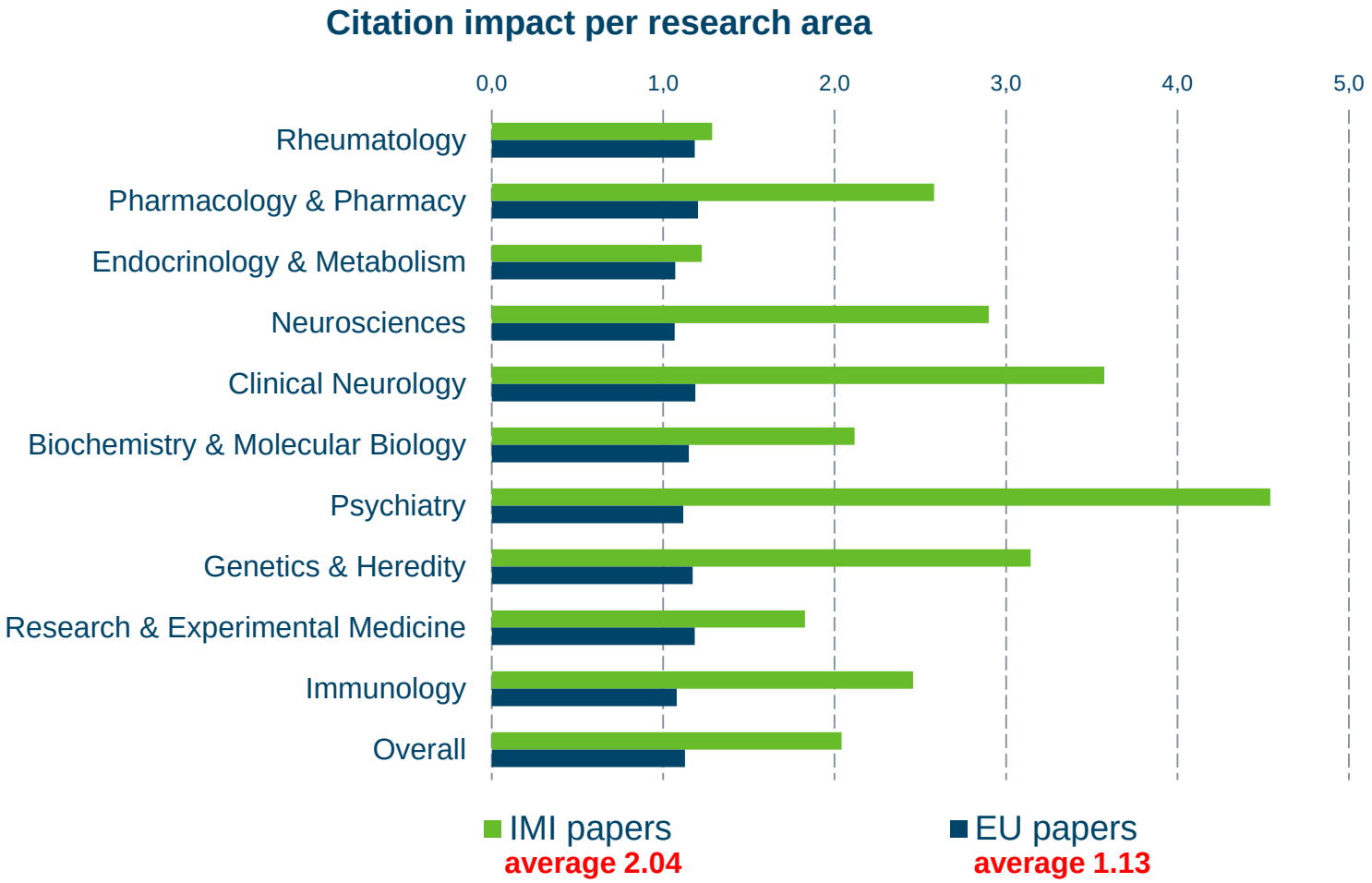
Research quality and dissemination of knowledge

~ 600 publications

~ 25000 citations



IMI1 & Brain

- AETIONOMY - Organising mechanistic knowledge about neurodegenerative diseases for the improvement of drug development and therapy
- EU-AIMS - European Autism Interventions - a Multicentre Study for Developing New Medications
- NEWMEDS - Novel methods leading to new medications in depression and schizophrenia
- PHARMACOG - Prediction of cognitive properties of new drug candidates for neurodegenerative diseases in early clinical development
- EPOC AD - European platform for proof of concept for prevention in Alzheimer’s Disease

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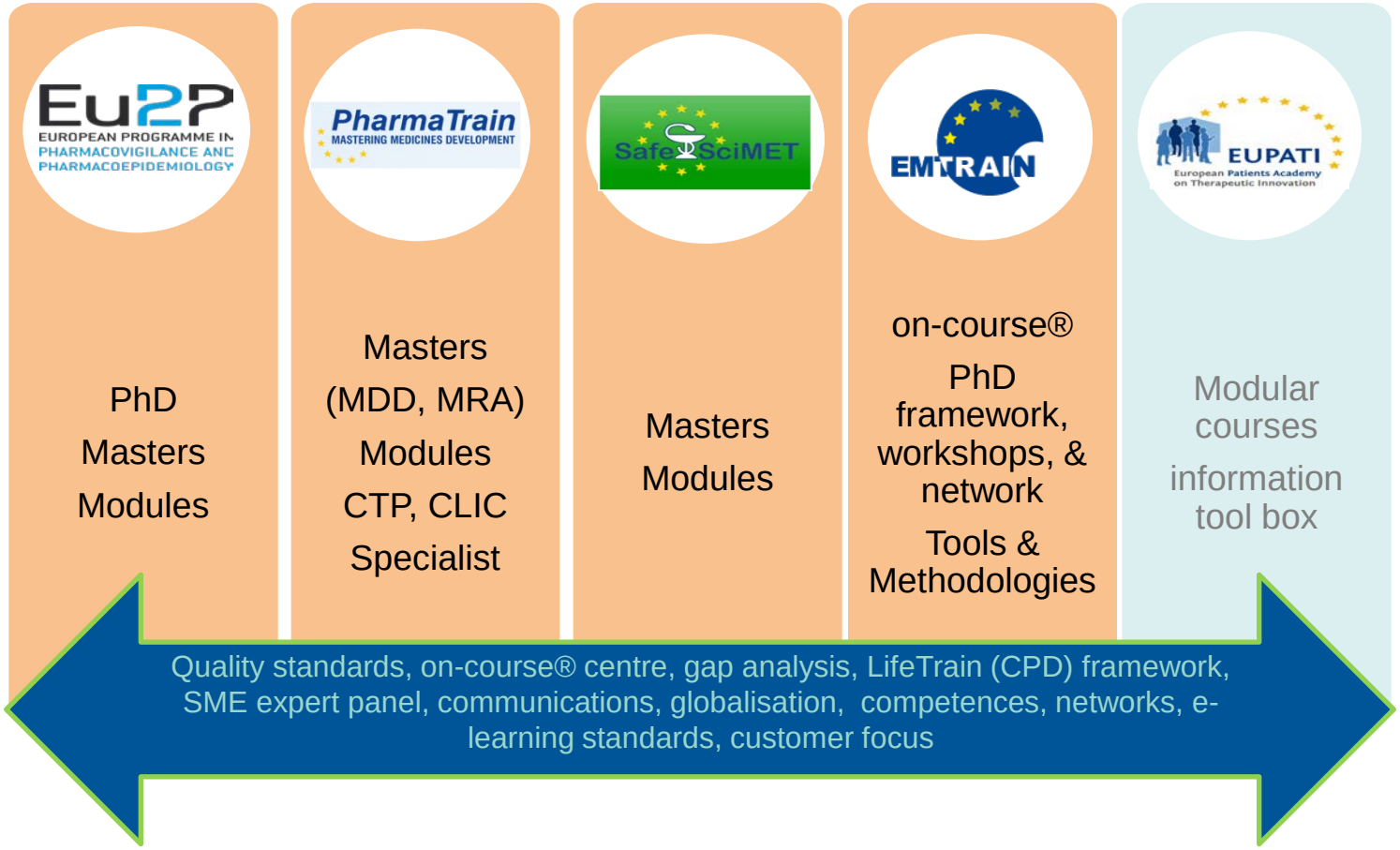
Education and Training



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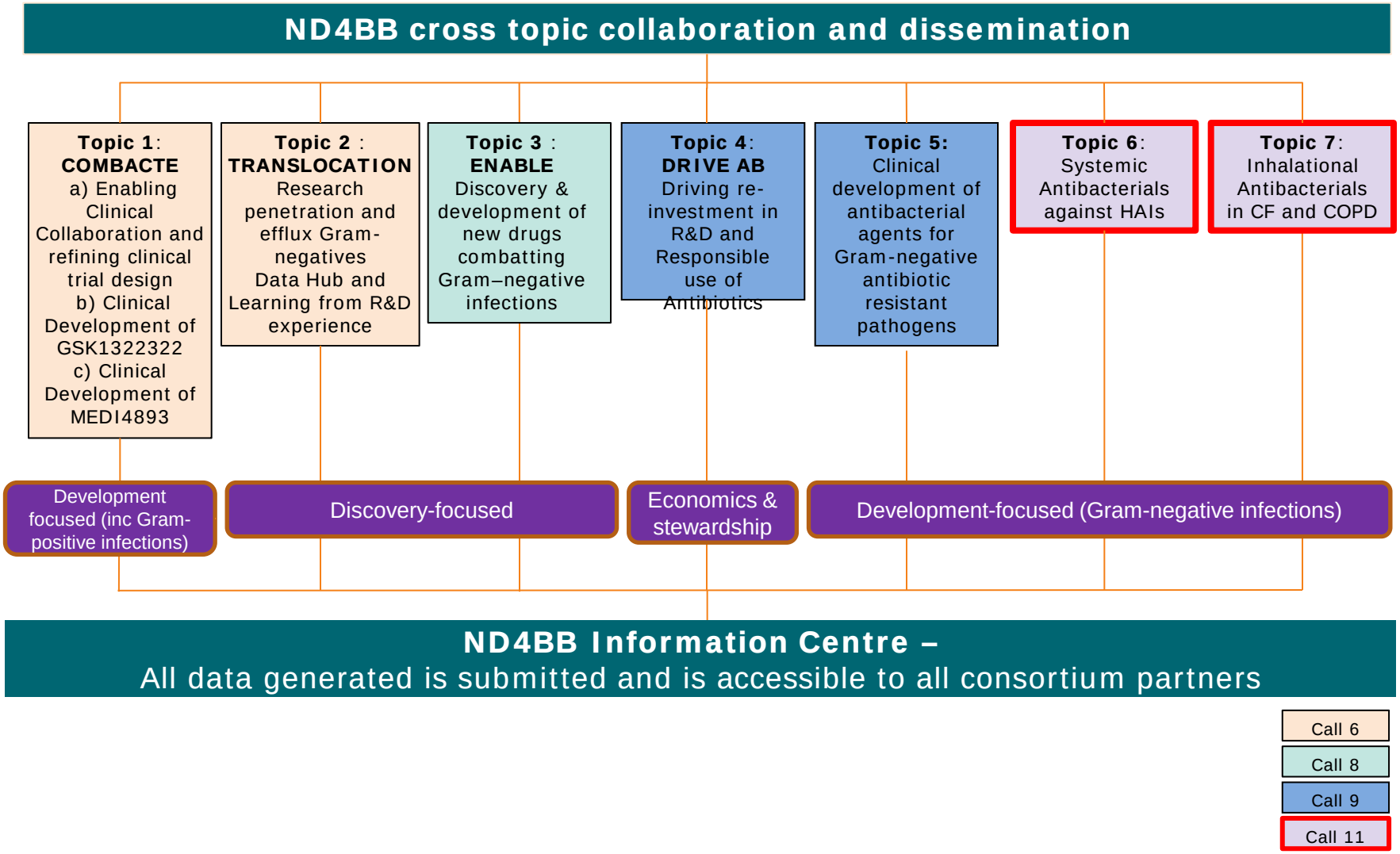
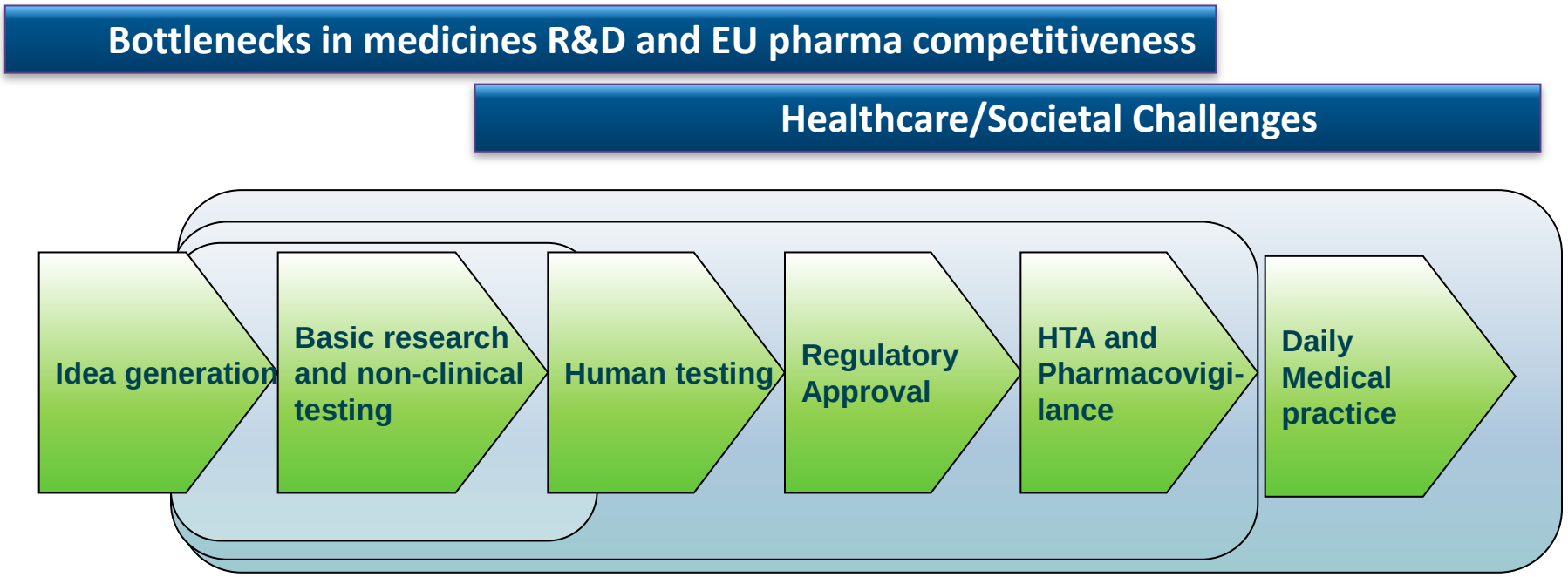
New Drugs for Bad Bugs (ND4BB)

An IMI1 comprehensive programme



From IMI to IMI2 – new opportunities

Innovative Medicines Initiative 1 & 2



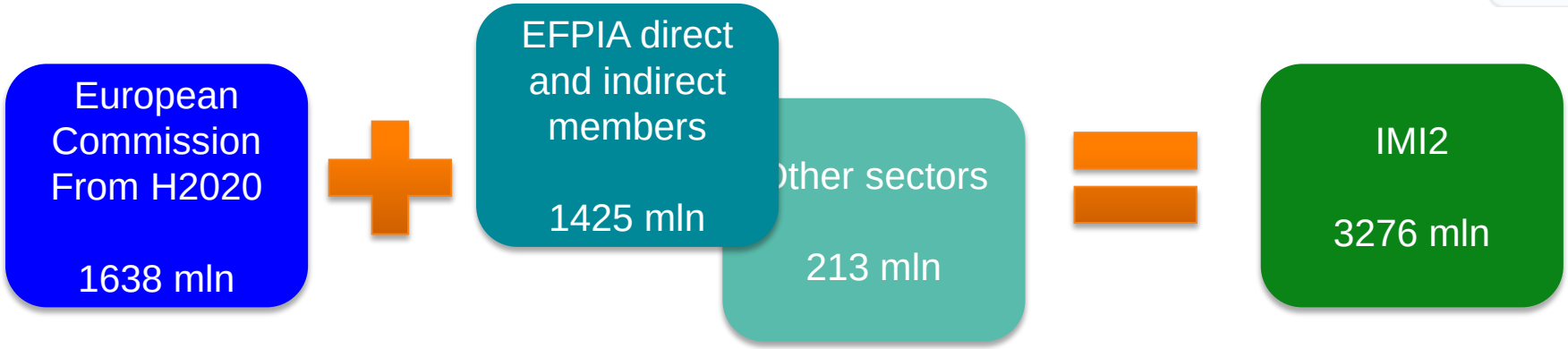
Primary focus of early IMI calls 2007 SRA

Shift to also addressing challenges in in society and healthcare 2011 SRA

IMI 2 includes real life medical practice 2013 SRA

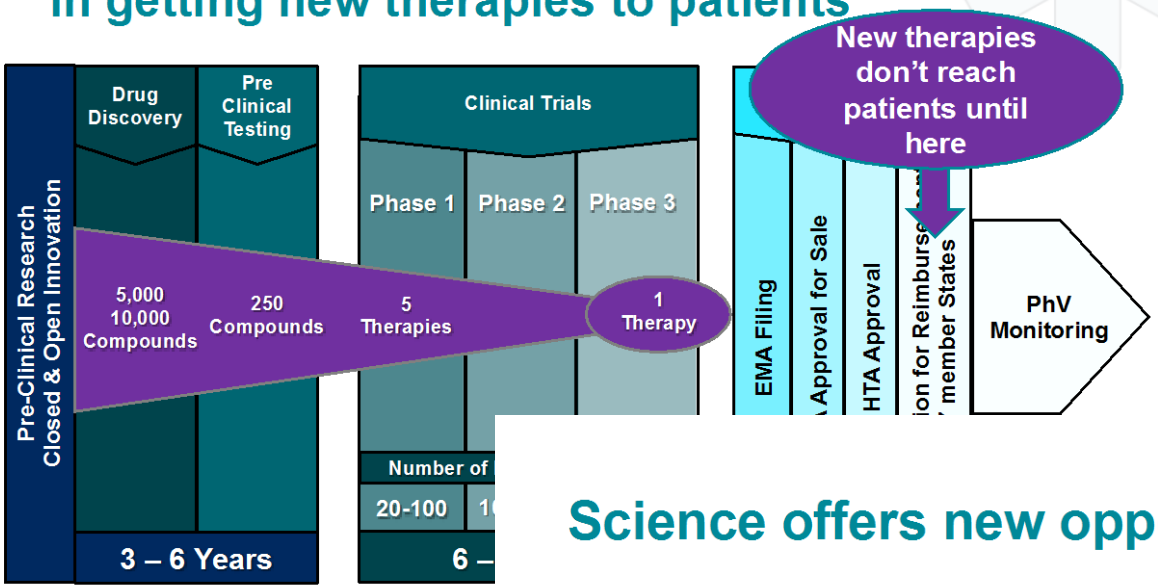
SRA – Strategic Research Agenda

IMI 2 – building on successes of IMI1



- Focused: stratified medicines and healthcare priorities
- Healthcare solutions: prevention and treatment
- End-to-end: R&D, regulatory and access – move integration a step further
- Multi-sector: within and beyond life sciences

Current EU pathways are expensive and slow in getting new therapies to patients



Total Cost: $2 - $4 Billion USD

Sources: Drug Discovery and Development
CBO, *Research and Development in the Ph*
Forbes, Matthew Herper, "The Truly Stagge

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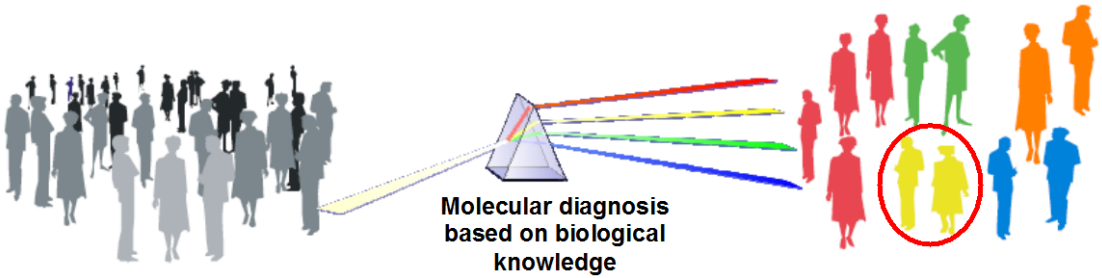
Science offers new opportunities



We treat a population.
Some respond and some don't

We treat a *targeted* population
They all respond

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IMI2 Strategic Research Agenda (SRA)

Comprehensive framework for a 10-year programme

Prepared with input from 80+ organisations (internet and targeted)

Project ideas from industry and third parties will be screened against it

http://goo.gl/jqMP9g

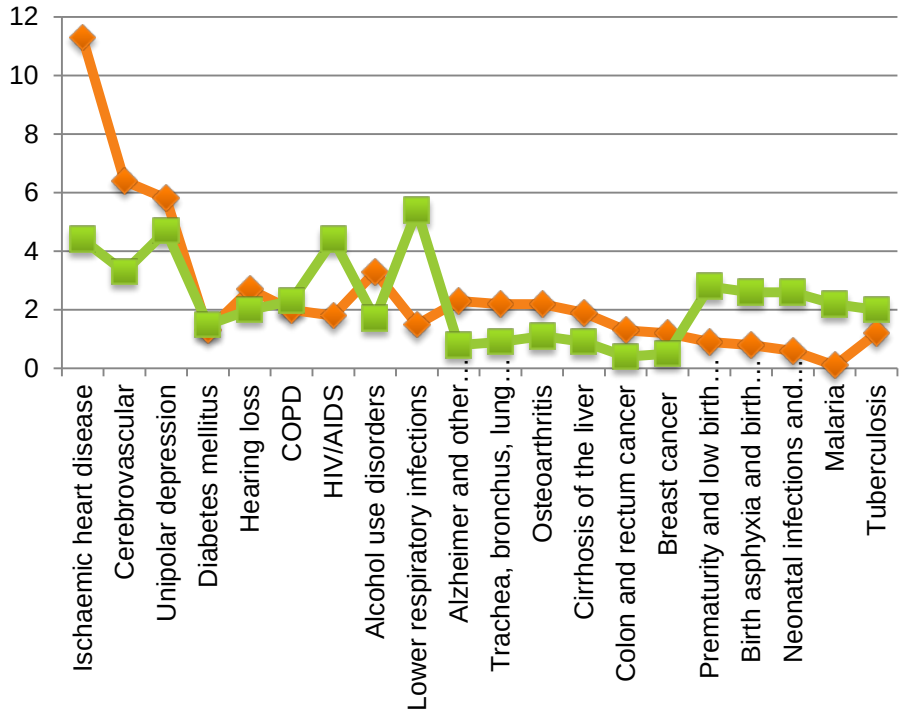
Objectives of IMI2 – what the Regulation says

- increase the success rate in clinical trials
- where possible, reduce the time to reach clinical proof of concept in medicine development
- develop new therapies for diseases for which there is a high unmet need and limited market incentives
- develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
- reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks;
- provide support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products.

Therapeutic areas covered by the IMI2 SRA

WHO 2013 report on priority medicines for Europe and the World

Percentage of DALYs for top 20 high burden diseases and conditions



Therapeutic Areas in IMI2 SRA

(no priority order)

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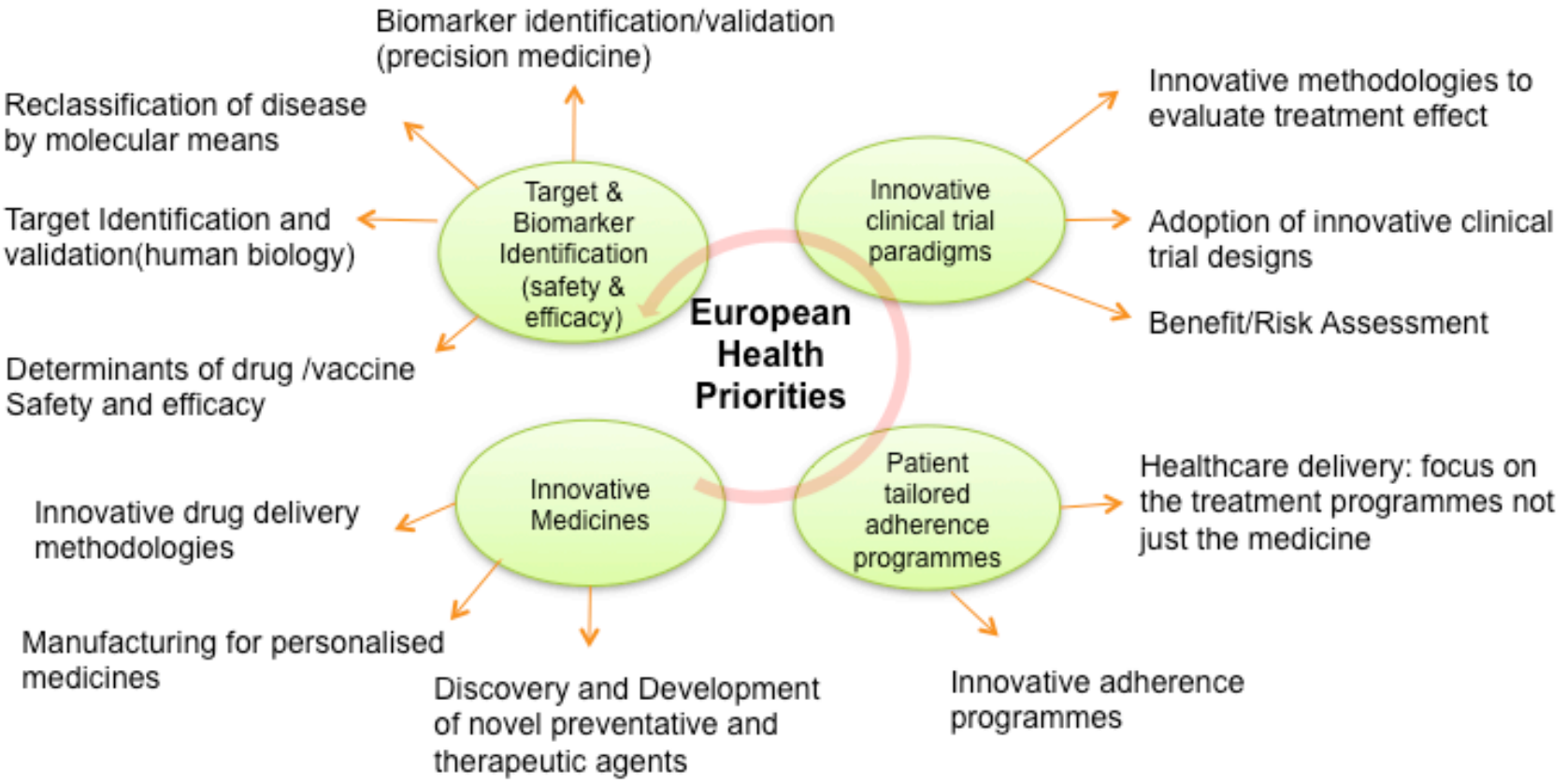
6. EUROPEAN HEALTH PRIORITIES

- 6.1. Antimicrobial resistance
- 6.2. Osteoarthritis
- 6.3. Cardiovascular diseases
- 6.4. Diabetes
- 6.5. Neurodegenerative diseases
- 6.6. Psychiatric diseases
- 6.7. Respiratory diseases
- 6.8. Immune-mediated diseases
- 6.9. Ageing-associated diseases
- 6.10. Cancer
- 6.11. Rare/Orphan Diseases
- 6.12. Vaccines

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



Drive change in delivery of medical practice

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IMI2 scientific programme: the need for focus

Therapeutic Areas and Cross-cutting Themes

1. **Neuro-degeneration**
   - Successfully prevent and treat dementia and other neurodegenerative diseases
2. **Prevention and treatment of immune-mediated disease**
   Advance immunological understanding to deliver new treatments and develop new and better vaccines for non-infectious diseases
3. **Metabolic disorders**
   - Tackle all phases of disease and its complications, including prevention and early interception
4. **Infection control**
   - Address multidrug resistance and create incentives for reinvestment (including antimicrobials, antivirals, vaccines) and develop new and better prophylactic vaccines
5. **Translational Safety**
   - Identification of predictors of safety and development of point of care for safety biomarkers and development of new human biology platform to predict toxicity and safety during early drug development

Differentiating Enablers for all themes

Towards early and effective patient access to innovative prevention and treatment solutions (MAPPs):

- Target validation based on human biology
- Stratified medicine, precision medicine
- Innovation in clinical trials
- Data generation and interpretation (knowledge management)
- Prevention, disease interception, patient adherence (incl. societal acceptance of vaccines)
- Effect on medical practice and outcomes (health/disease management)
- Regulatory framework (including pharmacovigilance)
- Patient access

When will this happen?

- Legislation/legal framework adopted - 6 May 2014
- Entry into force – June 2014
- Official launch and publication of first call – 9 July 2014

Your contact points

- IMI Executive Office **infodesk@imi.europa.eu**
- **Local IMI contact points** **www.imi.europa.eu/content/states-representatives-groups**
- Talk to your **Health National Contact Point** (NCP)

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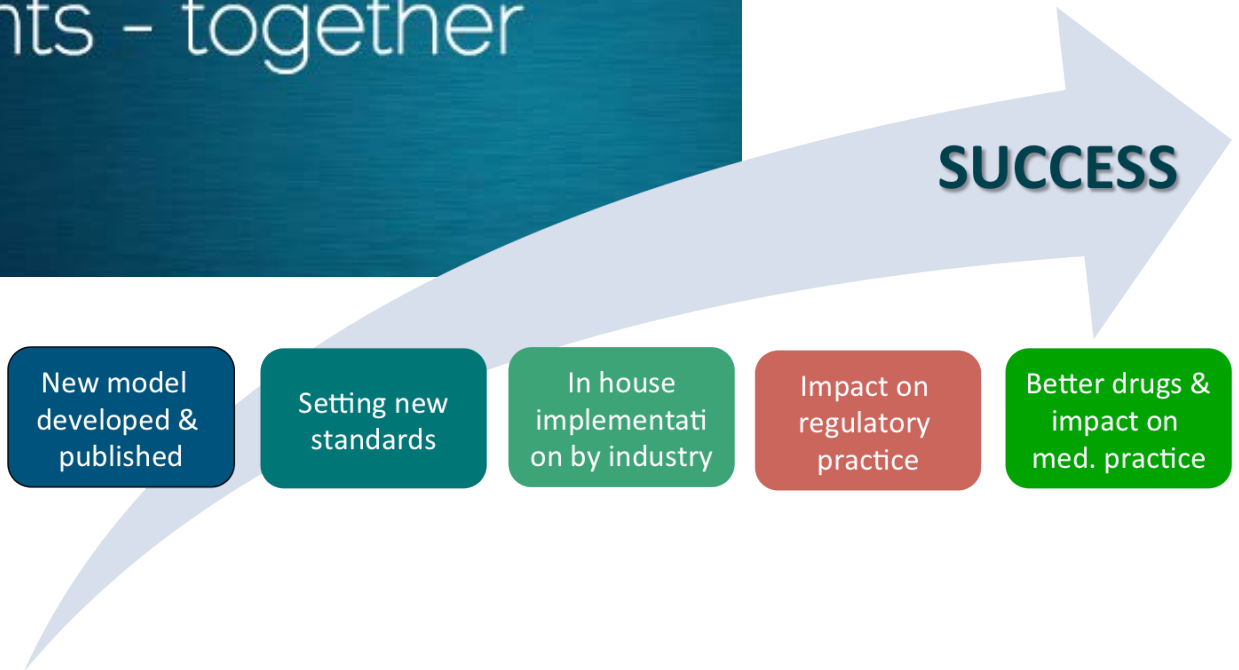
IMI and IMI2: from science to patients - together



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