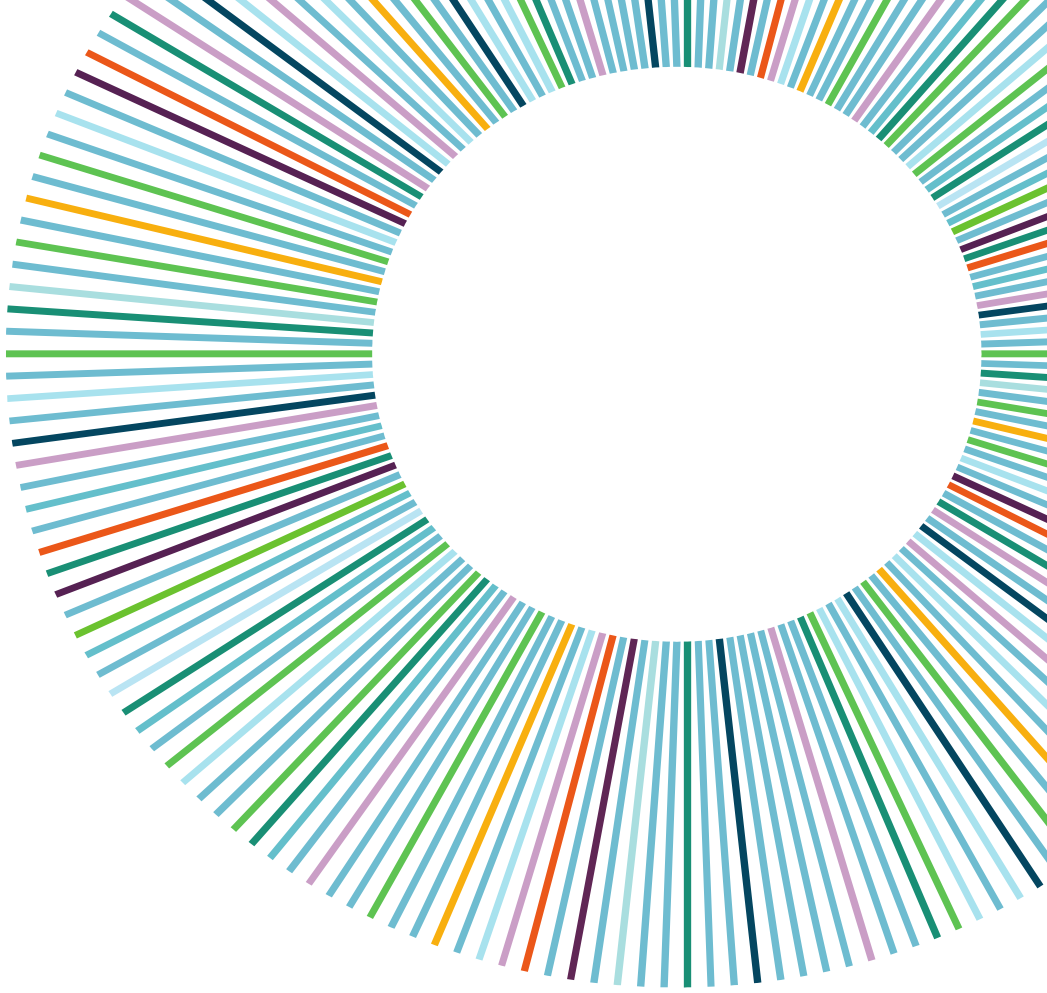
The Innovative Medicines Initiative – Building new models of collaborative research across Europe

Magali POINOT • IMI Office

IMI info day • Budapest, Hungary • 31 January 2019

efpia

10 YEARS OF LIGHTING THE WAY



10 YEARS OF BREAKTHROUGHS
A HEALTHIER FUTURE

imi innovative medicines initiative

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

innovative medicines initiative

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.

innovative medicines initiative

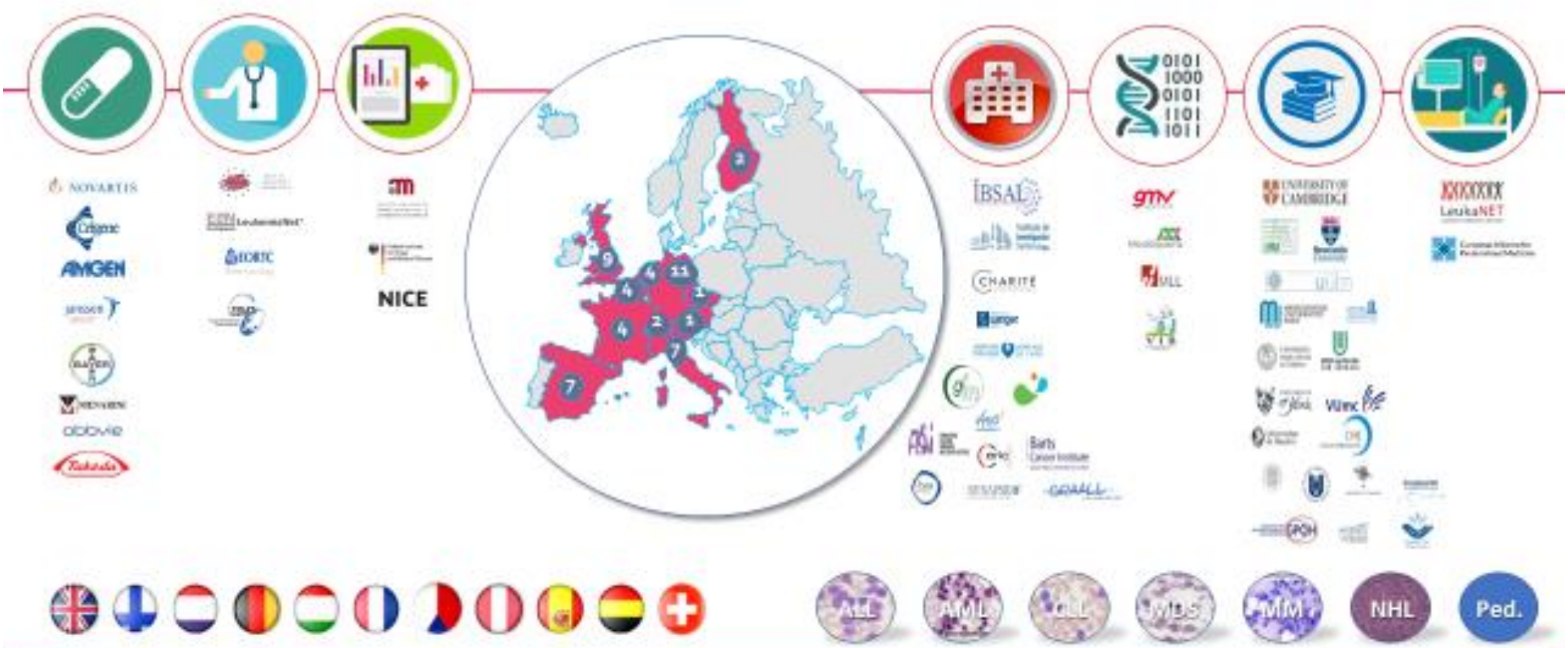
IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources
- Build a collaboration based on trust, creativity and innovative and critical thinking
- Learn from each other - new knowledge, skills, ways of working
- Take part in transformative research that will make a difference in drug development and ultimately patients' lives

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

innovative medicines initiative

How does an IMI project look like?
HARMONY - Big Data / Oncology



IMI – Europe's partnership for health

IMI2 Strategic Research Agenda

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Diabetes
- Neurodegene-rative 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

innovative medicines initiative

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 / Patners in Research

receive no funding

contribute to projects ‘in kind’

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

innovative medicines initiative

Enlarging the ecosytem

- Increasing role of non-pharma industry to advance the development of new approaches and technologies for the prevention, diagnosis and treatment of diseases with high impact on public health
- SMEs, patients, regulators, etc. are key players in the European pharmaceutical research and development landscape
- Synergies with other EU, national / regional and international programmes and partners
- Objectives:
  - Benefit from existing knowlegde and expertise
  - Maximise the pooling of resources and amplify scientific and financial investments
  - Facilitate / accelerate access, etc.

IMI Associated Partners

(only those contributing in excess of €1 million)

- Bill and Melinda Gates Foundation
- The Wellcome Trust
- The Simon Foundation
- Autism Speaks
- JDRF
- The Helmsley Charitable Trust
- TB Alliance

- Total Associated Partner Contributions to date over €150 million

innovative medicines initiative

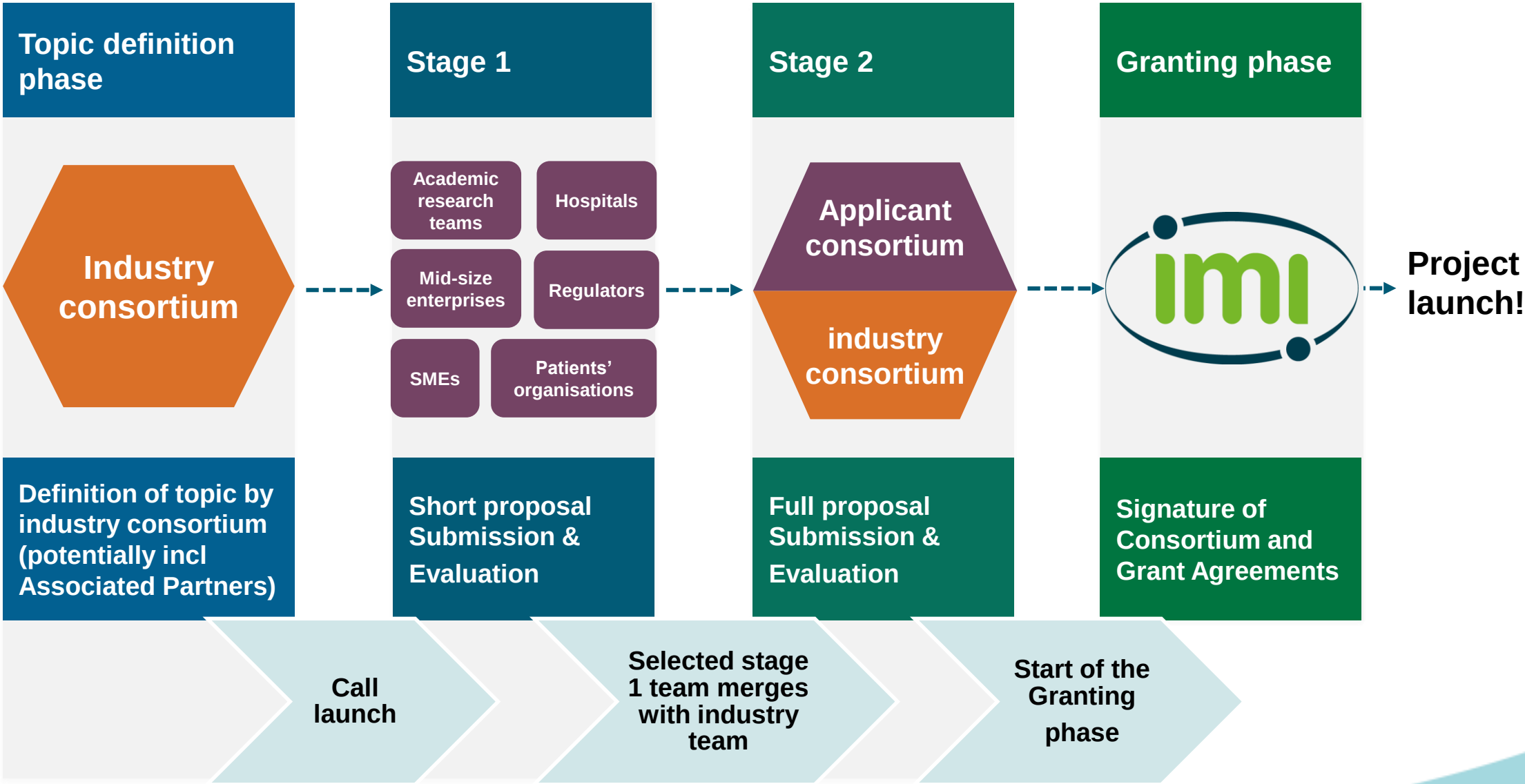
EFPIA Partners in Research

Some areas of achievements

- Technology platforms like ELF, EHR4CR, EMIF
- Gaps in the ecosystem
  - Paediatric CTN
  - A project on the use of medicines in pregnant women and during the neonatal period
- Market failures like AMR
- Complex but highly relevant public health burdens like dementia or other neurological conditions (pain, autism)

IMI2 Rules and Procedures
Main features

Typical IMI project life cycle



imi innovative medicines initiative

Key concepts for topic definition

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

Scale is a key to success and is provided through IMI funding

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

innovative medicines initiative

A single set of rules

- **Covering all H2020 research and innovation actions**
- **Adaptability where needed:**
  - Entities eligible for funding
  - IP

imi innovative medicines initiative

Attracting stakeholders

Any legal entity, regardless its place of establishment, carrying out work relevant to the Call objectives may be part of applicant consortia

But… not all participating entities are eligible for funding

innovative medicines initiative

Who is eligible for funding?

- Academic institutions
- Small & medium-sized enterprises (SMEs)
- Mid-sized enterprises (≤ €500m)
- Non-profit organisations e.g. research organisations, patient organisations, NGOs, public bodies, intergovernmental organisations etc.

Established in:

- **EU Member State**
- **Associated Country**

Other countries:
No funding ***unless participation deemed essential*** *by IMI2 JU for carrying out the action*

Art.1 Commission Delegated Regulation (EU) No 622/2014

innovative medicines initiative

One single funding rate per project – Beneficiaries receiving IMI funding

One project = One rate

For all beneficiaries and all activities

- 100% of the direct eligible costs
- Indirect costs: **25% flat rate**

innovative medicines initiative

A single set of evaluation criteria

- Two-stage evaluation: all three criteria considered at both stages
- Thresholds and weighting in the **Call documents** depending two-stages/single stage
- At stage 1 evaluation the **budget** is evaluated under criterion 3 ‘Quality and Efficiency of the Implementation’

Minimum of **3 independent experts**

Each proposal **evaluated ‘as it is’**, not as ‘what could be’

innovative medicines initiative

IMI IP policy to support innovation

- Opportunity of further development and/or validation of background assets
- Background and sideground assets protected (no transfer)
- New results owned by the generator(s) and right to transfer ownership / for non-exclusive license
- Result owner to design on the best protection modalities
- Access to expertise from the other partners on equal basis
- Access rights for exploitation purposes to be negotiated on a case-by-case basis
- Dissemination subject to conditions, such as respect of the legitimate interests

Your contact points

At the IMI Programme Office

- General queries: applicants@imi.europa.eu
- IP queries: IMI-IP-Helpdesk@imi.europa.eu

Local contacts

- IMI2 JU States Representatives Group: bit.ly/IMISRG
- Horizon 2020 Health National Contact Points: bit.ly/H2020_NCPs

innovative medicines initiative

Introduction to IMI2 Call 17

Launched on 22 January 2019

IMI2 Call 17 – Key dates

- Call launch: 22 January 2019
- Deadline for Short Proposal submission:

25 April 2019 (17:00:00 Brussels time)

Submission through the

EU Funding & Tenders Portal SEDIA

- Project start: ~ April 2020

innovative medicines initiative

IMI2 Call 17 – Optimising future obesity treatment

Topic 1 in a nutshell:

- Taxonomy of diseases for better understanding and enhancing prevention
- Database based on pre-existing observational and clinical data
- Sustainability

Webinar held on 29 January – Presentation, recording and list of participants available on our website

innovative medicines initiative

IMI2 Call 17 – Open access chemogenomics library and chemical probes for the druggable genome

Topic 2 in a nutshell:

- Open access set of chemical tools
- Artificial intelligence and machine learning applications
- 3 major therapeutic areas: immunology, oncology, neuroscience
- Link with the IMI ULTRA-DD projects!

Webinar held on 30 January – Presentation, recording and list of participants available on our website

innovative medicines initiative

IMI2 Call 17 – Intelligent prediction and identification of environmental risks posed by human medicinal products

Topic 3 in a nutshell:

- Ensure the environmental safety of human medicinal products by developing innovative & predictive tools to identify risks
- Determine greener drug design
- Develop an ecotoxicology database
- Link with the IMI iPIE and CHEM21 projects!

Webinar held on 23 January – Presentation, recording and list of participants available on our website

imi innovative medicines initiative

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 – *notably topics 2 and 3*
- Patient organisations – *notably topics 1 and 3*
- Regulatory bodies – *notably topics 1 and 3*
- Companies / organisations from related fields (e.g. diagnostics, animal health, IT, imaging etc…) – *all topics*

Webinar held on 25 January – Presentation, recording and list of participants available on our website

imi innovative medicines initiative

Why should SMEs and biotechs consider participating in an IMI project?

- By engaging with all stakeholders, sectors, initiatives and funders across Europe, IMI provides for a dynamic ecosystem for research and business network
- Collaboration with large pharmaceutical companies allows access to whole value chain of drug discovery
- IMI ecosystem creates opportunities for further development and validation of assets while protecting background IP
- 100% funding for EU-based entities

innovative medicines initiative

IMI2 Call 17 - Expected consortia

Stage 1 of two stage - Short Proposals

- **Consortia consisting of:**
  - IMI2 JU fundable legal entities carrying out activities relevant for achieving the project objectives
  - additional legal entities carrying out activities relevant for achieving the project objectives.

innovative medicines initiative

Conditions for IMI2 Call 17

H2020 Rules for participation apply to IMI2 JU Call for Proposals and Actions except where specifically derogated

- **Minimum conditions**

  RIA: at least three independent legal entities, each established in a different EU Member State or H2020 associated country

- **Two-stages**

  Stage 1 SPs from applicants requesting JU funding

  Stage 2 merging 1st ranked SPs with industry consortia

- **Evaluation criteria**

  At stage 1, all 3 criteria are evaluated (including budget)

innovative medicines initiative

Tips for writing a successful proposal

- Read **all** the call-relevant material
  www.imi.europa.eu
- Begin forming your consortium **early**
  Partner search tools & networking events
- Provide reviewers with all the information requested to allow them to evaluate your proposal
- **Finalise and submit your proposal early**
- Contact the **IMI Office** (**NOT** industry topic writers)
  infodesk@imi.europa.eu

imi innovative medicines initiative

Find project partners

- Network with **your contacts**
- **Network** with fellow webinar participants
- Use **Partner Search Tools:**
  - EU participant portal: https://ec.europa.eu/research/participants/portal/desktop/en/organisations/partner_search.html
  - German NCP partner search tool: www.imi-partnering.eu
- Get in touch with your **local IMI contact point**: www.imi.europa.eu/about-imi/governance/states-representatives-group
- Talk to your **Health National Contact Point** (NCP)
- Network on **social media** (e.g. IMI LinkedIn group)

innovative medicines initiative

Topics in the pipeline (2019-2020)

Topics in the pipeline (indicative info)

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
- Digital pathology

Oncology

- Patient-reported outcomes and quality of life endpoints

Other enablers of research topics

- Handling of biologic drug products

Topics in the pipeline (indicative info)

Big data, digital health, clinical trials and regulatory research

- ROADMAP 2: need and opportunity for public-private collaborative research to continue the RoadMap efforts
- Independent observatories of health outcomes for patients being the guardians of health data
- E-product information. Leveraging digital technology to drive the correct use and understanding of medicines: a user-centric approach to adherence and risk minimisation

Facilitating the translation of advanced therapies to patients in Europe

- Accelerating research and development of Advanced Therapies
- ATMP Patient Registries Outcomes Data and Evidence
- CAR-Ts
- Innovative Manufacturing of Advanced Therapeutic Medicinal Products, ATMPs

Save the date: IMI Stakeholder Forum 2019

Theme: Brain health & diseases in the digital era

12 June 2019

Brussels, Belgium

innovative medicines initiative

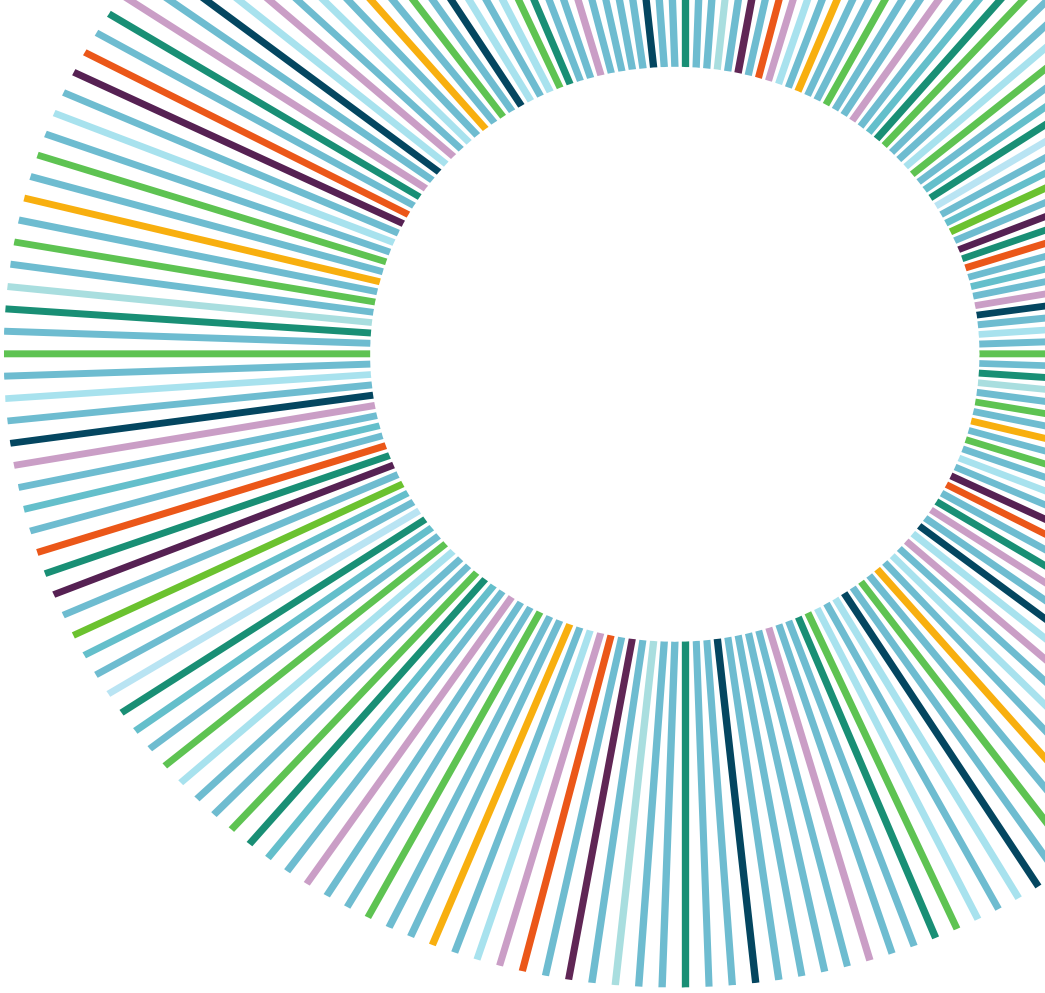
Visit our new website
www.imi.europa.eu

Sign up our newsletter
bit.ly/IMInewsletter

Follow us on Twitter
@IMI_JU

Join our LinkedIn group
bit.ly/LinkedInIMI

Email us
infodesk@imi.europa.eu



10 YEARS OF BREAKTHROUGHS
A HEALTHIER FUTURE

innovative medicines initiative

Thank you!

Magali.Poinot@imi.europa.eu