

Better Science, Better Health: New Healthcare Models

Pierre Meulien, IMI Executive Director
Better Science, Better Health: New Healthcare Models
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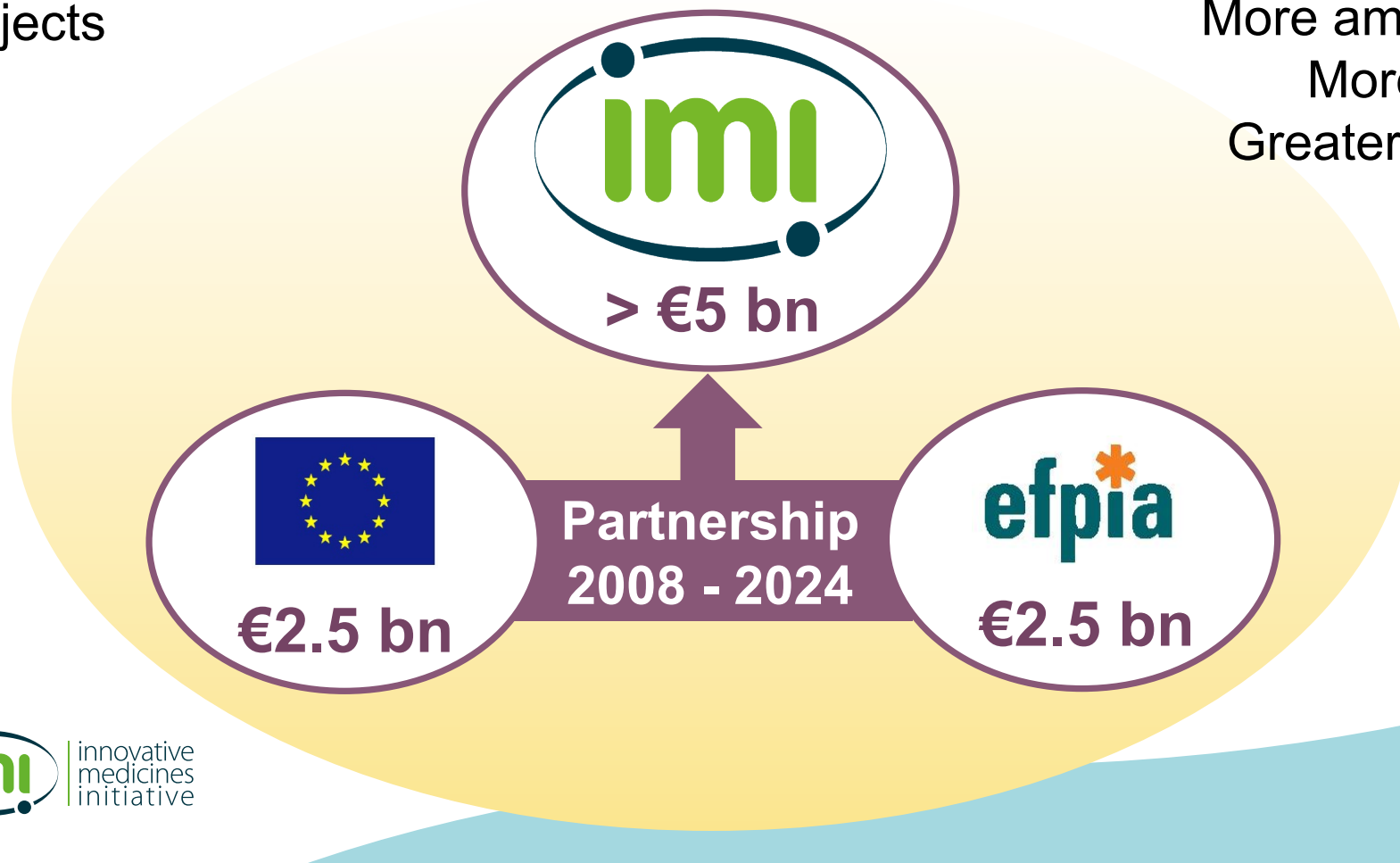
IMI – Europe's partnership for health

IMI1: 2008-2013

€2 bn budget
59 projects

IMI2: 2014-2024

€3.3 bn budget
More ambitious
More open
Greater scope



IMI – key concepts

- Non-competitive collaborative research
- Competitive Calls for proposals
- Open collaboration in public-private consortia
 - data sharing
 - dissemination of results...
- Industry contribution is in kind



Goals of the IMI2 programme

- **Increase the success rate of clinical trials** of new medicines & vaccines
- **Speed up** the earlier stages of **drug development**
- Develop **new treatments** for areas of **unmet need**
- Develop new **biological markers** to diagnose diseases and assess treatments
- Improve the drug development process by **creating tools** to assess the efficacy, safety and quality of medicines

IMI2 – building on successes of IMI1



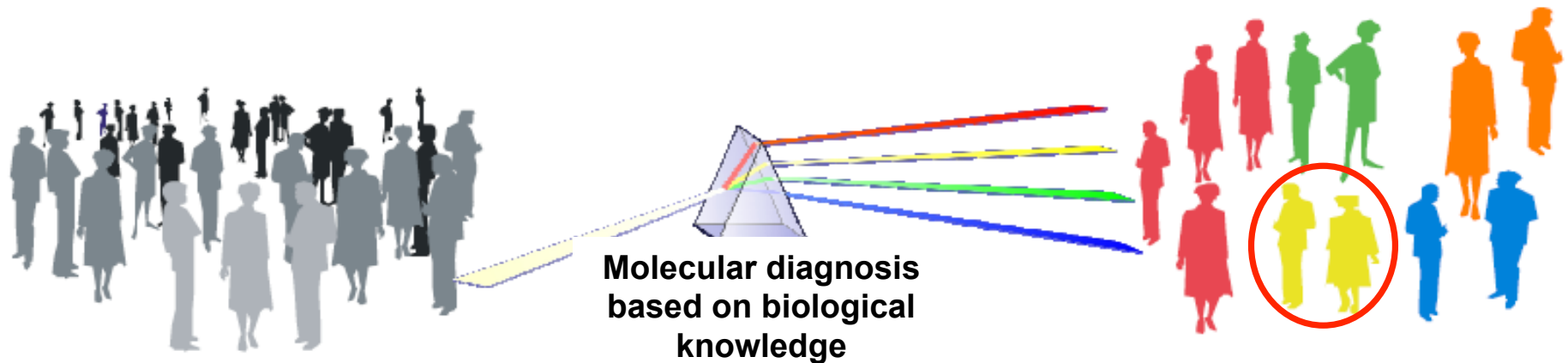
- Focused: **stratified medicines** and healthcare priorities
- Healthcare solutions: prevention and treatment
- **End-to-end**: R&D, regulatory and access – move integration a step further
- Multi-sector: **within and beyond life sciences**

The Vision for IMI2

From population



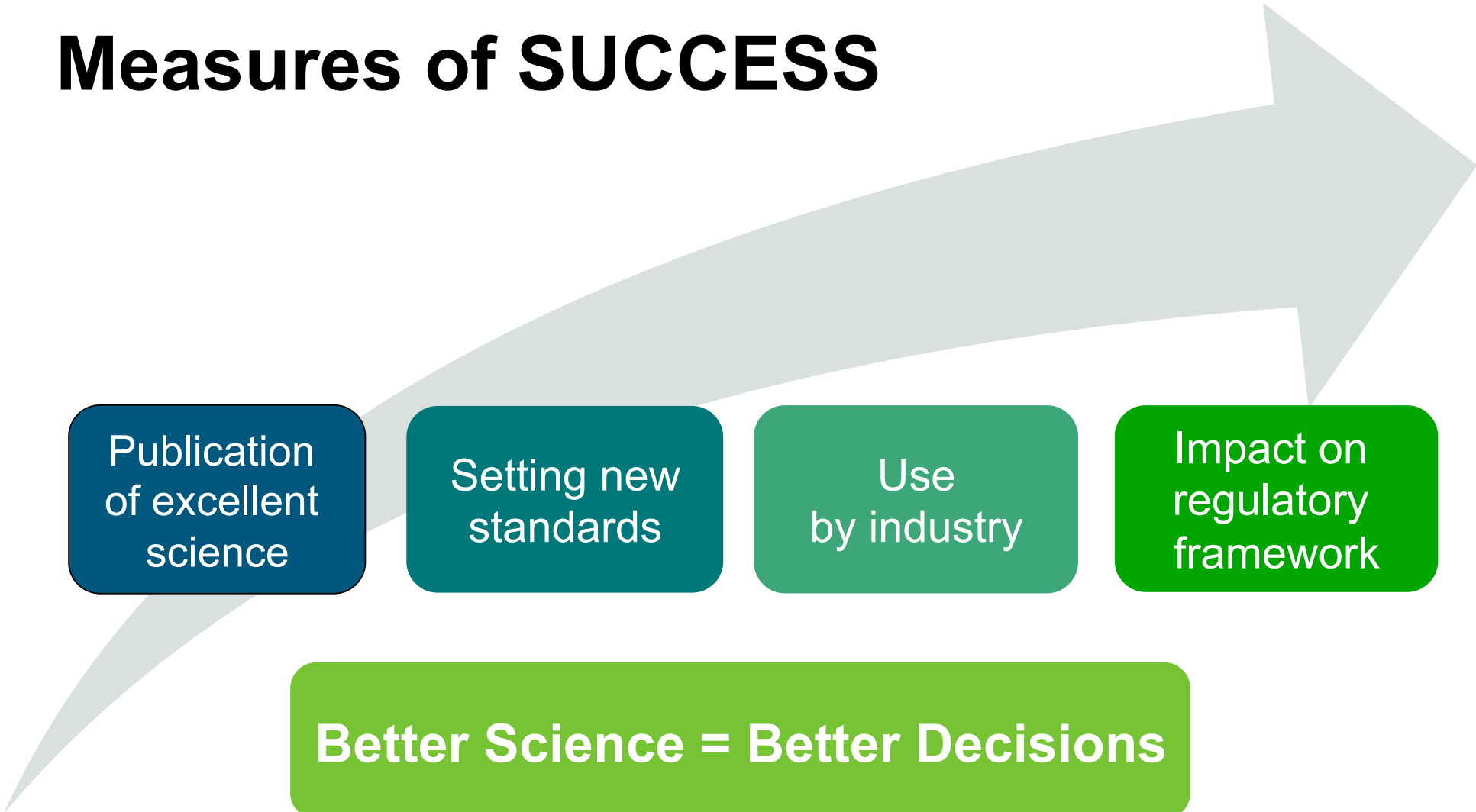
to individual



We “treat” a population.
Some respond and some don’t

We “treat” a *targeted* population
They all respond

Measures of SUCCESS



Publication
of excellent
science

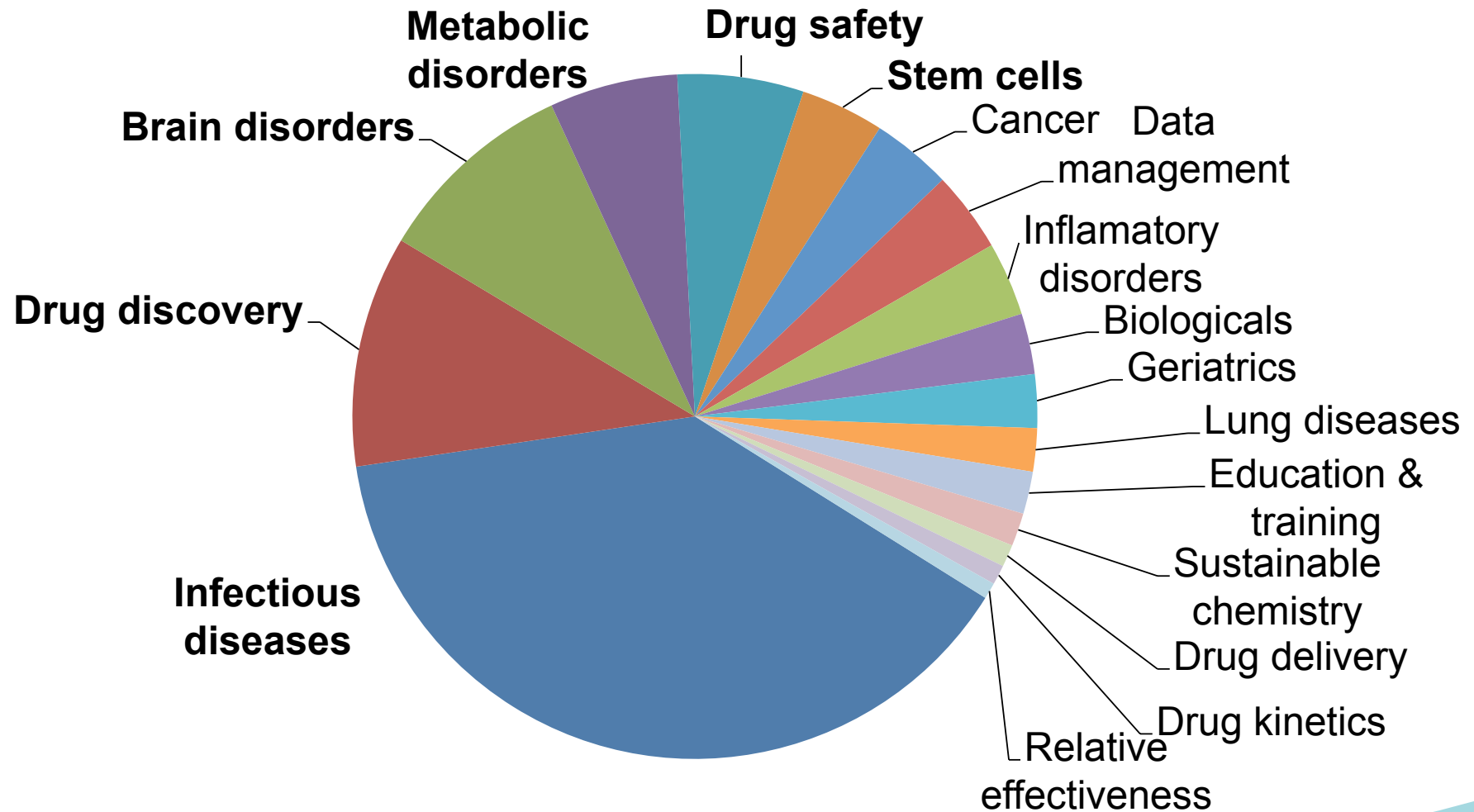
Setting new
standards

Use
by industry

Impact on
regulatory
framework

Better Science = Better Decisions

IMI 1 – € 2 bn budget breakdown



The problem

Antibiotic-resistant infections spread through Europe

**Superbug
that moves
faster than
science**

Three million Europeans catch infections in hospital annually

Antibiotics resistance 'as big a risk as terrorism' – UK medical chief

Antibiotic resistance: we must act now, says WHO

BAD BUGS, NO DRUGS

As Antibiotic Discovery Stagnates ...
A Public Health Crisis Brews



IDSA
Infectious Diseases Society of America

July 2004



Le Monde

17 Janvier 2008: La résistance des bactéries aux antibiotiques a atteint une dimension planétaire

IMI - New Drugs for Bad Bugs

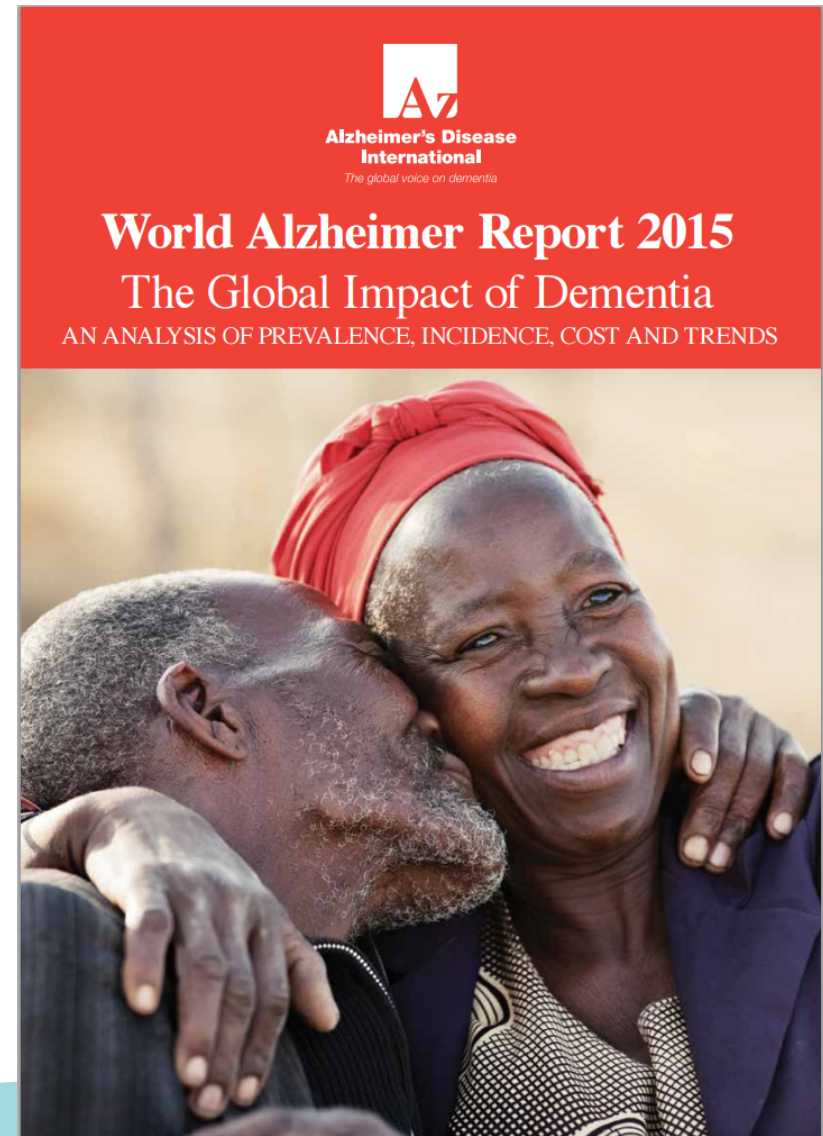
- How to get new drugs into bad bugs
 - Pan-European network of clinical/laboratory sites
 - Collaboration on clinical trials
 - Platform for antibiotic development
 - New business models
- Part of EU AMR programme
 - 7 projects
 - €700 million budget



Alzheimer's disease – a major unmet need

Alzheimer's disease in numbers...

- **46.8 million** affected globally
- **10.5 million** in Europe
- **Global cost** USD 818 billion (EUR 732 billion)



IMI action on Alzheimer's disease

PHARMA-COG

Matrix of biomarkers

- Test efficacy of new treatments

EMIF

Linking & analysing data

- Identify those at risk

AETIONOMY

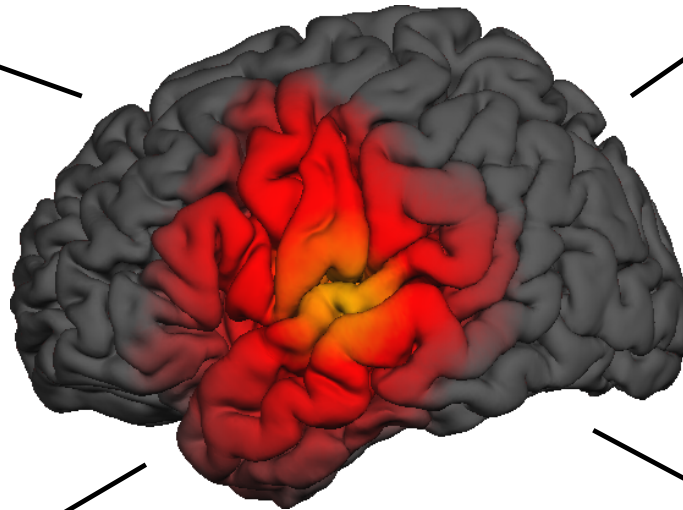
New classification of AD/PD

- Personalised treatments

EPAD

'Adaptive' clinical trials

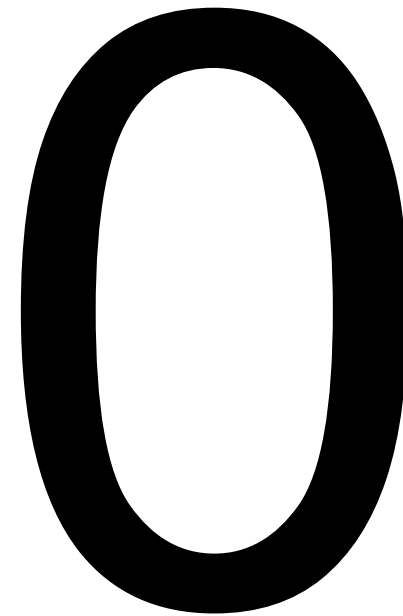
- Faster drug development & patient access



*Total budget
€169 million*

Autism – a common disorder

- Affects **1 in 110**
- Lifelong condition
- Difficulties in **social interaction & communication, unusual repetitive behaviours**
- Major impact on **families & carers**



IMI – delivering results on autism

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



IMI scientific output

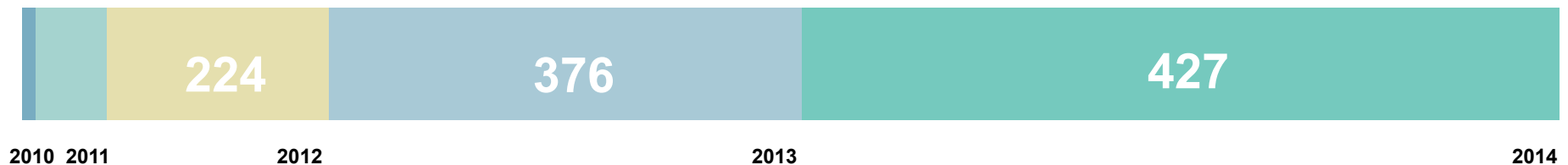
1134
PUBLICATIONS

9359
CITATIONS

2.19
CITATION IMPACT

24%
HIGHLY CITED

1134 publications by December 2014



Project highlights

BTCure
produced
the most
publications
212

Top 3 projects by
citation impact:
EU-AIMS
DIRECT
ORBITO

PROTECT
is the most
collaborative
across sectors &
internationally

Implementation of project results inside industry

Project	Area	Results description
IMIDIA	diabetes	The human beta cell line EndoC BetaH1 has been validated by Endocells and 3 pharma partners confirming their initial insulin secretion capacity. These cells have been successfully transferred as a research tool for drug discovery to industrial partners.
DDMoRe	knowledge management	Several drug/disease models identified by DDMORE are adopted or further developed inside the industry.
eTRIKS	knowledge management	Adoption of the eTRIKS results, TransMART system deployments in 5 pharmaceutical companies.
EUROPAIN	chronic pain	<p>Preclinical model of spontaneous pain in rodents has been developed, standardized, validated, and is already used for internal decision making in the drug development process.</p> <p>The ultraviolet B (UVB) pain model has also started to be used for in house R&D.</p>

Impact on regulatory framework

Project	Area	Results description
PROactive	COPD	Qualification Advice completed at the EMA.
EU-AIMS	autism	Started EMA formal scientific advice procedure for qualification of 5 biomarkers in ASD .
eTOX	drug safety	Scientific Advice Procedure was initiated at EMA.
MARCAR	cancer	Potential impact for ICH S1 carcinogenicity testing guideline revisions.
Safe-T	drug safety	Developed and now progressed towards an aligned EMA/FDA qualification a set of novel safety biomarkers for drug-induced kidney, liver, and vascular injury.
DDMoRe	knowledge management	In May 2012 an advisory meeting with EMA and FDA representatives was held. Through a Modelling Review Group , DDMoRe is in regular contact with both the EMA and FDA regarding the qualification of the content of the project's Model Library.

SME success stories



Thanks to IMI the company went from **6 to 50 employees**. Now they are ready to further expand.



“1st product released to the market in 2013 – **IMI was instrumental in validation of the first cell line product**, 2nd product release planned this year, 3rd diagnostic product in development.

In preparation: **a new patent filing** to protect technologies for the creation of third generation human beta cell lines.

Developing a blood panel for AD for diagnosis, stratification and companion diagnostics in AD. **The Panel was tested on 300 patients in IMI project.**



Developed in silico models for predicting toxicity, which were validated by pharmas in eTOX. Now they have **signed a contract with one of the companies to use their models in house.**



Conclusions

IMI as a productive Public Private Partnership for Innovative Medicines

- Magnet for collaboration and co-investment
- End-to-end integration between the research and the consumer of innovation (payers and patients)
- Neutral platform for Pharmaceutical companies to collaborate and share data and knowledge
- Open model attracting other disciplines (ICT sector etc) to join

Thank you!

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