

Building new models of collaborative research across Europe – IMI2

Magali POINOT • Advisor to the Executive Director, IMI Office
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The need for new models – public-private partnerships

- Because drug development -from biological mechanisms to clinical trial designs and regulatory pathways- is **still** very complex, risky, lengthy and expensive.
- Because new ideas responding to and transformative outcomes for both industrial needs and public health challenge are **even more** needed.
- IMI is not for everything (and might not suit to everyone)

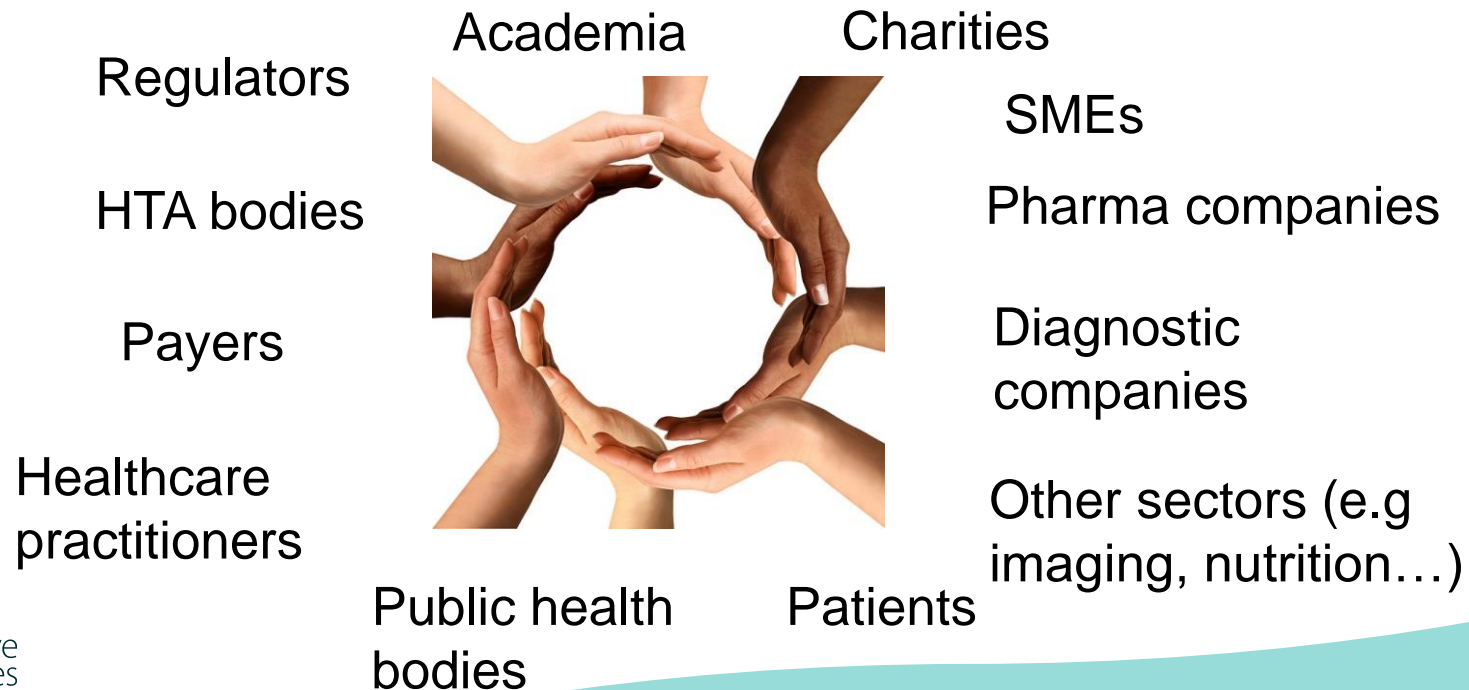
FORM SHOULD FOLLOW FUNCTION

- But for certain specific things public-private partnerships are probably the only way of making progress

IMI – Ecosystem for innovative collaborations

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges in areas of unmet medical needs**.

All partners needed to find transformative solutions to **reduce late stage attrition, speed patient access** and **improve health outcomes** and find solutions for a sustainable healthcare system



IMI – Europe's partnership for health

IMI2 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

Aligned with WHO priorities

Over 11 500 researchers from an international, cross-sector community



IMI2 budget (2014 – 2020)

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 /
Partners in
Research

receive no
funding
contribute to
projects 'in kind'

Associated
Partners e.g.
charities, non-
EFPIA
companies



In practice

IMI2 Associated Partners

(only those contributing in excess of €1 million)

- Bill and Melinda Gates Foundation
 - The Wellcome Trust
 - The Simons Foundation
 - Autism Speaks
 - JDRF
 - The Helmsley Charitable Trust
 - TB Alliance
-
- Total Associated Partners contributions to date over €160 million

EFPIA Partners in Research



<https://www.efpia.eu/about-us/membership/>

From Idea to Call Launch

Idea for a topic in line with IMI2 objectives and SRA

Industrial partners (can also include Associated partners) align themselves around a real challenge for industry and agree to work together and commit resources

New ideas from public sector, universities, SMEs etc. are needed to address the challenge - see [Submit your idea](#) webpage

Outcomes should be transformative for the industry as well as having a clear “public” value

Consultation with IMI2 bodies (~ 3 weeks)

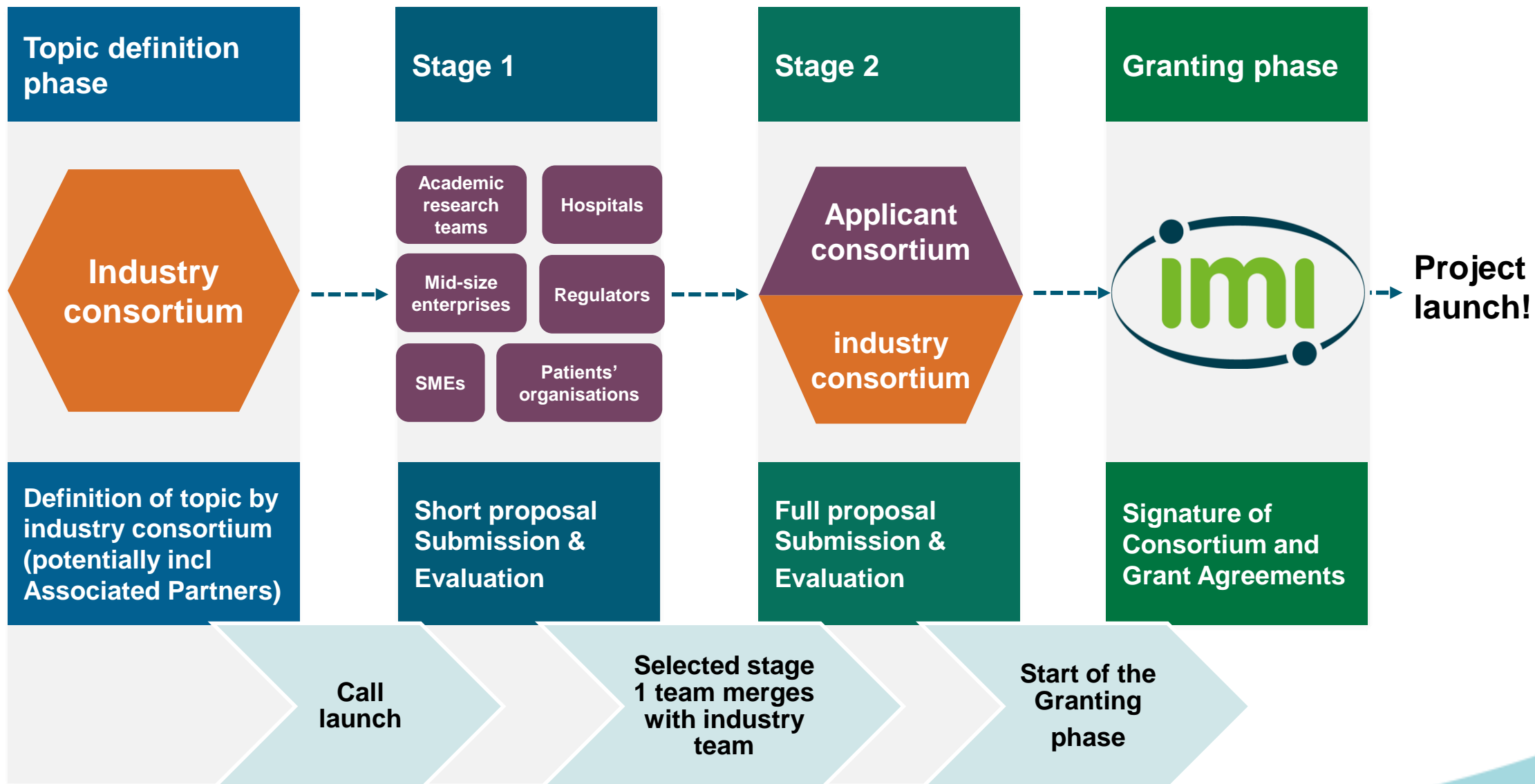
States Representatives Group - Scientific Committee - EC

Comments to be addressed and reflected in revised topic text

Governing Board procedure approving Call for proposals

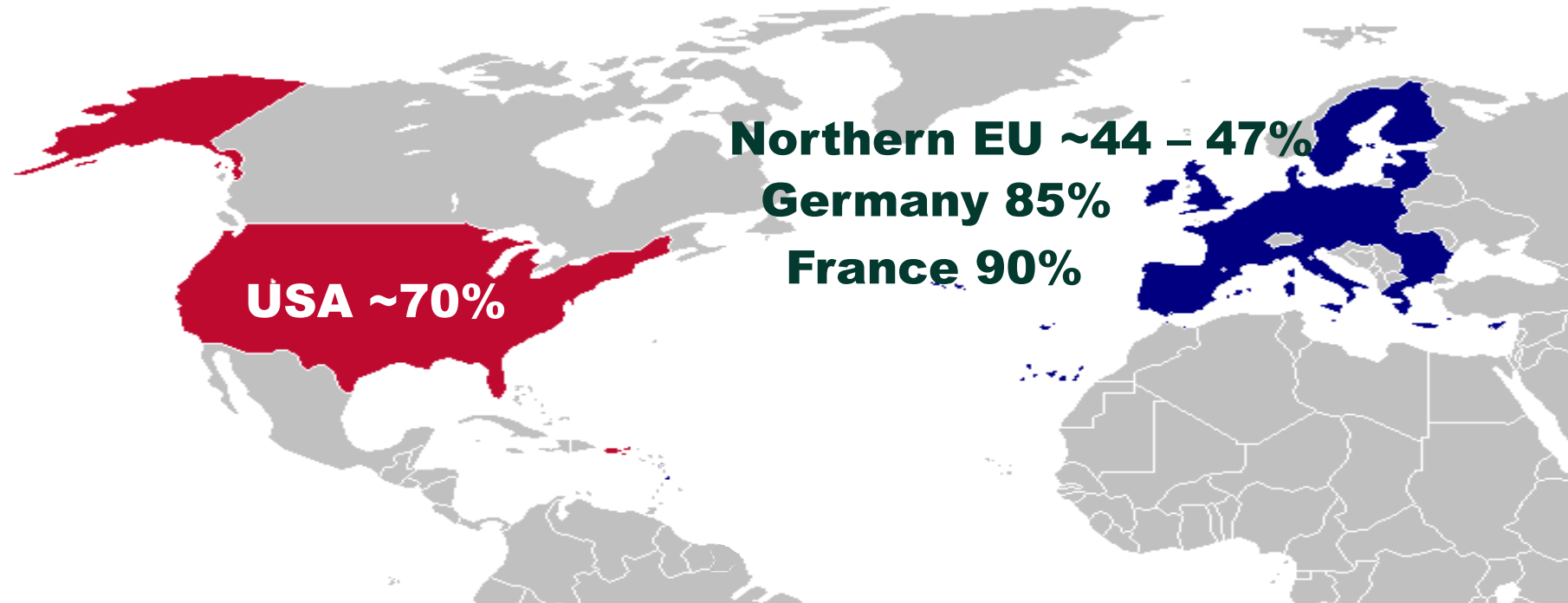
Call launch and communication *webinars, info days, etc.*

How does the two stage procedure work?



What makes a good IMI topic?

e.g. **ConcePTION** - Understanding medication effects during pregnancy and lactation



- 230 million pregnancies worldwide in 2012
- 5.1 million children born - EU-28 in 2014
- 6 million children born - US
- Medication use in pregnancy is common
 - Estimation in the EU: 2 million pregnancies each year

What makes a good IMI topic?

e.g. ConcePTION - Understanding medication effects during pregnancy and lactation

- The project brings together an unprecedented 88 organizations from 22 countries, including the European Medicines Agency, drug manufacturers, academia, public health organizations, and teratology networks
- IMI2 JU - ideal neutral framework:
 - Precompetitive nature (aims are not focused on any pharmaceutical product)
 - Gap in the ecosystem
 - Transparency across stakeholders
 - Enable sharing data in a secure environment
 - Health authorities & patient groups key partners in creating value
 - Patient and societal benefits

How does an IMI project look like?

e.g. Mobilise-D - Revolutionizing assessment of mobility loss using digital technology



brings together clinicians, scientists, prominent academic centres, businesses, and the world's largest pharmaceutical and medical industries



Examples from a decade of successes

- Gaps in the ecosystem like Paediatric CTN
- Market failures like AMR
- Complex but highly relevant public health burdens like dementia or other neurological conditions (pain, autism)
- Technology platforms like ELF, EHR4CR, EMIF
- Ebola vaccines and diagnostics
- Several clinical trials networks (1800 sites across Europe) and 39 cohorts and registries to optimize clinical trials
- Tools to predict toxicity approved by regulators
- First ever human beta cell line culture which changed the way diabetes research is done

€5.3bn
BUDGET

121
PROJECTS

2278
PARTICIPANTS

>7 000
PROJECT OUTPUTS

>3 800
PUBLICATIONS

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In-depth stories about some of
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MAPS AND STATISTICS

Our projects have partners across
Europe and beyond. Find them
with the help of this interactive
tool.



CATALOGUE OF PROJECT TOOLS

Accelerate your own research.
Have a look at the list of accessible
tools generated by our projects.



Example of contribution to the catalogue of project tools

EBISC

EBISC catalogue

Catalogue of human iPS cells being made available to academic and commercial researchers for use in disease modelling and other forms of preclinical research

[link](#)

Free



Global supplier of iPSC lines

Cell Line Catalogue

For customers

For depositors

About EBISC

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iPSC line catalogue

801 cell line

Search cell lines

Disease

Donor sex

Donor age

Derivation

Name	Donor disease status	Genetic modification	Donor sex	Donor age	Derivation
EDi018-C	bipolar disorder	/	female		Sendai virus
ESi003-A	X-linked creatine transporter deficiency	/	male		Retrovirus
ESi004-A	Gaucher disease	/	female		Lentivirus expressing CRE recombinase

Example of success story

Support for patients with respiratory diseases

13/03/2019



IMI's PRO-active project has developed new patient-centred tools and approaches to help people with chronic obstructive respiratory disease (COPD) get more personalised treatments - a means to boost their activity levels, health and well-being.

COPD affects 1 in 10 of all people aged 50 and over and is a leading cause of death. The disease is characterised by breathlessness, coughing and often excessive mucus production, all of which make any physical activity uncomfortable and difficult for sufferers. In Europe alone, some 300 000 Europeans die each year from COPD.

Physical inactivity is a key predictor of death in patients with COPD. The IMI project PRO-active has developed new tools to help researchers and clinicians measure the impact of the disease on patients experience with physical activity and the physical difficulties patients encounter. This information can now be used to assess the impact of effective treatments on an outcome that is directly relevant to patients.

'Lack of physical activity is an indicator of mortality,' says project coordinator Thierry Troosters of the Katholieke Universiteit Leuven in Belgium. 'Patients with COPD who drop their physical activity levels are more likely to die than people who maintain those levels. We could already measure physical activity, but now we have a tool that captures how patients experience it.'

The new tools are providing doctors, nurses and other healthcare workers and researchers with unique information on the effect of treatment on their patients, he adds. They will also feed into the way new medicines and other interventions are assessed and benchmarked, based on patients' experiences.

A focus on patient experience

By combining wearable physical activity monitors with short daily surveys, researchers found an effective way to gauge symptom-related stress experienced when patients were active. Three different kinds of activity monitors were trialled to find the most sensitive ones, which are best suited for people with chronic diseases.

Input from patients was key to the development of the PRO-active tool. COPD sufferers themselves designed the user-friendly questions for the surveys and patient organisations were also given important managerial roles on the ethics committee board of the project.

'We want to get insights from the patients' perspective on how an intervention benefits them directly,' says Troosters, explaining how normally treatment testing focuses on physiological results, but not patient experiences.

For further results of the project please refer to the IMI website: <http://www.imi.europa.eu>





Introduction to coming IMI2 Calls

IMI2 Call 18 – 6 topics

Translational safety:

- Central repository of digital pathology slides to support the development of artificial intelligence tools.

Big data, digital health, clinical trials and regulatory research:

- Health outcomes observatories – empower patients with tools to measure their outcomes in a standardised manner creating transparency of health outcomes.
- Improving patient access, understanding and adherence to healthcare information: an integrated digital health information project.

IMI2 Call 18 – 6 topics

Oncology:

- Establishing international standards in the analysis of patient reported outcomes and health-related quality of life data in cancer clinical trials.

Facilitating the translation of advanced therapies to patients in Europe:

- Accelerating research & development for advanced therapy medicinal products.
- Supporting the development of chimeric antigen receptor T cell.

IMI2 Call 18 – Key dates

- Call launch: 26 June 2019
- Topics texts are **already published** on the IMI website
- **Webinar** topic presentations: end June- beginning of July as well as SME dedicated webinar, Rules & Procedures webinar
- Deadline Short Proposal submission: 26 September 2019
- Submission through the EU Funding & Tenders Portal [SEDIA](#)
- Project start: Autumn 2020

IMI2 Call 19 - Restricted call to maximise impact of IMI2 JU objectives and scientific priorities

- Published as a single-stage Call;
- Restricted to the original consortia of actions funded under topics published in the IMI2 JU Annual Work Plan of 2014 and of 2015, since only these actions are sufficiently advanced in their implementation to be considered for follow-up activities, and;
- Limited to those topics where the corresponding Work Plan already pre-informed potential applicants about the possibility of a later restricted Call.

Applicant consortia will be competing for a maximum total EU contribution of € 20M

IMI2 Call 19 – Key dates

- Call launch: 26 June 2019
- Topics text **already published** on the IMI website
- **Webinar** topic presentations: end June- beginning of July as well as SME dedicated webinar, Rules & Procedures webinar
- Deadline Full Proposal submission: 26 September 2019
- Submission through the EU Funding & Tenders Portal [SEDIA](#)
- Project start: Spring 2020

Participation of SMEs, patient groups, regulators, non-pharma sectors

We encourage the participation of a wide range of health research and drug development stakeholders in our projects.

- SMEs and mid-sized companies
- Patient organisations
- Regulatory bodies
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc...)

Topics in the longer term pipeline (2019-2020)

IMI2 Call in 2020 – Key information

- Two Calls currently planned: January / June
- Topics under consideration for inclusion in future IMI Calls published on the IMI website
- Draft topics text published: +/- 2 months before official Call launch
- Indicative budget for 2020: ~ € 265 Mio (IMI funding only)
- Webinar topic presentations organised: at official Call launch
- Deadline for submitting Short Proposals: 3 months after official Call launch

Topics in the pipeline (indicative)

Neurodegeneration / neuroscience

- Digital transformation of clinical trial endpoints in pain
- Placebo effect in pain
- Psychiatric ratings using intermediate stratified markers

Immunology

- Psoriatic arthritis

Infection control & vaccines

- New topic(s) under the AMR Accelerator

Translational safety

- Dosing in specific populations

Other enablers of research topics

- Handling of biologic drug products

Topics in the pipeline (indicative)

Big data, digital health, clinical trials and regulatory research

- ROADMAP 2: need and opportunity for public-private collaborative research to continue the RoadMap efforts

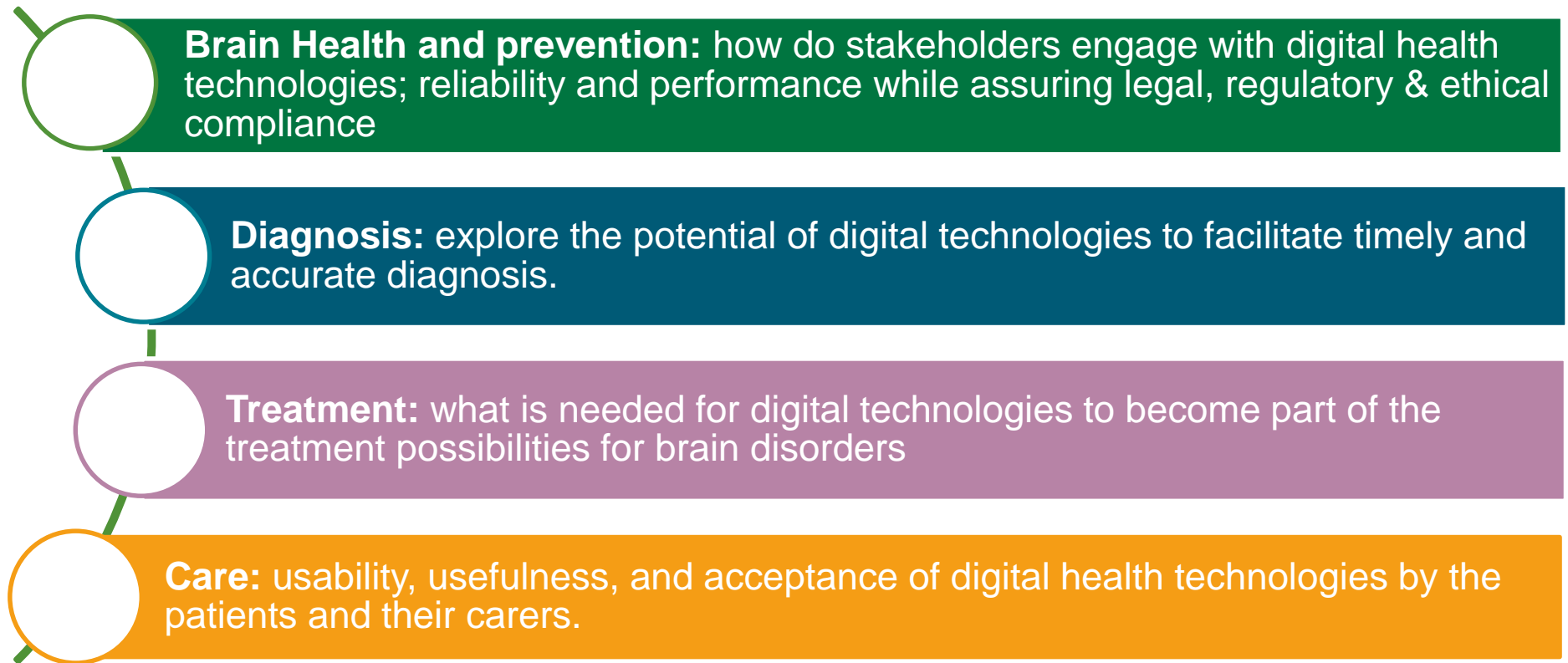
Facilitating the translation of advanced therapies to patients in Europe

- ATMP Patient Registries Outcomes Data and Evidence
- Innovative Manufacturing of Advanced Therapeutic Medicinal Products, ATMPs

Stakeholder Forum 2019 “Brain health and diseases in the digital era - 2020 & beyond”

Wednesday 12 June at Royal Museum of Fine Arts of Belgium

Built around 4 sessions following the patient’s path from prevention to care



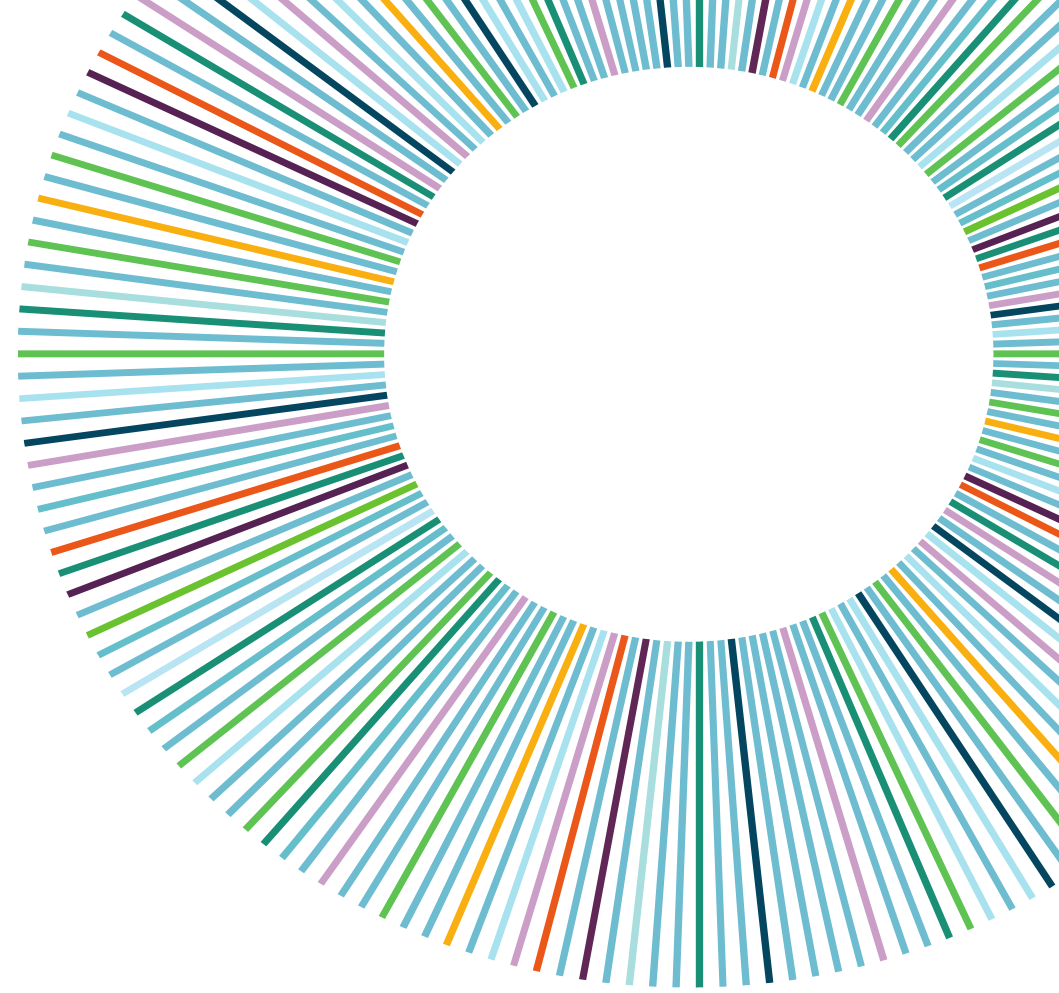
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**10 YEARS OF
BREAKTHROUGHS**
A HEALTHIER
FUTURE



Thank you!