Innovative Medicines Initiative (IMI)

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20 October 2015 – STAMP meeting Brussels

IMI – European's partnership for health

- Focus on unmet needs
- Non-competitive collaborative research
- Neutral trusted platform to align public and private interests
- Competitive Calls for proposals
- Pool expertise, knowledge, resources
- Open collaboration in public-private consortia
- Data sharing, dissemination of results…
- Industry contribution is in kind
- Aligned on Horizon 2020 (rules, templates, cost model…)

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IMI 2 budget (2014 – 2024)

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

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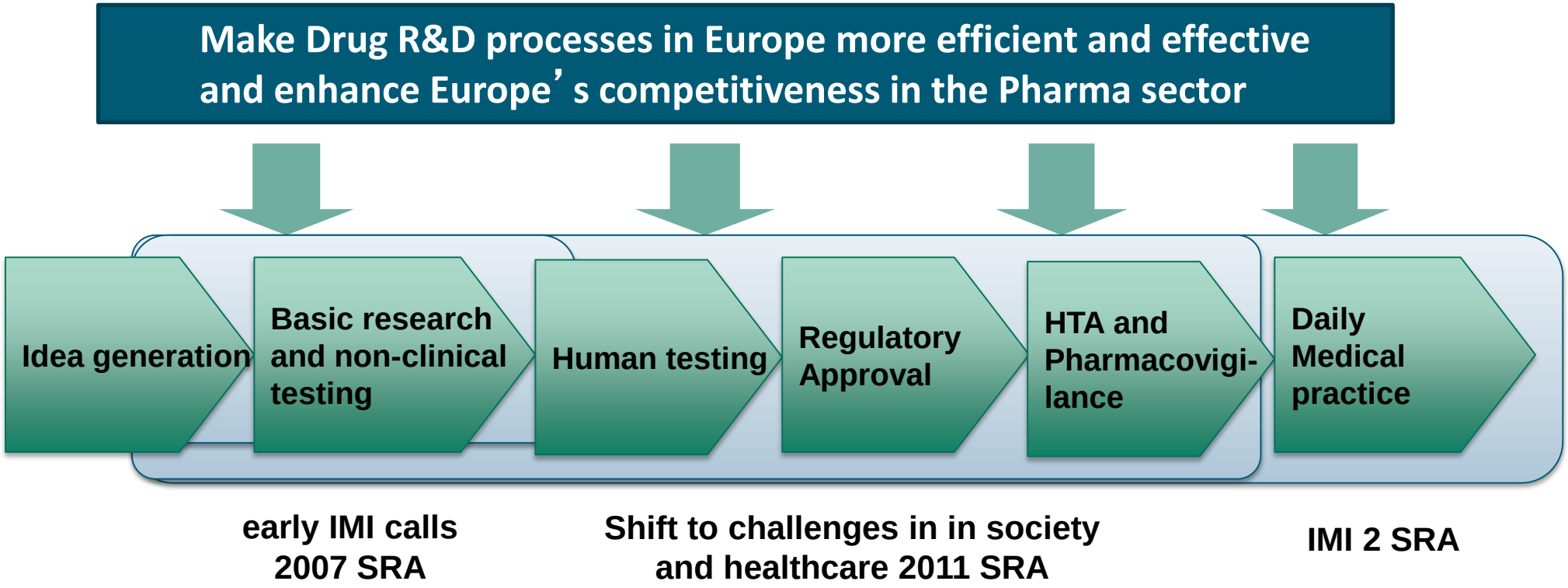
Evolution of IMI – from bottlenecks in industry to bottlenecks in industry and society



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
- **Collaboration across sectors**

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IMI projects - improving the drug development pathway

Target & Biomarker Identification (safety & efficacy); improved models

better defined patients to treat

Innovative drug development

improved processes

Innovative clinical trial paradigms

Optimise innovative trial design, simulation/modelling, better biomarkers/endpoints/PRO, better use of real world data, monitoring, methodologies

BETTER SCIENCE = BETTER DECISION MAKING

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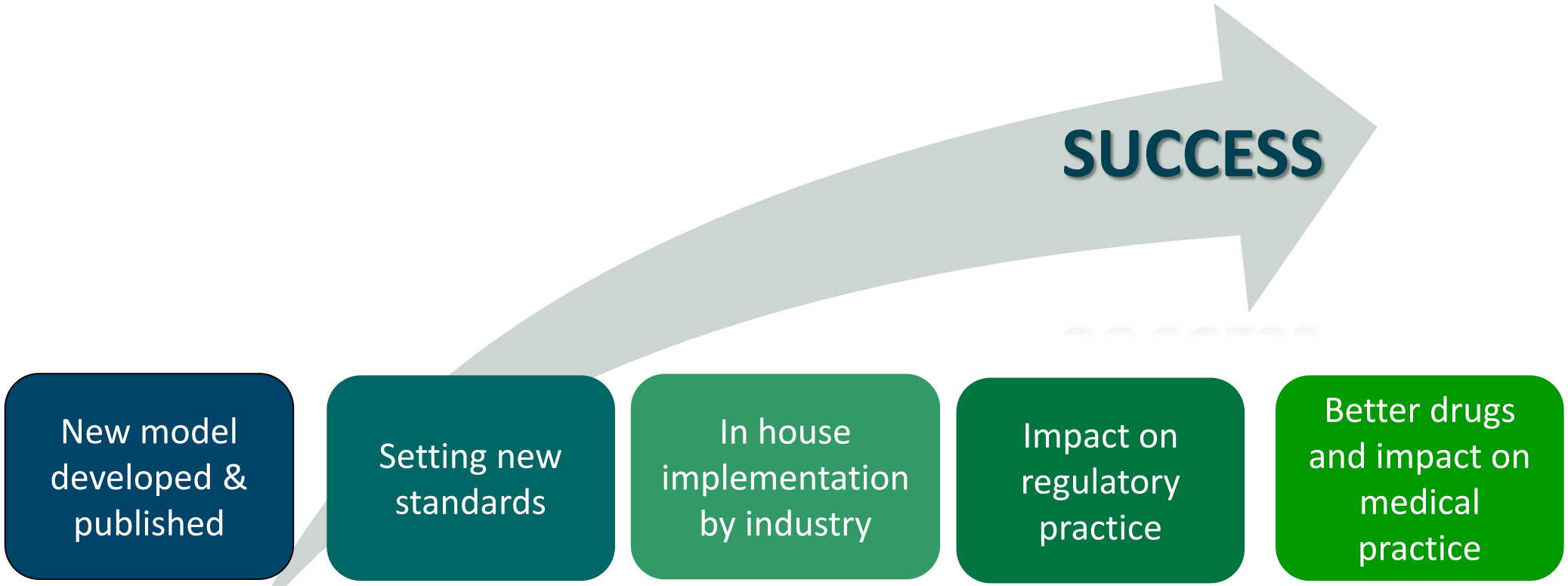
Measures of success



TRANSLATE SCIENCE INTO REGULATORY PATHWAYS AND REAL WORLD PRACTICE

PATIENTS ACCESS TO INNOVATIVE PREVENTIVE & THERAPEUTIC OPTIONS

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IMI ongoing projects
some examples

IMI's safety projects

SAFE-T

- 153 potential biomarker candidates for drug-induced injury of kidney, liver & vascular system evaluated
- 17 exploratory clinical studies

eTOX

Largest database on preclinical safety data providing access to unpublished safety data

90 in silico models for safety prediction delivered

MIP-DILI

To identify and validate an improved panel of in vitro "best practice assays" for predicting drug-induced liver injury in the human population

marcar
towards novel biomarkers for cancer risk assessment

Understanding non-genotoxic carcinogenesis
early biomarkers and molecular classification of tumours in non genotoxic carcinogenesis

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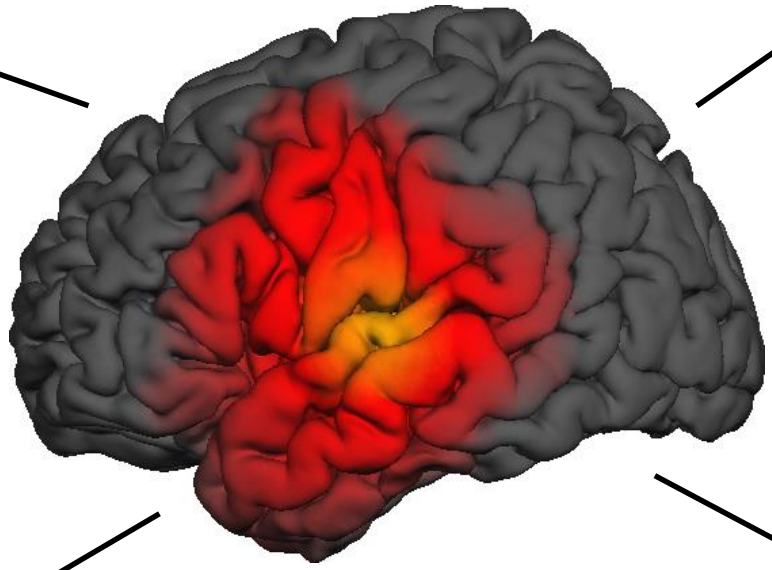
IMI action on Alzheimer's disease

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

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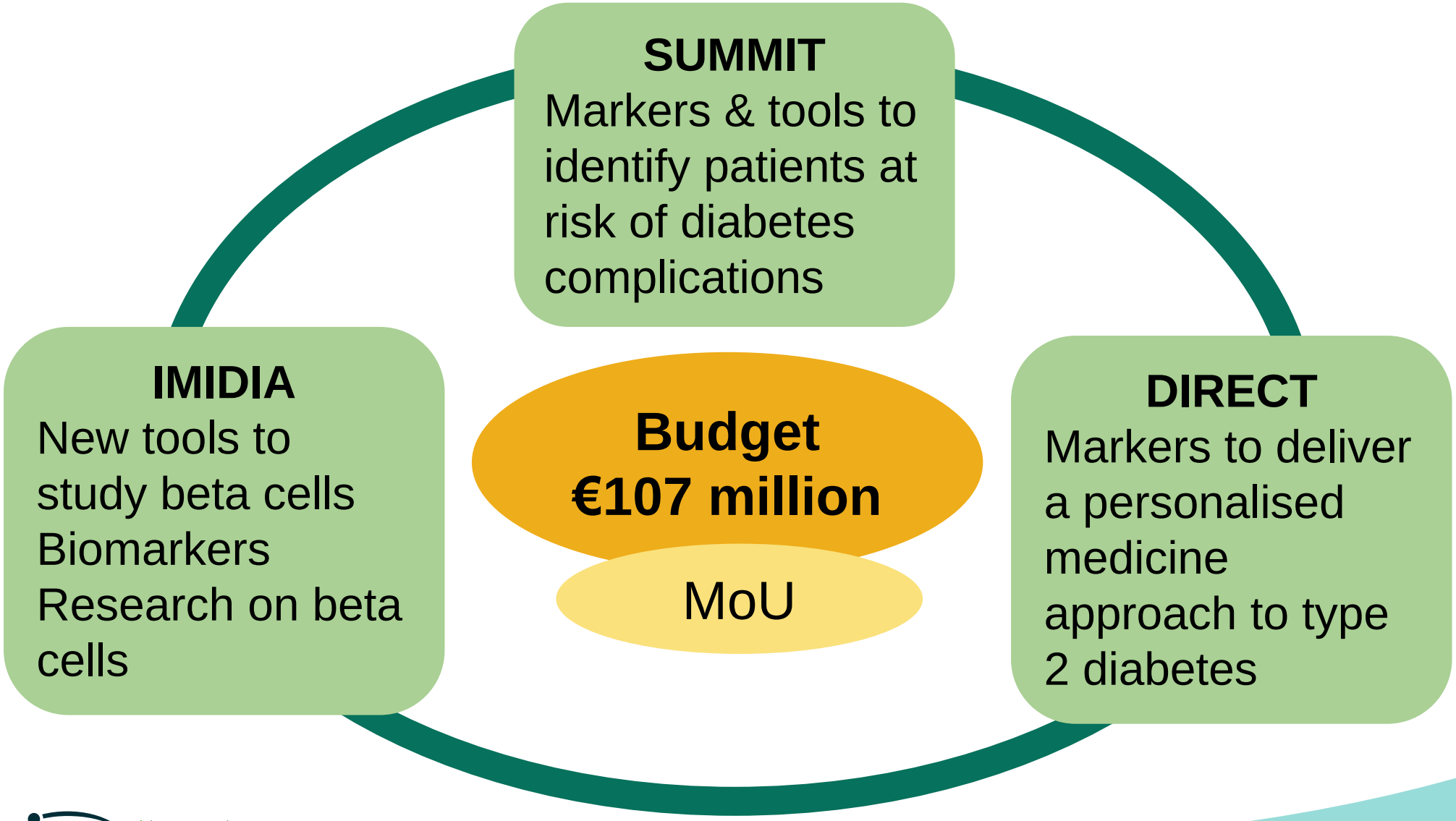
IMI diabetes programme



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IMI's cancer projects

CANCER-ID
Establishment of standard protocols for, and clinical validation of, blood-based biomarkers

ONCOTRACK
Developing & assessing novel approaches for identification of new markers for colon cancer

Budget
€86 million

PREDECT
Developing advanced, transferable *in vitro* models for breast, prostate and lung cancers

QUIC-CONCEPT
Tools & imaging biomarkers that show earlier and more accurately how tumours respond to drugs in clinical trials

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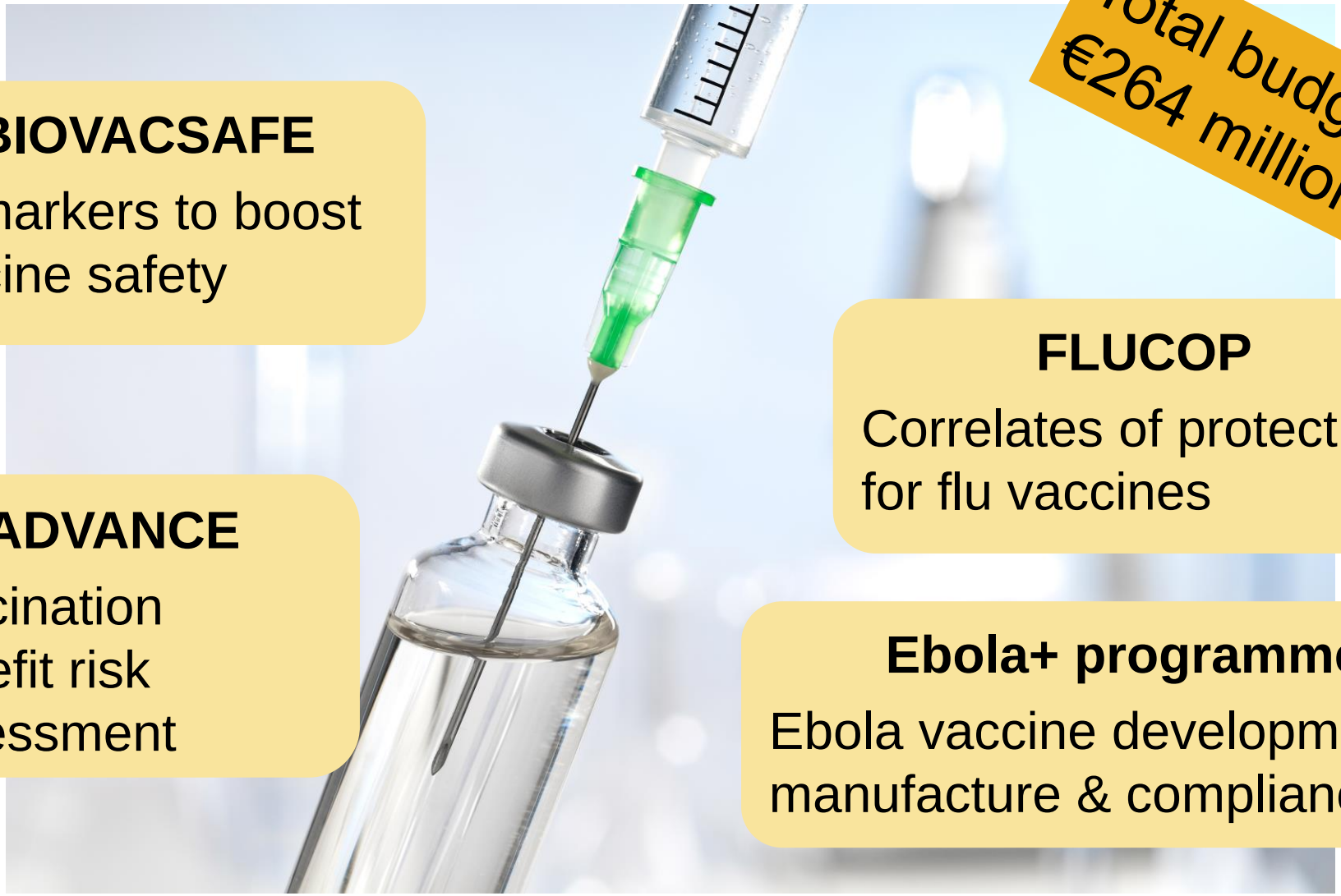
IMI vaccine projects



Total budget: €264 million

BIOVACSAFE

Biomarkers to boost vaccine safety

FLUCOP

Correlates of protection for flu vaccines

ADVANCE

Vaccination benefit risk assessment

Ebola+ programme

Ebola vaccine development, manufacture & compliance

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IMI response against antimicrobial resistance New Drugs for Bad Bugs (ND4BB)

Cross-project communication & collaboration

TRANS-LOCATION

Research on penetration & efflux in Gram-negatives

Data hub & learning from R&D experience

ENABLE

Discovery & development of new drugs combatting Gram-negative infections

COMBACTE

Enabling clinical collaboration & refining clinical trial design

Clinical development of compounds for Gram positives

COMBACTE-CARE

Clinical development of antibacterial agents for Gram-negative, antibiotic resistant pathogens

COMBACTE-MAGNET

Systemic molecules against healthcare-associated infections

iABC

Inhaled antibacterials in bronchiec-tasis and cystic fibrosis

DRIVE-AB

Driving reinvestment in R&D & responsible use of antibiotics

ND4BB Information Centre

All data generated is submitted and made accessible to all partners

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Drug discovery

Drug development (Gram-positives)

Drug development (Gram-negatives)

Economics & stewardship

Ebola+ programme overview

IMI2 Ebola and other filoviral haemorrhagic fevers programme
Joint Information repository, Scientific Advisory Board, Ethics Board

Pipelines	Vaccine development Phase I, II, III	Vaccine manufacture	Vaccine deployment & compliance with vaccination regimens	Rapid diagnostic tests
Total budget: €219m	VSV-EBOVAC Sclavo Vacc. Assoc.	EBOMAN Vibalogics, Janssen		EbolaMoDRAD Public Health Institute Sweden
Projects started early 2015	EBOVAC 1 LSHTM, Janssen		EBODAC LSHTM, Janssen	FILODIAG GNA Biosolutions
	EBOVAC 2 Inserm, Janssen			Mofina Public Health England, Altona

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Other IMI projects looking at novel models in clinical development

- **Better definition of the disease**

U-BIOPRED: handprint of severe asthma generated using system biology approach http://www.europeanlung.org/en/projects-and-research/projects/u-biopred/home

Europain: collect a database of patient data to give a tool for more reliable diagnostic criteria to chronic pain http://www.imieuropain.org

BTCure: new diagnostic methods to discover the early forms of RA and RA-like diseases & new tools to differentiate the different forms http://btcure.eu

New classification of patient groups based on the underlying causes of their disease:

PRECISEADS: for autoimmune diseases, particularly SLE and RA http://www.precisesads.eu

AETONOMY: for neurodegenerative diseases, particularly Alzheimer's and Parkinson's diseases http://www.aetionomy.eu

Sprintt: scientifically sound, and clinically-relevant operational definition of Physical Frailty & Sarcopenia (PF&S), to allow the identification of older individuals affected by this condition http://www.mysprintt.eu

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Other IMI projects looking at novel models in clinical development

- **Electronic Health Records for Clinical Research**

EHR4CR: Open IT platform that unlocks the information stored in EHR for improving clinical research by offering multitude of services (e.g. protocol feasibility based on real world data, site selection, patient recruitment...) www.ehr4cr.eu

- **EHR/Cohort/registries**

EMIF: Leverage of existing patient health data on > 40 M adults & children from EHR data sources (population-based registries, hospital-based databases, national registries, biobanks, etc.). www.emif.eu

- **Modelling/Simulation**

DDMoRe: Public drug & disease model repository supported by an open source interoperability framework CT simulation, model-based adaptive optimal design…www.ddmore.eu

- **PRO**

PROACTIVE: PRO for capturing physical activity in COPD http://www.proactivecopd.com/

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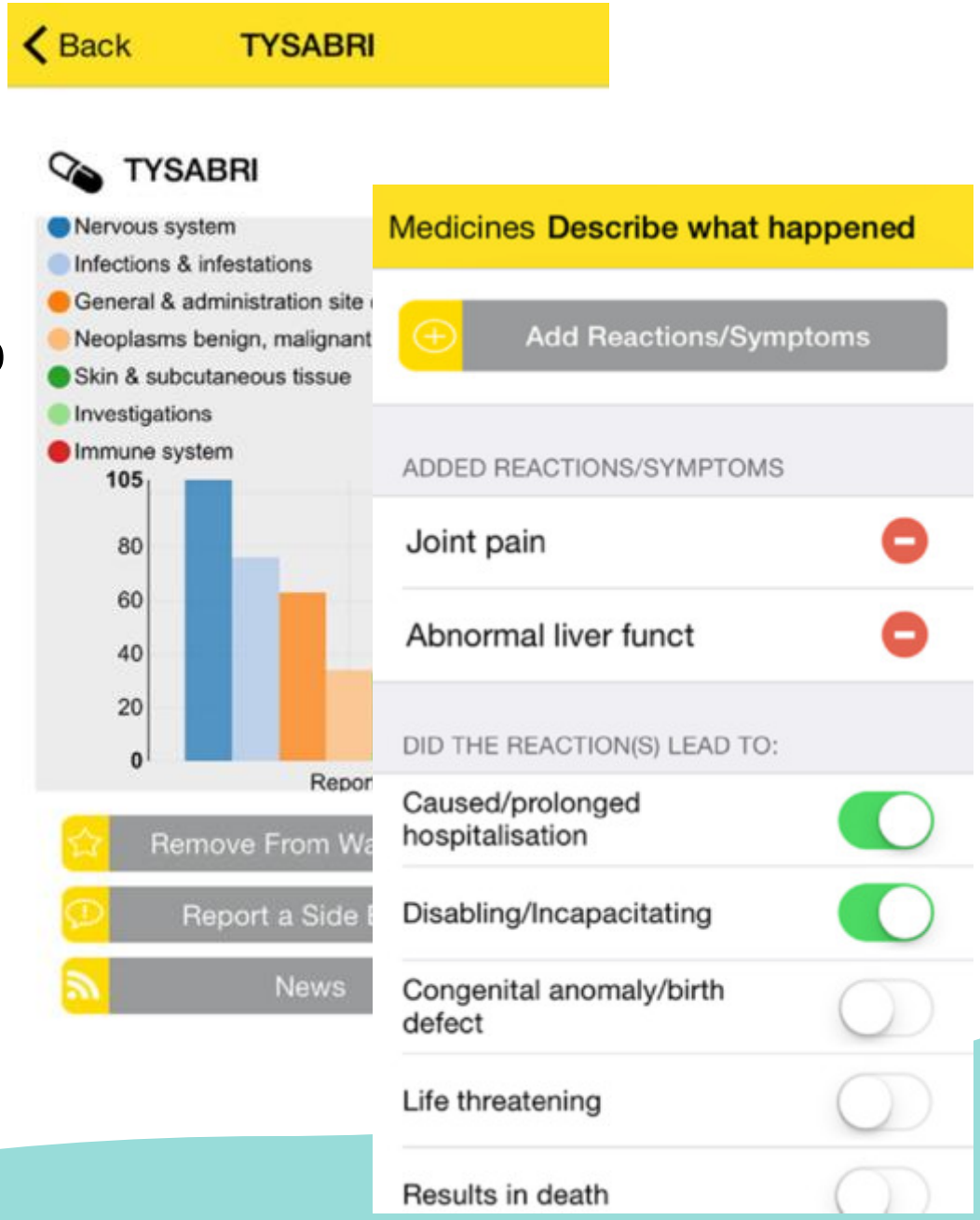
WEB-RADR - recognising adverse drug reactions

- Mobile phone app to report suspected ADRs to regulators - DELIVERED
- Assess use of app to provide info on medicines
- Explore identification of potential safety issues from user comments in social media.
- Develop recommendations for use mobile technologies and social media in pharmacovigilance & monitoring of medicines safety.



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GETREAL - Incorporating real-life clinical data into drug development

Explore how robust new methods of real-world evidence (RWE) collection and synthesis may be adopted earlier in pharmaceutical R&D and the healthcare decision making process

Get Real

www.imi-getreal.eu

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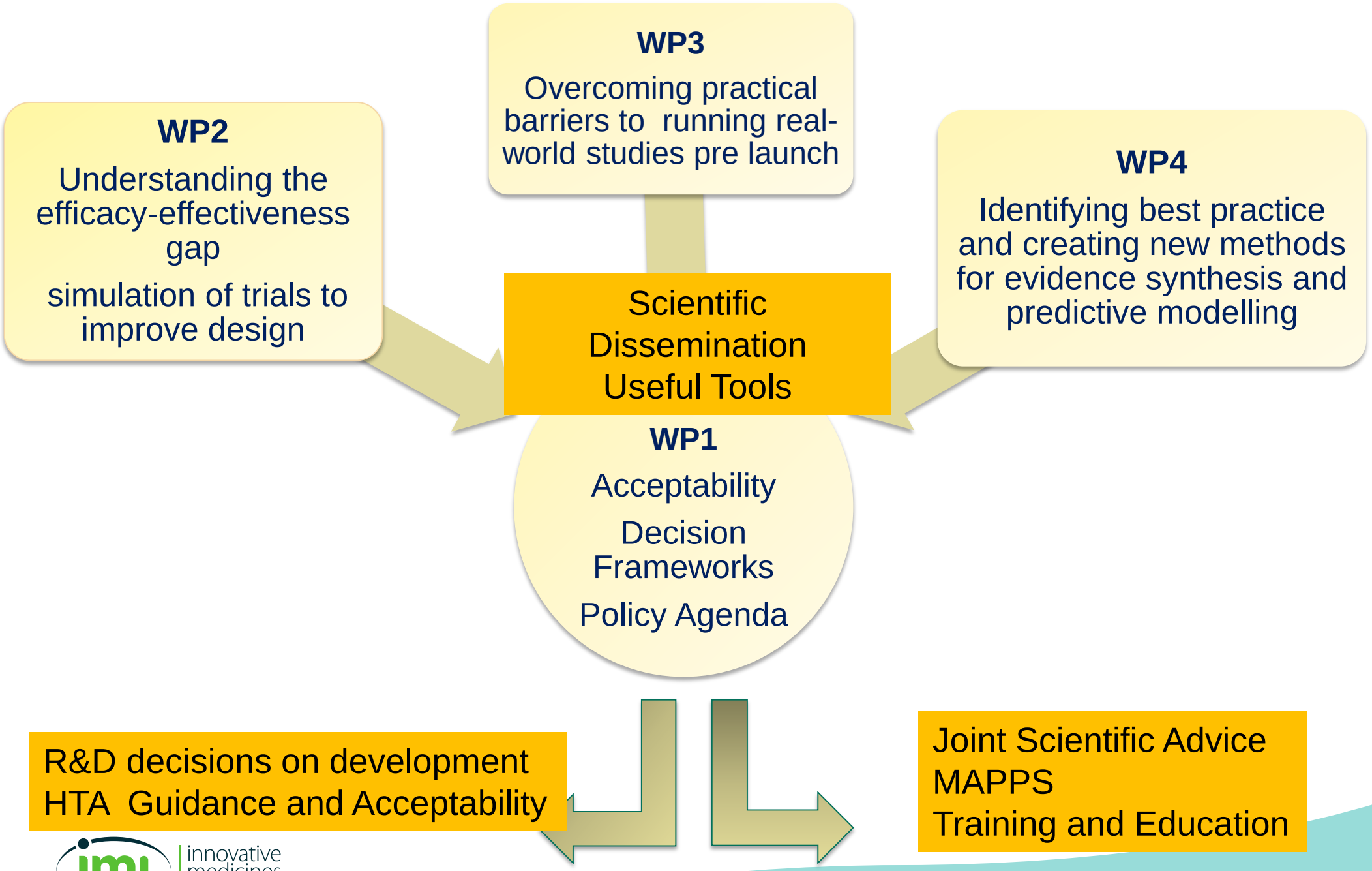
GETREAL OVERVIEW



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Key deliverables

- Decision-making framework to aid the design of drug development strategies
- Recommendations for regulatory and HTA policy development
- Guidance on methodologies for:
  - conducting and analysing RE research pre-authorisation
  - using EHR in conducting studies pre-authorisation
  - conducting data synthesis of wide range of source studies of different types
- Guidance to address operational, statistical and ethical issues in conducting pragmatic/adaptive designs pre-authorisation
- Software for conducting data synthesis
- Training & education

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Current status

Many achievements

Conference presence, publications

- Public consultation on 2 documents:
  - Report on Current Policies and Perspectives on real world data
  - Glossary of key terms in the area of relative effectiveness and real-world data.
- Case study topics identified
- Workshops carried out
- Research framework and literature reviews on E2E gaps

MAPPs - from concept to action

MAPPs - an evolution of the current development paradigm to an integrated process where ALL stakeholders involved in the decision making process participate from the start

- Explore feasibility & benefits of adaptive approaches in the context of current regulatory framework
- Consider initiatives and opportunities such as the EMA Pilot, and share learnings
- Consider value of IMI projects outputs in flexible development & access pathways
- Develop guiding principles
- Align understanding with all stakeholders
- Identify new IMI2 topics

➔ **Decision made to establish a Coordination and Support Action to coordinate MAPPs activities in IMI**

➔ ADAPT SMART selected through competitive process

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Launched September 2015

ADAPT SMART: Accelerated Development of Appropriate Patient Therapies

- Unprecedented **platform** with stakeholders regulators, HTA/payers, companies, academics, healthcare professionals, patients build to:
  - Identify relevant MAPPs activities, synthesizing learnings from ongoing or completed pilots and case studies, creating a MAPPs repository of knowledge & opportunities;
  - Identify scientific challenges & opportunities for MAPPs implementation and facilitate aligned understanding;
  - Support new IMI 2 projects by including MAPPs enablers (tools and methodologies) to address/exploit the identified challenges and opportunities;
  - Conduct horizon scanning & gap analysis; advice and/or recommend future research activities to IMI, other stakeholders to further the implementation of MAPPs.

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ADAPT-SMART

Through dialogue with all relevant stakeholders **recommendations** will contribute to:

- **aligning understanding** of impact of MAPPs vs current paradigm
- **proving and developing** workable MAPPs concepts
- **facilitate and accelerate** the implementation of MAPPs

Duration: 30 months

ADAPTSMART

http://adaptsmart.eu/

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IMI 2 –Calls for proposals

IMI 2 – Call 3

- Remote assessment of disease and relapse (RADAR) - CNS
- Assessing risk and progression of prediabetes and type 2 diabetes to enable disease modification
- Linking clinical neuropsychiatry and quantitative neurobiology
- The consistency approach to quality control in vaccine manufacture
- Pertussis vaccination research
- Knowledge repository to enable patient focused medicine development

Launched December 2014
Full proposal submission deadline end September 2015

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IMI 2 – Call 5

- Patient perspective elicitation on benefits and risks of medicinal products
- Diabetic kidney disease biomarkers
- Inflammation and Alzheimer's disease: modulating microglia function – focussing on TREM2 and CD33
- Understanding the role of amyloid imaging biomarkers in the diagnosis and management of patients across the spectrum of cognitive impairment
- Evolving models of patient engagement and access for earlier identification of Alzheimer's disease
- From ApoE biology to validated Alzheimer's disease targets

Launched July 2015
Deadline for short proposals: 13 October 2015

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IMI 2 – Call 6

- Development of Quantitative System Toxicology (QST) approaches to improve the understanding of the safety of new medicines
- Establishing impact of RSV (respiratory syncytial virus) infection, resultant disease and public health approach to reducing the consequences

Topics under **Big Data for Better Outcomes** programme

- Real World Outcomes Across the AD (Alzheimer's disease) Spectrum (ROADS) to Better Care
- Development of an outcomes-focused platform to empower policy makers and clinicians to optimise care for patients with haematologic malignancies

Launched 30 September 2015
Deadline for short proposals: 12 January 2016

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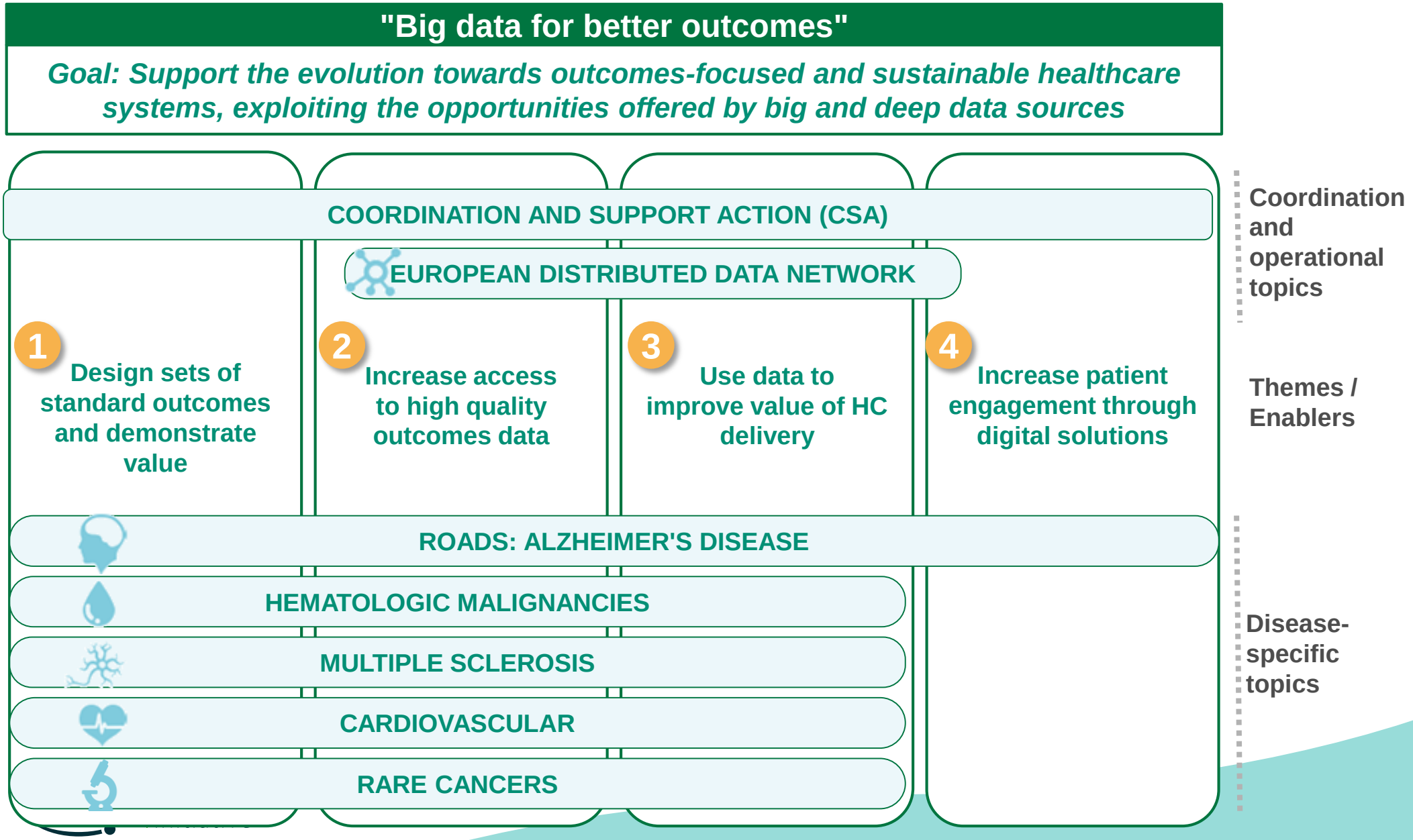
Big data for better outcomes



IMI: an engine for advancing regulatory science

- Science-based evidence to improve the drug development throughout the whole life-cycle and to stimulate innovation
- Identify pathways to integrate new scientific advances into the regulatory/HTA decision making process
- Drivers to evolve policies towards flexible development & access pathways that balance early patient access, public health and societal benefits
- Value of a neutral partnership to involve all stakeholders, especially patients, Regulators, HTA bodies/payers for collaborating, sharing data & knowledge and fostering creative collective intelligence to find solutions for a sustainable healthcare system

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