

The IMI research program in neurodegeneration: delivering on the promise

Elisabetta Vaudano
PhD DVM

www.imi.europa.eu



@IMI_JU

The global impact of dementia

The global impact of dementia

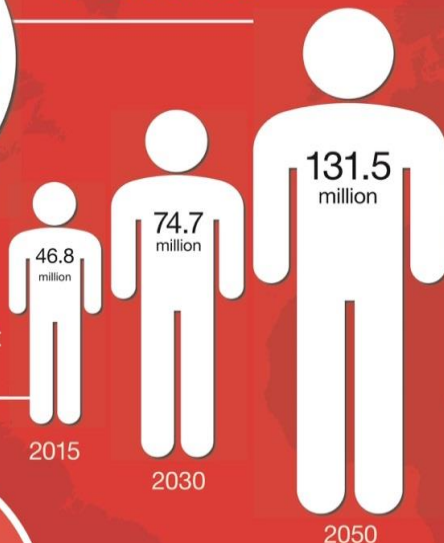


Around the world, there will be 9.9 million new cases of dementia in 2015,

one every 3 seconds

46.8 million people worldwide are living with dementia in 2015.

This number will almost double every 20 years.



68% 2050

Much of the increase will take place in low and middle income countries (LMICs): in 2015, 58% of all people with dementia live in LMICs, rising to 63% in 2030 and 68% in 2050.



2015

2018

The total estimated worldwide cost of dementia in 2015 is US\$ 818 billion.

By 2018, dementia will become a trillion dollar disease, rising to

US\$ 2 trillion by 2030

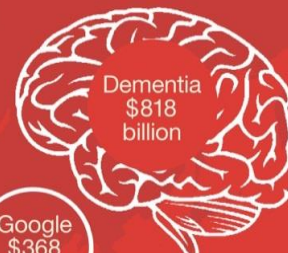
If global dementia care were a country, it would be the

18th largest economy

in the world exceeding the market values of companies such as Apple and Google



Apple
\$742 billion



Dementia
\$818 billion



Google
\$368 billion

(source: Forbes 2015 ranking).



This map shows the estimated number of people living with dementia in each world region in 2015.

We must now involve more countries and regions in the global action on dementia.



Alzheimer's Disease International

The global voice on dementia

The World Alzheimer Report 2015 was independently researched by King's College London and supported by Bupa.

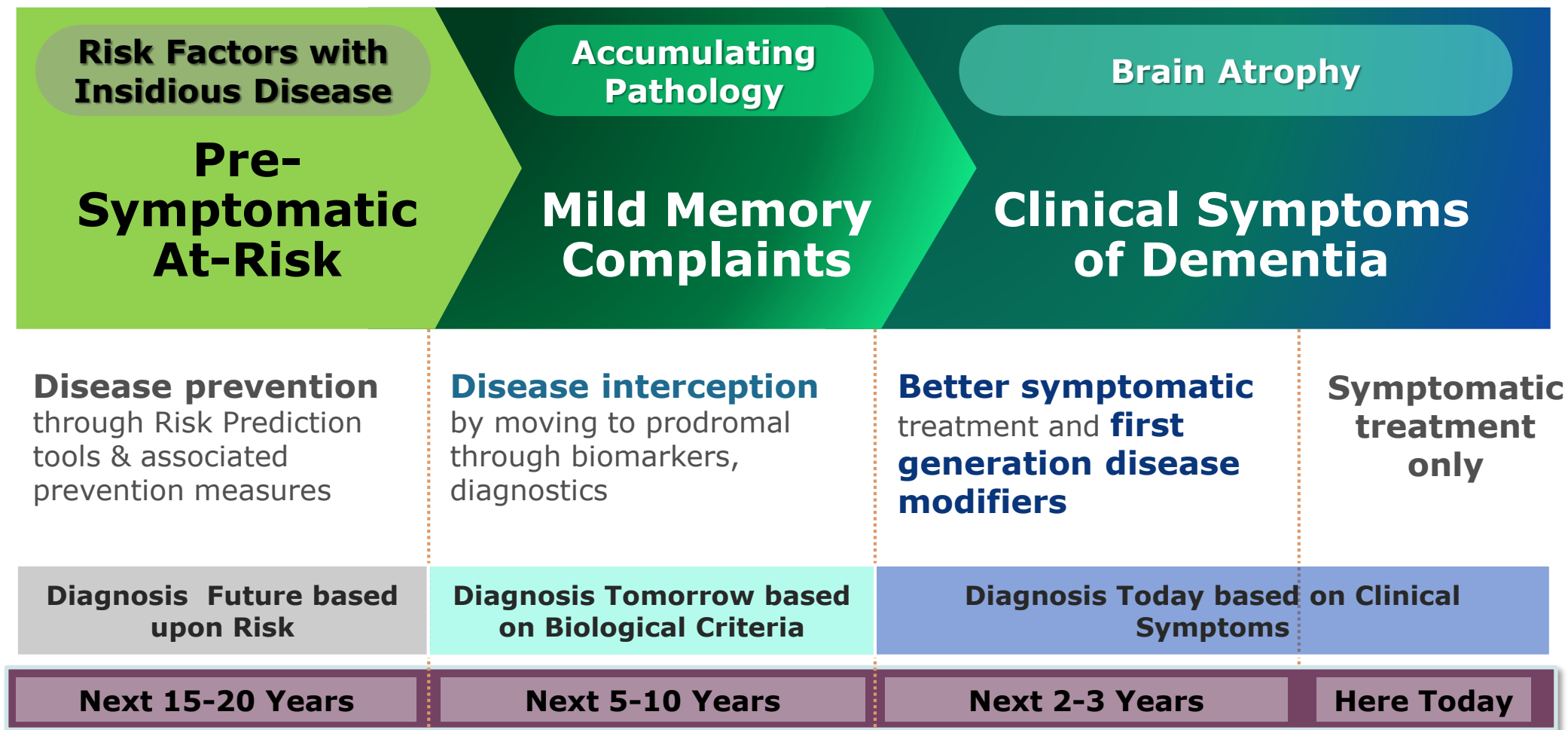
Neurodegeneration high unmet medical need

- Large and increasing unmet need
 - 5-8 mill Alzheimer patients in Europe
- Approved treatments based on two targets
 - **Acetyl Choline Esterase Inhibitors (3 drugs)**
 - Late 1970: Cholinergic hypothesis: Reduced choline acetyl transferase in AD patients
 - 1991 Tacrine approved in (discontinued in 2013), synthesized in 1948
 - **1996** Donepezil approved
 - **NMDA receptor antagonism**
 - 2003 Memantine approved, Synthesized in 1962. Used for undefined neurological disorders in Germany to 1989

Both the research community and industry have invested heavily on Alzheimer's Disease R&D since 2002

- Published approx 65.000 papers with Alzheimer in abstract (Pubmed)
- > 120 different transgenic “Alzheimer models” generated
- 2002-2012 (clinicaltrials.gov)
 - 413 clinical trials
 - 244 unique compounds tested
 - 1 compound approved
- **One new drug in 2003!**

Diagnosis and Therapeutics Moving Earlier



Neurodegeneration Therapeutics is moving earlier in disease process: the concept of disease interception



<http://www.euro.who.int/en/health-topics/noncommunicable-diseases/mental-health/data-and-statistics>

A **high percentage** of people on welfare benefits or disability pensions have, as their primary condition, a mental disorder and a serious mental illness associates considerably with lower monthly earnings.

The global cost of mental disorders



In 2010, the global cost of mental disorders was estimated to be approximately **US\$2.5 trillion**

by 2030, that figure is projected to go up by **240%**, to **US\$6.0 trillion**.

In 2010, **54%** of that burden was borne by low- and middle-income countries, by 2030, that is projected to reach **58%**.

The status of drug development for mental disorders

There is a high unmet medical need for new drugs for mental disorders

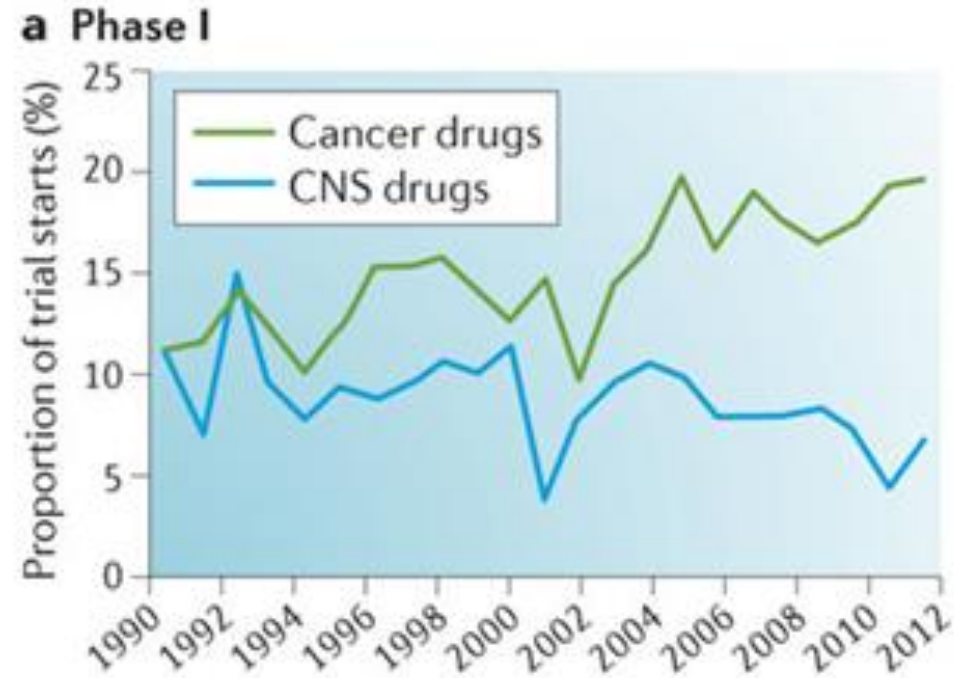
In the WHO European Region,



3 out of 4 people suffering from major depression

do not receive adequate treatment.

But in the last 20 years CNS drug development has significantly slowed down



IMI – Europe's partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need



Brain disorders/neurodegeneration: a priority area for IMI from its start

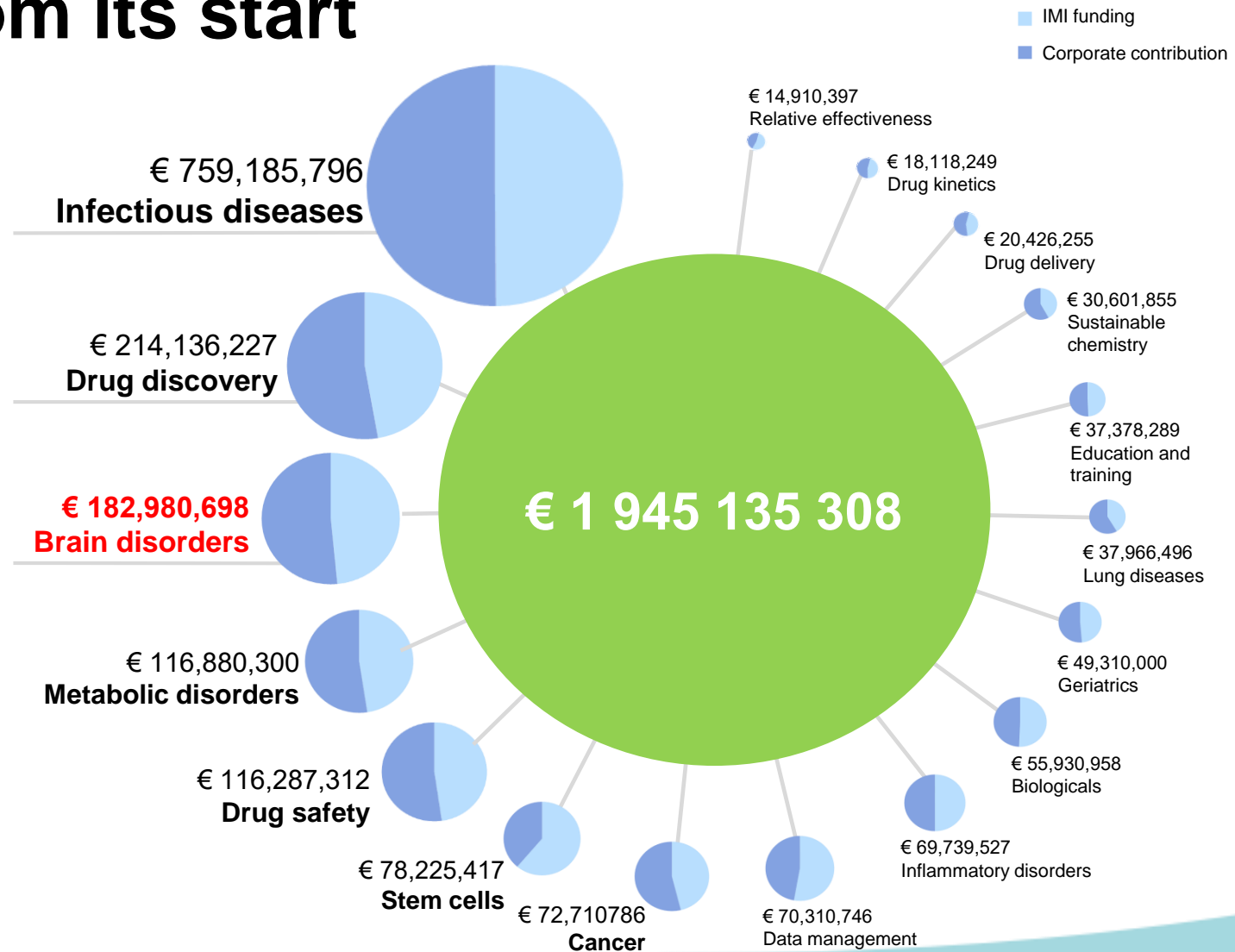
Partners

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

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
Grünenthal	Vifor
GSK	



IMI1 CNS Project Portfolio (2009-2014)-Overall budget: € 182.9 Mill €

AETIONOMY: Organising mechanistic knowledge about neurodegenerative diseases for the improvement of drug development and therapy (2014-2018)

EU-AIMS: European Autism Interventions - a Multicentre Study for Developing New Medications (2012-2018)

EMIF: European Medical Information Framework (2013-2017)

EPAD: European prevention of Alzheimer's dementia consortium (2015-2019)

EUROPAIN: Understanding chronic pain and improving its treatment (2009-2015)

NEWMEDS: Novel methods leading to new medications in depression and schizophrenia (2009-2015)

Pharma-Cog: Prediction of cognitive properties of new drug candidates for neurodegenerative diseases in early clinical development (2010-2015)

IMI Alzheimer's Disease Platform

H2020: SOCIETAL CHALLENGES: HEALTH



© Gerd Altmann

19 March 2015

IMI Alzheimer's projects launch joint platform

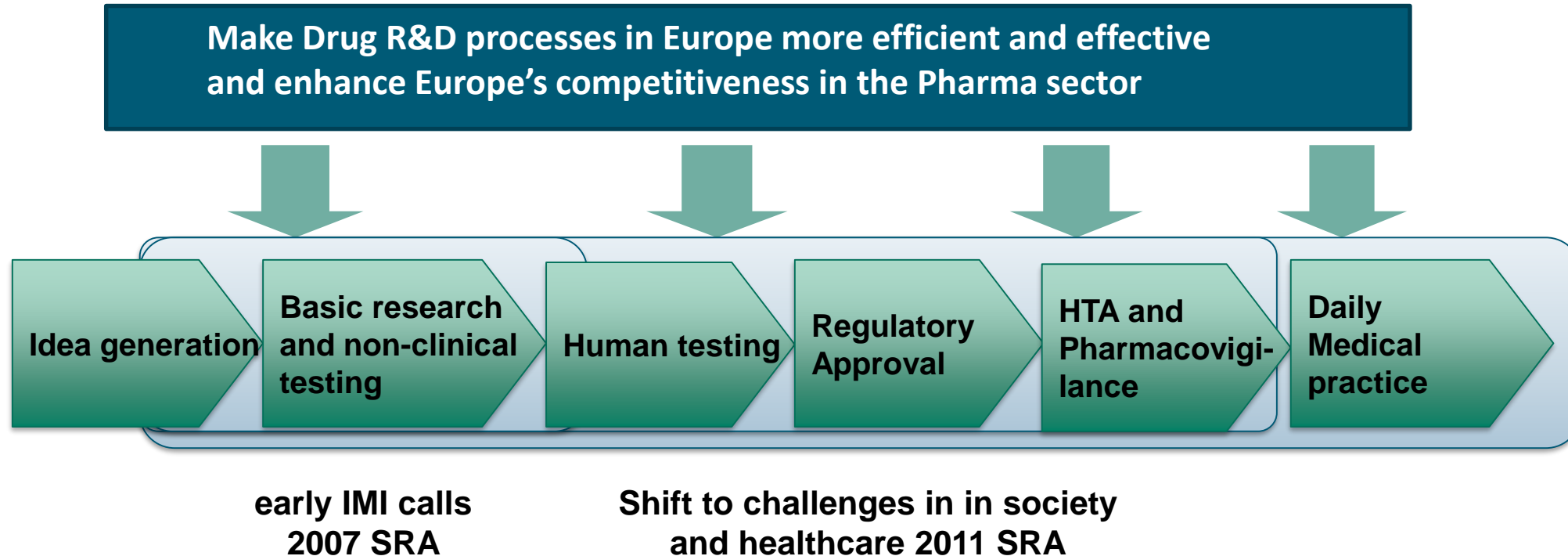


AETIO $\frac{N|O}{M|Y}$



Facilitate collaboration to help deliver results faster, create efficiencies and create value

IMI evolution – from bottlenecks in industry to bottlenecks in industry and society



IMI2 SRA

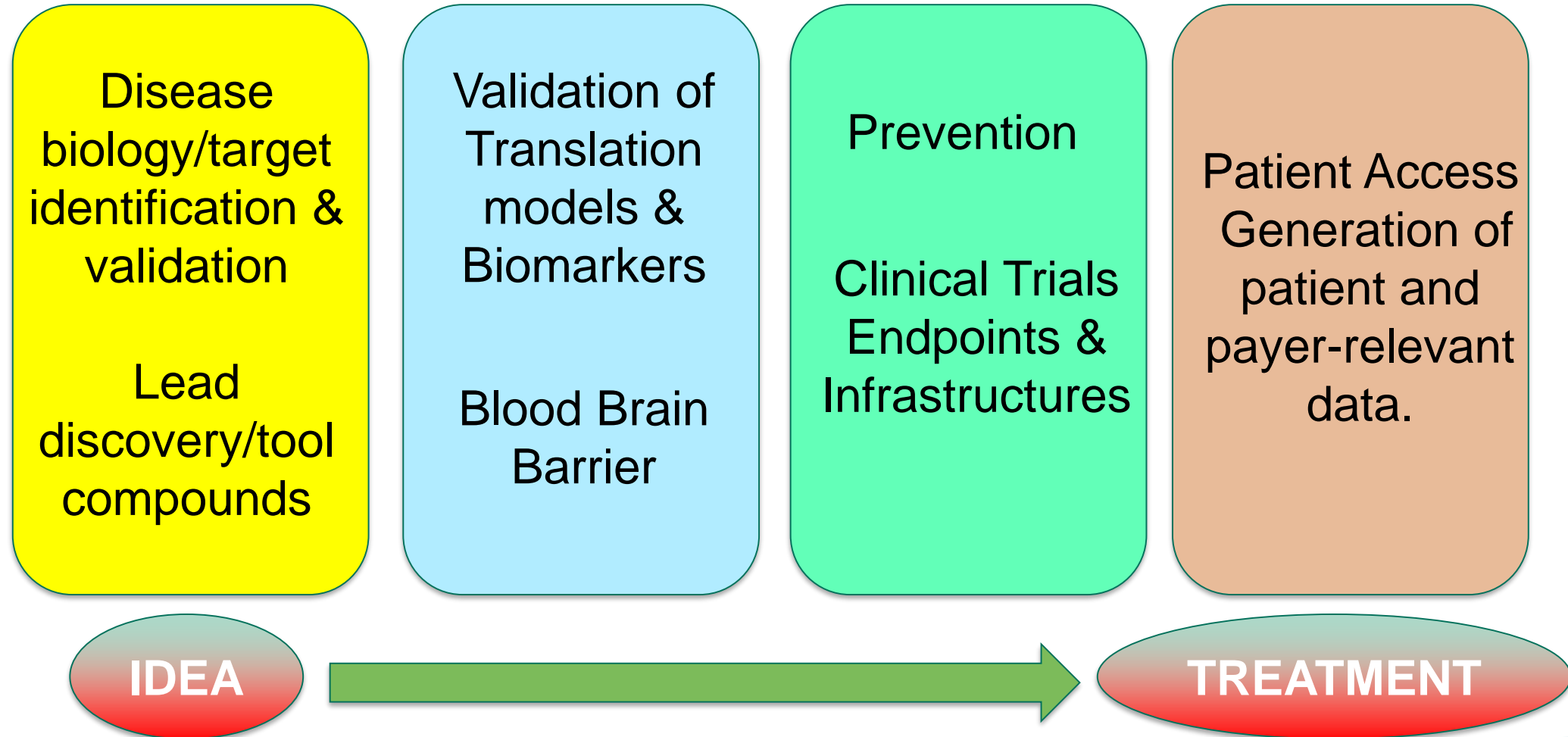
- **Healthcare priorities** based on **WHO 2013 report**
 - Vision of “**stratified**” **medicines**: **prevention, treatment and health management**
 - **End-to-end approach**; product lifecycle **from discovery, through development to healthcare delivery and patient access to innovative medicines**
- Cross-sectors collaboration**

IMI2 overall objectives: very relevant for neurodegenerative disease research

- **improve the current drug development process** through development of tools, standards & approaches to assess **efficacy**, **safety** & **quality** of health products.
- **develop diagnostic & treatment biomarkers** for diseases clearly linked to clinical relevance & approved by regulators
- **reduce time to clinical proof of concept** (e.g. for cancer, immunological, respiratory, **neurological/neurodegen.** diseases)
- **increase success rate in clinical trials** of priority meds (WHO)
- **develop new therapies** for diseases with **high unmet need**, (e.g. **Alzheimer's**) & **limited market incentives** (e.g. AMR)
- **reduce failure rate of vaccine candidates** in phase III trials through new biomarkers for efficacy & safety checks

- IMI2 legislation, Article 2b

Brain disorders with focus on Neurodegeneration: a strategic area of IMI2



IMI2 CNS ongoing Project Portfolio (2014-2018)-

Overall budget: > € 280 Mill €

Disease Biology for
New Drug and Target
Identification &
Validation

- **ADAPTED** - Alzheimer's disease apolipoprotein pathology for treatment elucidation and development
- **PHAGO** - Inflammation and AD: modulating microglia function - focusing on TREM2 and CD33
- **IMPRiND** – *Inhibiting Misfolded protein Propagation in Neurodegenerative Diseases*
- **NGN-PET** - Modelling Neuron Glia Networks into a drug discovery platform for Pain Efficacious Treatments

Clinical trials

- **PRISM**: Psychiatric Ratings using Intermediate Stratified Markers: providing quantitative biological measures to facilitate the discovery and development of new treatments for social and cognitive deficits in AD, SZ, and MD
- **RADAR-CNS**: Remote Assessment of Disease and Relapse in Central Nervous System Disorders
- **AMYPAD** - Amyloid imaging to prevent Alzheimer's disease
- **PAIN CARE** - Improving the care of patients suffering from acute or chronic pain
- **AIMS2-TRIALS** Personalised medicine approaches in autism spectrum disorders
- **RADAR-AD** - Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with Alzheimer's Disease (RADAR-AD)

Patient access

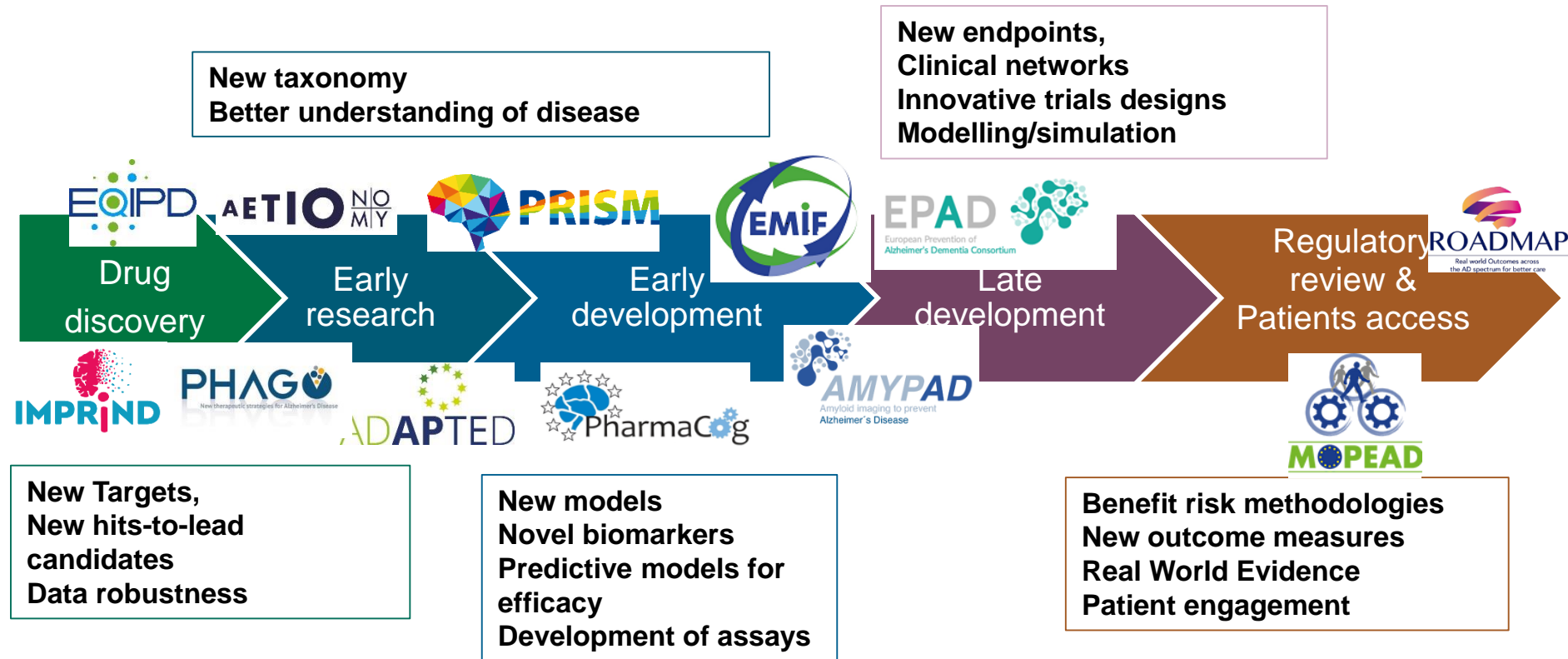
- **ROADMAP** - Real world outcomes across the AD spectrum for better care: multi-modal data access platform
- **MOPEAD** - Models of patient engagement for Alzheimer's disease

Other

- **EQIPD**: Data Quality In Preclinical Research and development



Projects in neurodegeneration cover the whole value chain



- **End-to-end approach** from discovery through all the way to patient access of innovative medicines;
- Vision of “**personalised**” medicines”: prevention, treatment and health management

IMI2 CNS upcoming projects

Disease
Biology for
New Drug and
Target
Identification &
Validation

- **Call 13** - Mitochondrial Dysfunction in Neurodegeneration
- **Call 15** – Development and validation of translational platforms in support of synaptopathy drug discovery

Clinical trials

- **Call 12** - Pilot programme on a Clinical Compound Bank for Repurposing: Neurodegenerative diseases
- **Call 15** - Digital Transformation of Clinical Trial Endpoints in neurodegenerative and immune-mediated diseases
- **Call 15:-** Integrated research platforms enabling patient-centric drug development

Other Enablers

- **Call 12** - Discovery and characterization of blood-brain barrier targets and transport mechanisms for brain delivery of therapeutics to treat neurodegenerative & metabolic diseases
- **Call 13** - A sustainable European induced pluripotent stem cell platform
- **Call 13** - Support and coordination action for the projects in the neurodegeneration area of the Innovative Medicines Initiative*

Neuroscience and digital technology

DARPA's latest neuroscience research aims to give soldiers super-human abilities

N3 is looking to achieve higher levels of brain-system communications without surgery



The soldier of the future?

<https://www.v3.co.uk/v3-uk/news/3062609/darpas-latest-neuroscience-research-aims-to-give-soldiers-super-human-abilities>

Implementing digital technology for Brain Health

<https://wfneurology.org/2018-02-01-openaccess>



To solve the challenges of brain disorders and the huge societal impact it is necessary an approach to problem solving that cuts across disciplinary boundaries. We need to integrates knowledge, tools, and thought strategies from various fields for tackling challenges that exist at the interfaces of multiple fields. From interdisciplinary science to convergence science

Breaking the silos



Convergence to break up brain disorders silos

SHARE

April 2017; 7 (2)

FROM THE EDITOR'S DESK



The convergence of neurology and psychiatry



First published April 10, 2017, DOI: <https://doi.org/10.1212/CPJ.0000000000000353>





 FULL PDF

 CITATION

 PERMISSIONS

 COMMENT

 Check for updates

 Am score 10

Downloads 4

Article

Info



Prof. Joseph B. Martin, MD, PhD, former Dean of Harvard Medical School, wrote: “Neurology and psychiatry have, for much of the past century, been separated by an artificial wall created by the divergence of their philosophical approaches and research and treatment methods. Scientific advances in recent decades have made it clear that this separation is arbitrary and counterproductive. Neurologic and psychiatric research are moving closer together in the tools they use, the questions they ask, and the theoretical frameworks they employ.”¹

IMI2 budget

EU funding goes to:

Universities

SMEs

Mid-sized companies

Patient groups

etc...



€1.638 bn



€1.425 bn

Other
€213 m

IMI 2 total budget
€3.276 billion

EFPIA companies

receive no funding

contribute to projects 'in kind'

Associated Partners

(e.g. charities, non-EFPIA companies)

receive no funding
contribute to projects 'in kind'

Matching of EU funding and EFPIA + Other contributions at programme level (not a project level)

Outlook for 2019 - 2020

- Future topics currently under development – details will be published in Annual Work Plan 2019
- Draft topic texts will be published online 6-8 weeks before Call launch
- Sign up to our newsletter & follow us on social media for updates
- Think big areas and bottom up initiatives

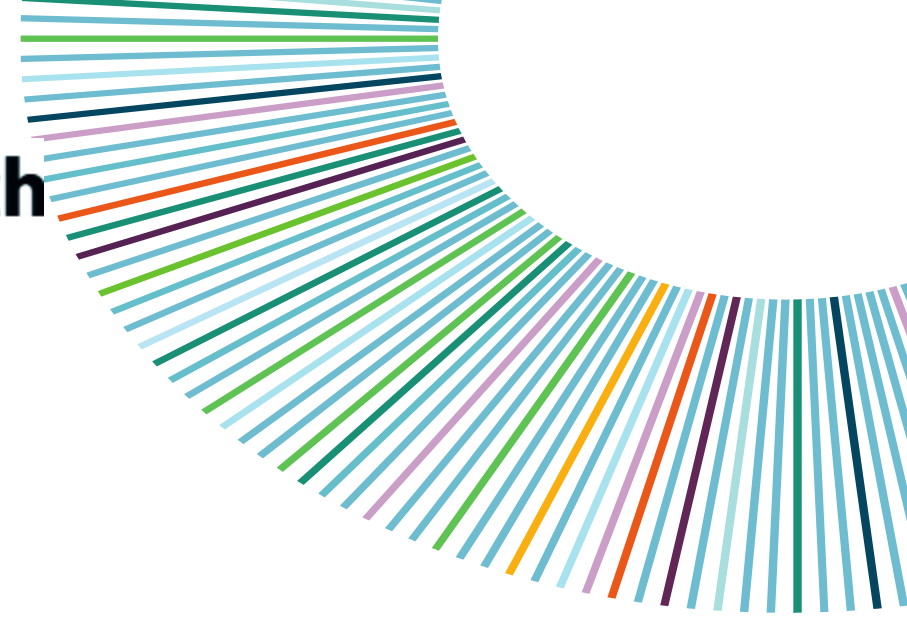
‘Think big’ areas

- Immunology
- Antimicrobial resistance
- Digital Health / Big Data
- Modernisation of clinical trials and regulatory pathways

Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan Diseases
- Vaccines
- Enablers of Research

10 years of transforming medical research



IMI Scientific Symposium

Towards personalised medicines | Patient-centric approaches | Enablers for drug discovery & development | Collaborating to fight infections

22-23 October 2018

<https://www.imi.europa.eu/news-events/events/imi-10th-anniversary-scientific-symposium>

#IMITenYears
#IMICarryTheTorch



After 10 years of IMI and with 2 years left of Calls is time for impact analysis: focus on mission and objectives

Innovative Medicines Initiative 2 JU [BE] | <https://www.imi.europa.eu/about-imi/mission-objectives>

Google Scholar Experts Welcome - eIMI Portal H2020-JTI-IMI2-2016 ISA - eIMI Portal EMI Google 2. Amendments - Eur WebEx Enterprise Site

Home About IMI Get involved Apply for funding Projects & results News & events Resources for projects

Home | About IMI | IMI mission and objectives

IMI mission and objectives

Our mission

At the Innovative Medicines Initiative (IMI), we are working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. We do this by facilitating collaboration between the key players involved in healthcare research, including universities, research centres, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators. IMI is the world's biggest public-private partnership (PPP) in the life sciences. It is a partnership between the European Union (represented by the [European Commission](#)) and the European pharmaceutical industry (represented by [EFPIA](#), the European Federation of Pharmaceutical Industries and Associations). Through the IMI2 programme, we have a [€3.3 billion budget](#) for the period 2014-2020.

Our objectives

The goal of IMI, particularly in its second phase (IMI2, 2014-2020) is to develop next generation vaccines, medicines and treatments, such as new antibiotics. Our projects will provide Europeans, including the increasing numbers of older people, with more efficient and effective medicines and treatments. Greater coordination across industry sectors will result in more reliable and faster clinical trials, and better regulation. Our research and innovation efforts will also open new commercial possibilities based on new services and products. The research, industry and societal sectors involved in IMI2 will benefit from the cooperation and knowledge sharing which take place in these projects.


In particular, our projects aim to:

IMI2...pdf ^

The Innovative Medicines Initiative (IMI) is a partnership between the European Union and the European pharmaceutical industry. IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

<https://www.imi.europa.eu/about-imi/mission-objectives>

Measuring the impact of IMI2 projects

In order to measure the progress and outcomes of IMI2 projects, the IMI Governing Board has approved a set of 10 IMI-specific key performance indicators (KPIs) that will be monitored yearly as part of IMI2 Annual Activity Reports for the year 2018 and beyond. To look up the 10 IMI-specific KPIs click [here](#) .

The Commissioner on IMI



Radical collaboration' is shaking up the pharmaceutical industry – Carlos Moedas 28/06/2018.'

<https://www.imi.europa.eu/projects-results/success-stories-projects/radical-collaboration-shaking-pharmaceutical-industry>



IMI and Horizon Europe

- We still do not know anything and will not know until some time next year about the new partnerships in Horizon Europe
- Impact analysis next year will be critical
- IMI has to demonstrate its value and impact!!
- We expect all IMI Neuroscience projects to contribute with excellent impactful results and good examples of radical collaboration and convergence of technology and science: AETIONOMY has been a front runner!

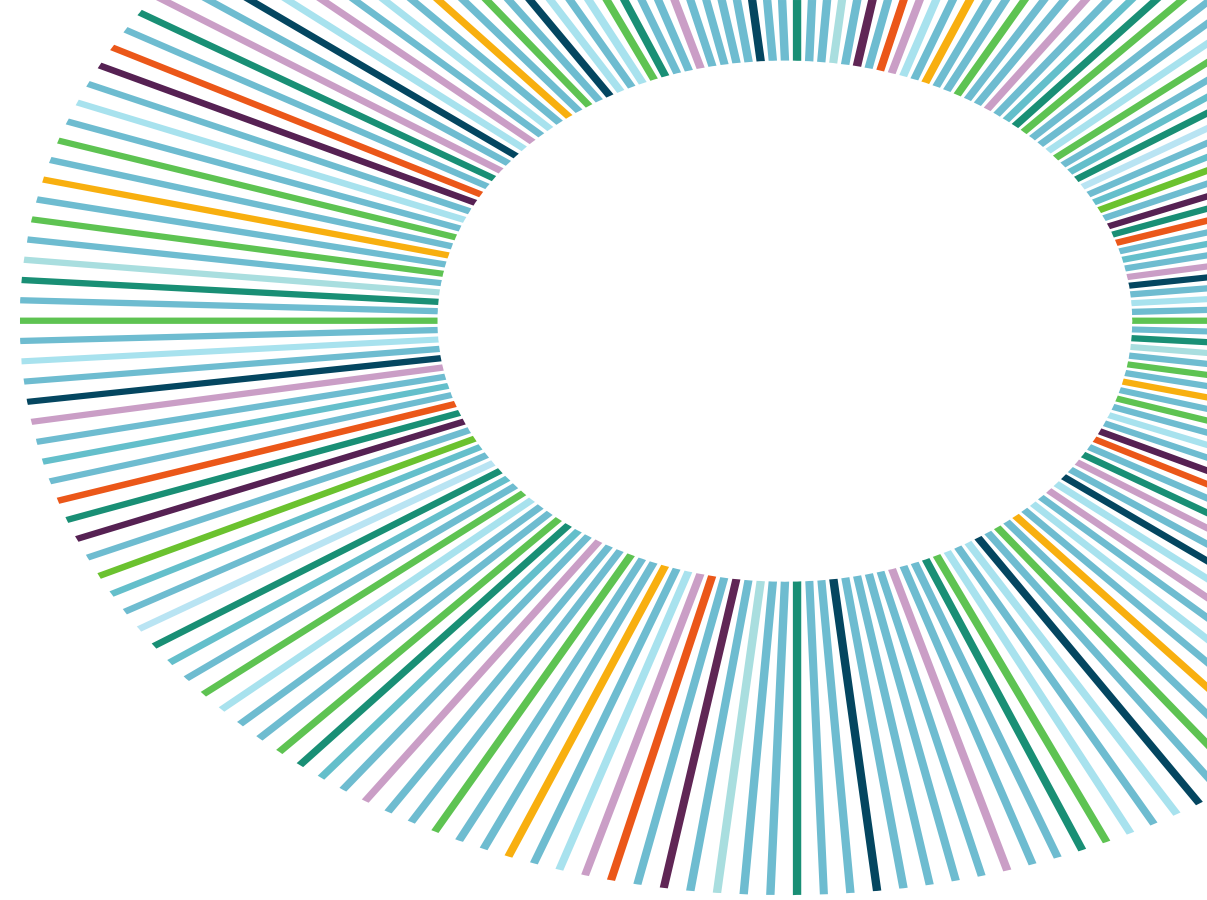
Visit our website
www.imi.europa.eu

Sign up our newsletter
bit.ly/IMInewsletter

Follow us on Twitter
[@IMI_JU](https://twitter.com/IMI_JU)

Join our LinkedIn group
bit.ly/LinkedInIMI

Email us
infodesk@imi.europa.eu



**10 YEARS OF
BREAKTHROUGHS**
A HEALTHIER
FUTURE



Thank you!

elisabetta.vaudano@imi.europa.eu