The Innovative Medicines Initiative – Europe's partnership for health

Elisabetta Vaudano

IMI2 Information Day Milano, Italy 22 January 2020

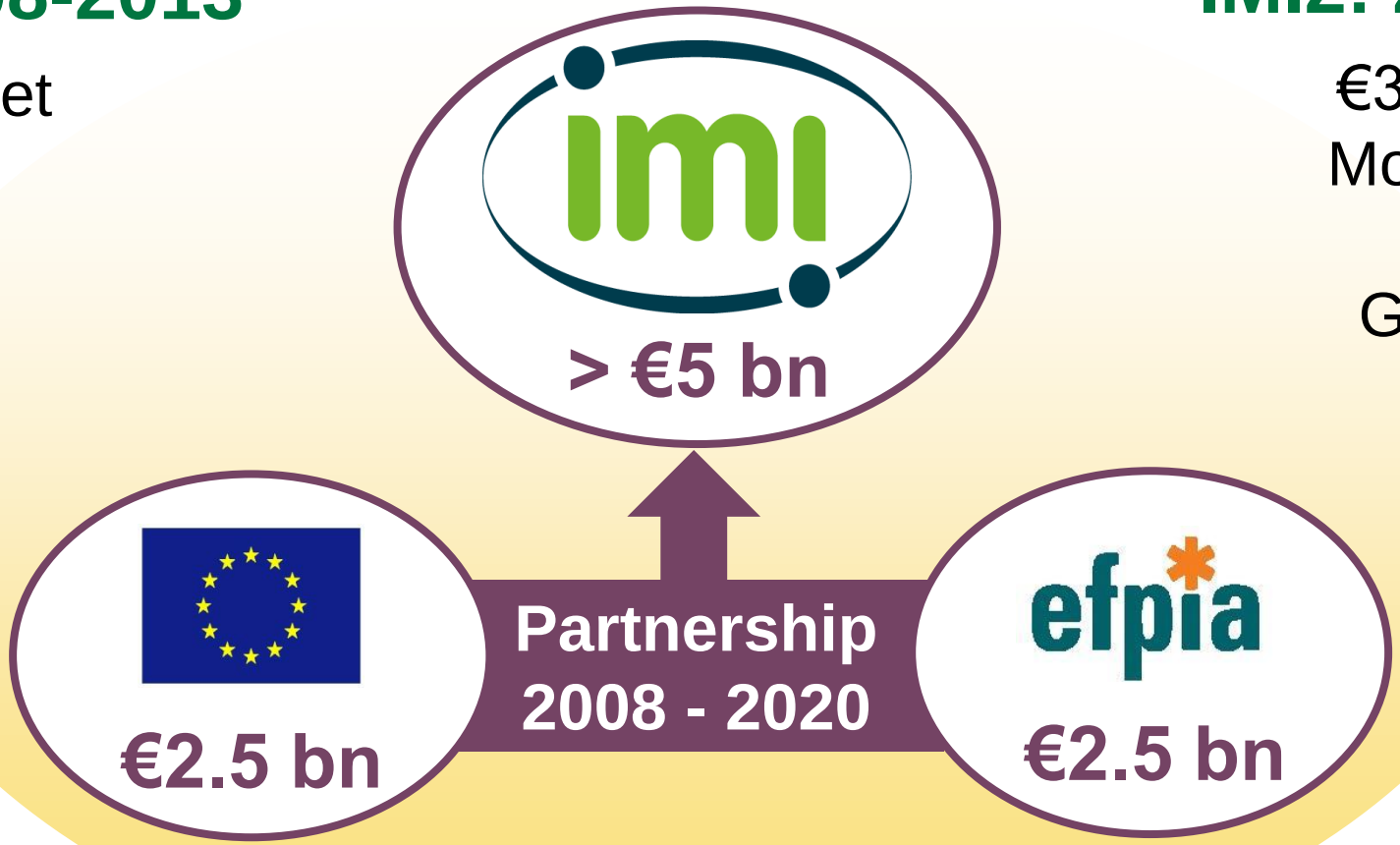
IMI – Europe's partnership for health

IMI1: 2008-2013

€2 bn budget
59 projects

IMI2: 2014-2020

€3.3 bn budget
More ambitious
More open
Greater scope



EU contribution from FP7 / H2020

Pharma contribution 'in kind'

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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.

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IMI2 overall objectives

- **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 -

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IMI – Why Europe's partnership for health?

Because drug development is very…

Because…

- Biological mechanisms underlying disease are complex
- Clinical trial designs need to be adapted to scientific knowledge
- Regulatory pathways should be adapted due to scientific drivers

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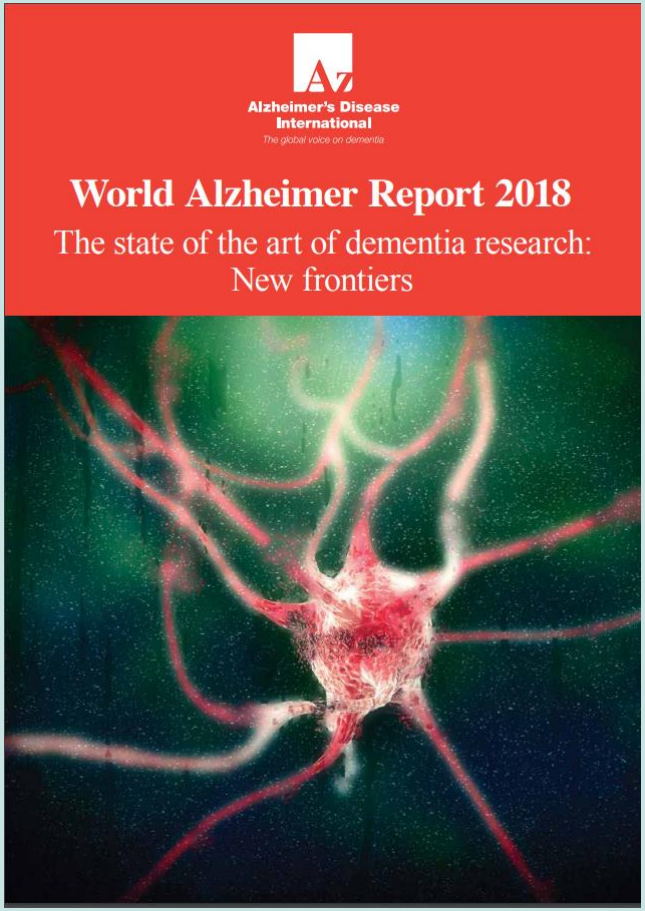
Alzheimer’s disease – a major unmet need

Alzheimer’s disease in numbers:

- **50 million**
  affected globally
- **10.5 million**
  in Europe
- **Global cost**
  USD 1 trillion
  / EUR 890 billion



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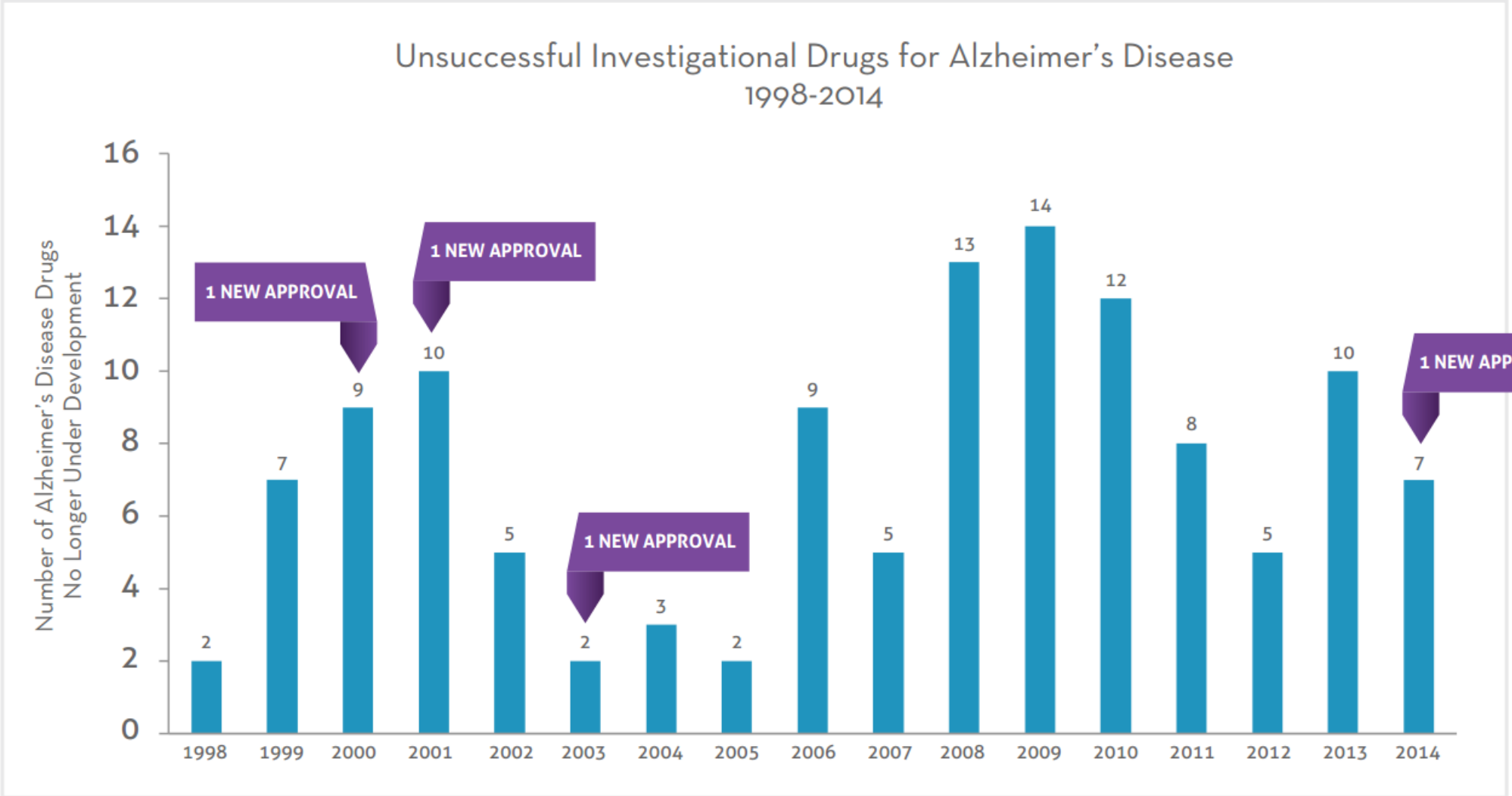

123 Total Unsuccessful Drugs | **4** Total Approved Medicines

Source: PhRMA analysis of Adis R&D Insight Database, 17 June 2015.

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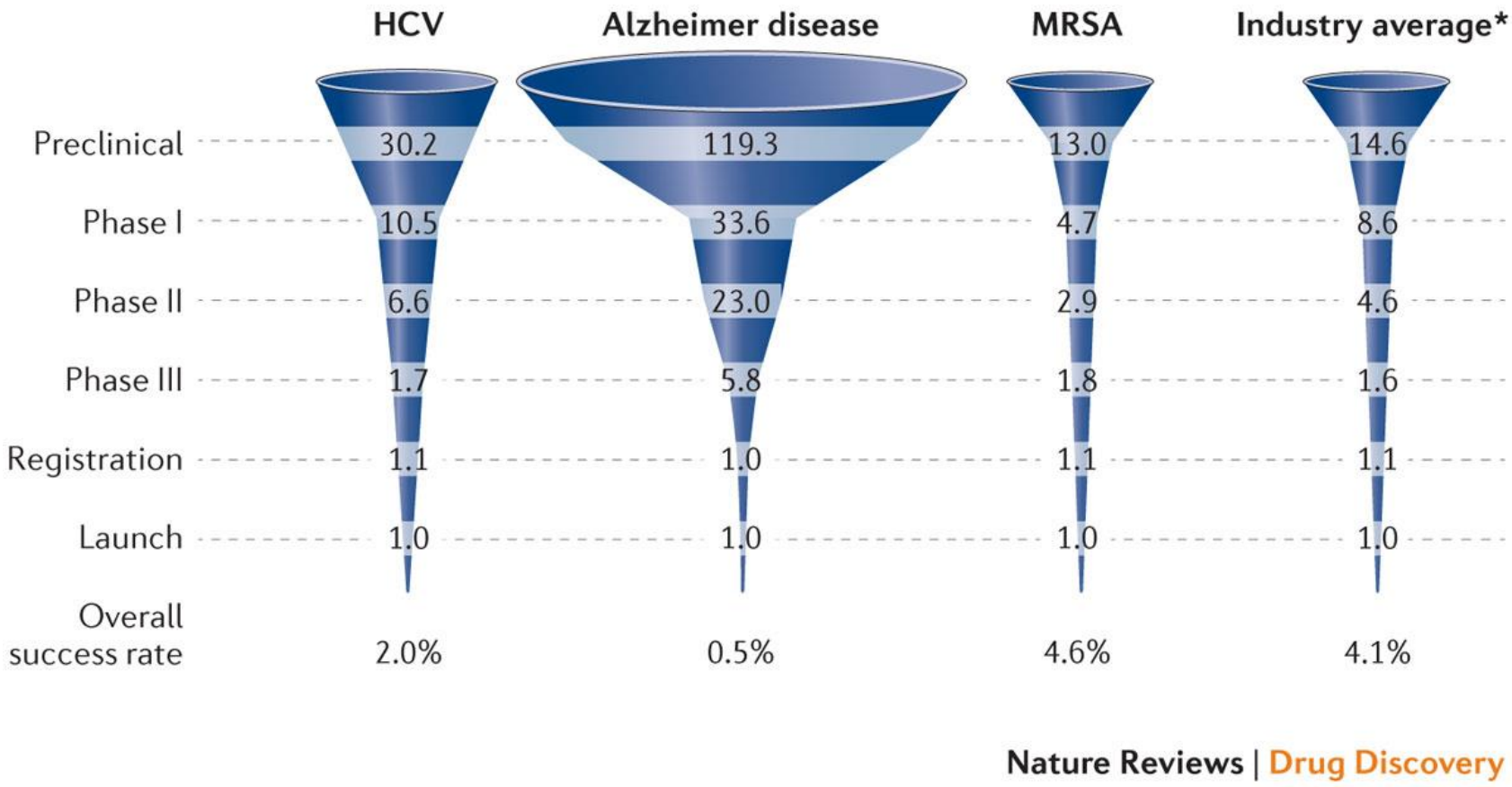
What does it take to make a drug for Alzheimer's disease?



Dirk Calcoen, Laura Elias & Xiaomeng Yu
Nature Reviews Drug Discovery 14, 161–162 (2015) doi:10.1038/nrd4570

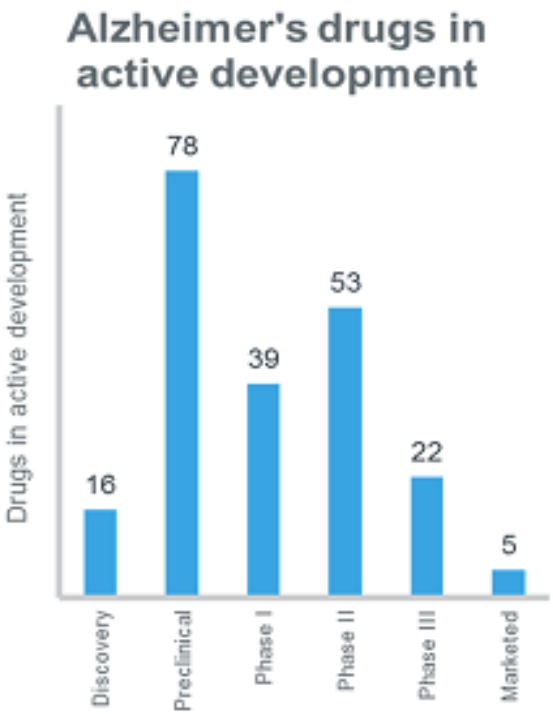


Figure 1a: Alzheimer's drugs in active development

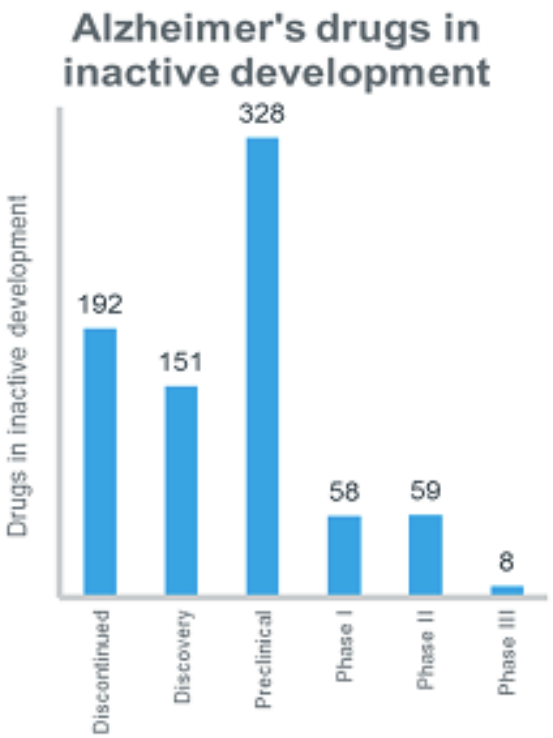
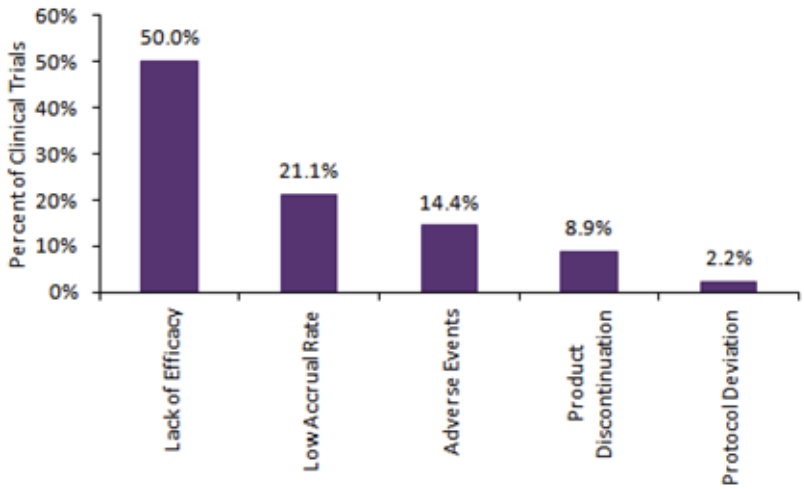


Figure 1b: Inactive and discontinued Alzheimer's drugs



Source: GlobalData, Pharma Intelligence Center (Accessed November 5, 2019)
GlobalData

Most Alzheimer's trials still stuck in phase 1: we still need to learn more on this complex condition

Accessed 20200120 from https://www.iqvia.com/blogs/2019/05/dwindling-alzheimer-s-landscape
And https://www.clinicaltrialsarena.com/comment/alzheimers-disease-majority-of-clinical-trials-in-phase-i/

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IMI – Why Europe's partnership for health?

Because despite decades of research we still don't have…

- Enough antibiotics in development
- A cure for diabetes
- A cure for dementia
- An Ebola vaccine

So IMI is…

- Supporting projects across the whole spectrum of medical R&D and drug development, incl. understanding diseases
- Identifying & developing potential drugs
- Testing safety / efficacy
- Improving clinical trial design

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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

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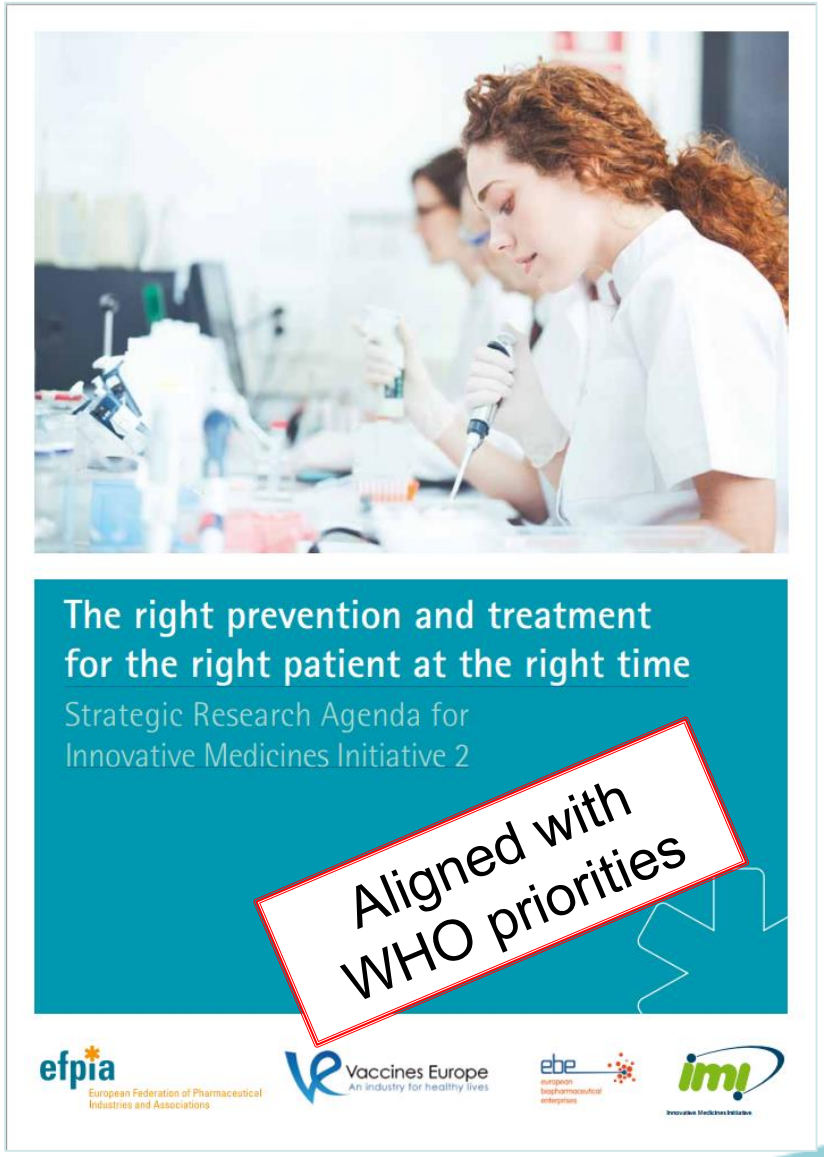
IMI 2 Strategic Research Agenda

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



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An ecosystem for innovative collaboration

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

- Cutting-edge research
- Scale, by combining funding, skills and resources
- Trust, creativity and innovative and critical thinking
- Transformative research
- Learning from each other

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IMI: we make connections and break silos

Picture Credit: Public Works Knowledge Network

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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

Academia

Charities

Regulators

SMEs

HTA bodies

Pharma companies

Payers

Diagnostic companies

Healthcare practitioners

Other sectors (e.g imaging, nutrition…)

Public health bodies

Patients

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‘Form should follow function’

IMI is not for everyone

IMI is not for everything

But for specific challenges PPPs are the only way to progress

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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

Receive no funding

contribute to projects in kind

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IMI2 Associated Partners (as of December 2019)

Accelerate Diagnostics	KTH Royal Institute of Technology
Autism Speaks	Helmsley Charitable Trust
Autistica	McGill University
BD Switzerland Sarl	Medicines for Europe
Bill and Melinda Gates Foundation (BMGF)	Medicines for Malaria Venture (MMV)
Bio-rad Laboratories	Obesity Action Coalition
Cepheid Europe	Ontario Institute for Cancer Research
CHDI Foundation	Parkinson's UK
Children's Tumor Foundation	Simon Foundation Autism Research (SFARI)
Coalition for Epidemic Preparedness (CEPI)	Software AG
Datapharm	Springworks Therapeutics
Diamond Light Source	T1D Exchange
European Hematology Association (EHA)	TB Alliance
International Diabetes Foundation (IDF)	Trial Nation
Invicro	University of Dundee
JDRF	Wellcome Trust

Total Number of Associated Partners:	32
Total Commitment:	EUR 170,112,560

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EFPIA partners in research

BenevolentAI
BRUKER
COVANCE SOLUTIONS MADE REAL
McKinsey&Company
medidata
Medtronic
Clarivate Analytics
ELLEGAARD
ERT
nanoString
NOKIA
PsychoGenics
FUJIFILM Value from Innovation
GE Healthcare
ICON A Symbol of Excellence
Q-LINEA
sas
Science 37
illumina
ImaginAb
INSTITUT MERIEUX
SomaLogic
VARIAN
ZEISS
IQVIA
Life Molecular Imaging
Lonza
zoetis

Accessed on 20200120 https://www.efpia.eu/about-us/membership/

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The role of the Programme Office

As a neutral broker…

- to **implement programmes and activities** in the common interest of all stakeholders
- to monitor the **use of public funds** and industry investment
- to guarantee **fair and reasonable conditions** for optimal knowledge exploitation and dissemination
- to **facilitate the interaction** between stakeholders, including Intellectual Property agreements
- to **actively communicate** and promote IMI and its activities

How is a project idea generated?

Industrial 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

Scale is a key to success and is provided by IMI funding and the outcomes should be transformative for the industry as well as having a clear “public” value

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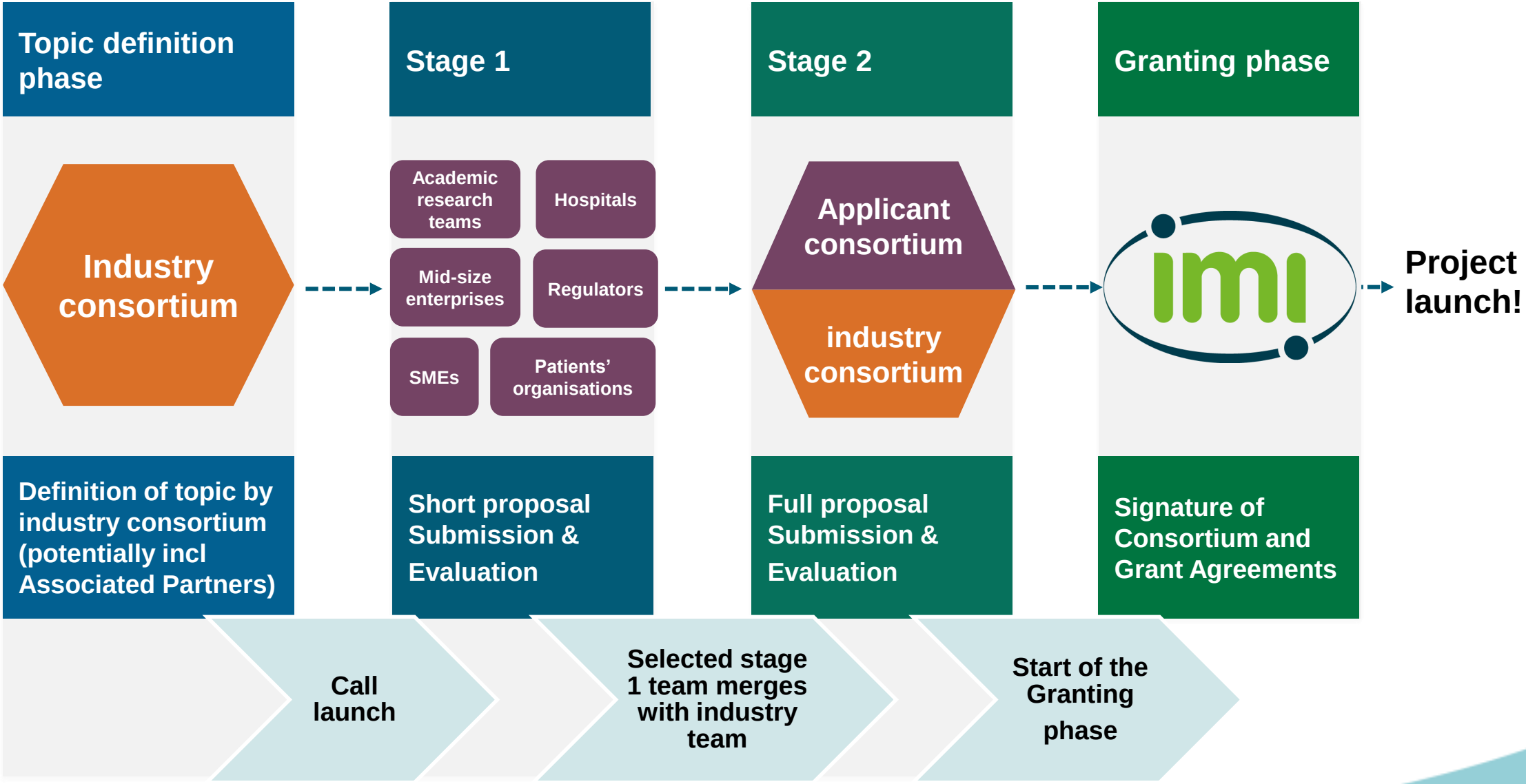
How is a project generated



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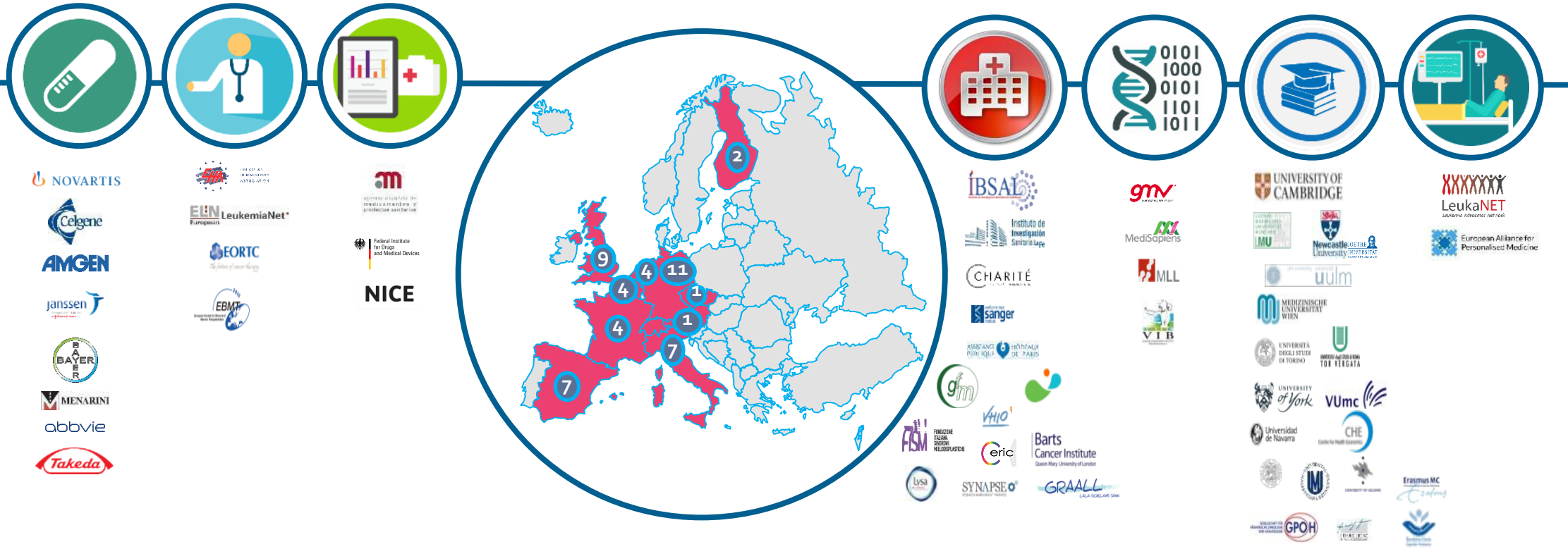
What does an IMI project look like?

HARMONY
Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Hematology



53 organisations from 11 countries, working accross 7 hematological malignancies

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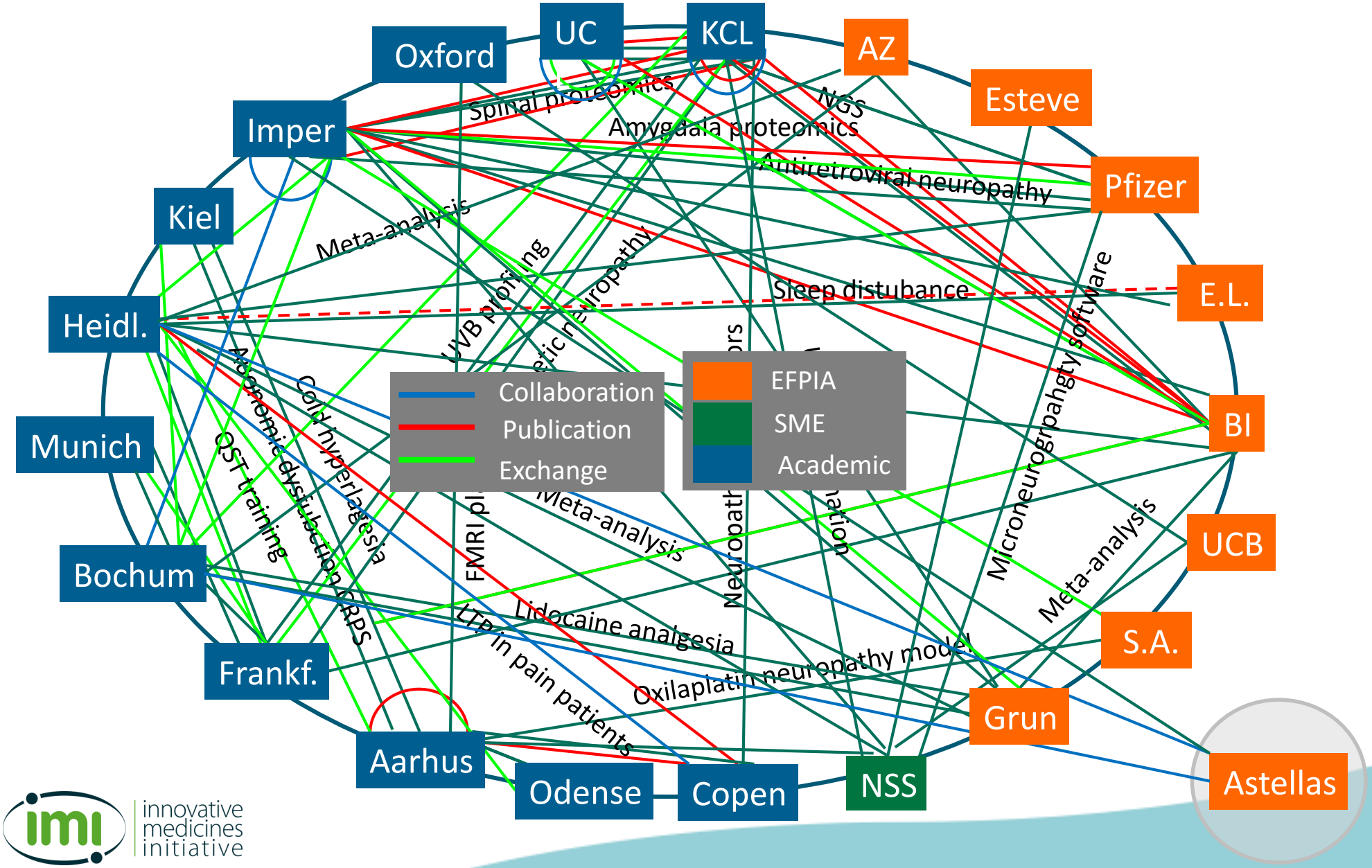
Collaborations in an IMI project



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How are projects monitored?

- Scientific and financial report (once a year)
- Deliverables (throughout the duration of the action)
- A review normally at the mid term (IMI can ask for review at any time of the duration)
- Final report
- Closure meeting/legacy management

The Innovative Medicines Initiative – some examples of portfolio and outputs

IMI in a nutshell

We are an EU public-private partnership funding health research and innovation

€5.3bn	144	3 127	>7 000	>3 800
BUDGET	PROJECTS	PARTICIPANTS	PROJECT OUTPUTS	PUBLICATIONS

20 Calls for proposals launched between 2014 and 2020, two more to be launched by summer 2020

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IMI projects achievements so far

		Nr.
Compound-related achievements	New biomarkers/candidates/Leads/Hits/Targets (identified or currently consider or under evaluation)	**90**
New models-related innovations	New animal-in vivo/in vitro/in silico models	**24**
Clinical trials/infrastructure/network	Clinical trials (completed or on-going)/testing activity/infrastructure/network/design	**31**
New Tools to facilitate drug development	New tools (PRO/registries/protocols/libraries/HTA/Database/knowledge-management system/methodology&processes/network/tech platform/IT infrastructure/Quality system/cell-lines/prototype/biobank/compound collection/validation tools)	**179**
Product-related achievements	Devices/diagnostics/medicinal product/vaccines/services	**9**
Go-to-market	Commercialisation/licencing/spin-out/trade-marks/patents	**33**
Regulatory-related achievements	Inclusion in regulatory guidelines/regulatory letter of support/submission for qualification opinion/qualified opinion/CE mark	**15**
Publications	Total number of Web of Science publications arising from IMI projects between 2010 and 2018	**4,937**
Global reach of IMI's research activities	Number of countries (worldwide) with at least 1 IMI-funded paper	**98**
Trainings	Training activities as reported by the projects as part of their dissemination activities	**1,663**

Data source: IMI Performance evaluation survey 2018, IMI1+IMI2 and Bibliometrics report data up to 2018, SyGma/Compass EC self-reporting tool

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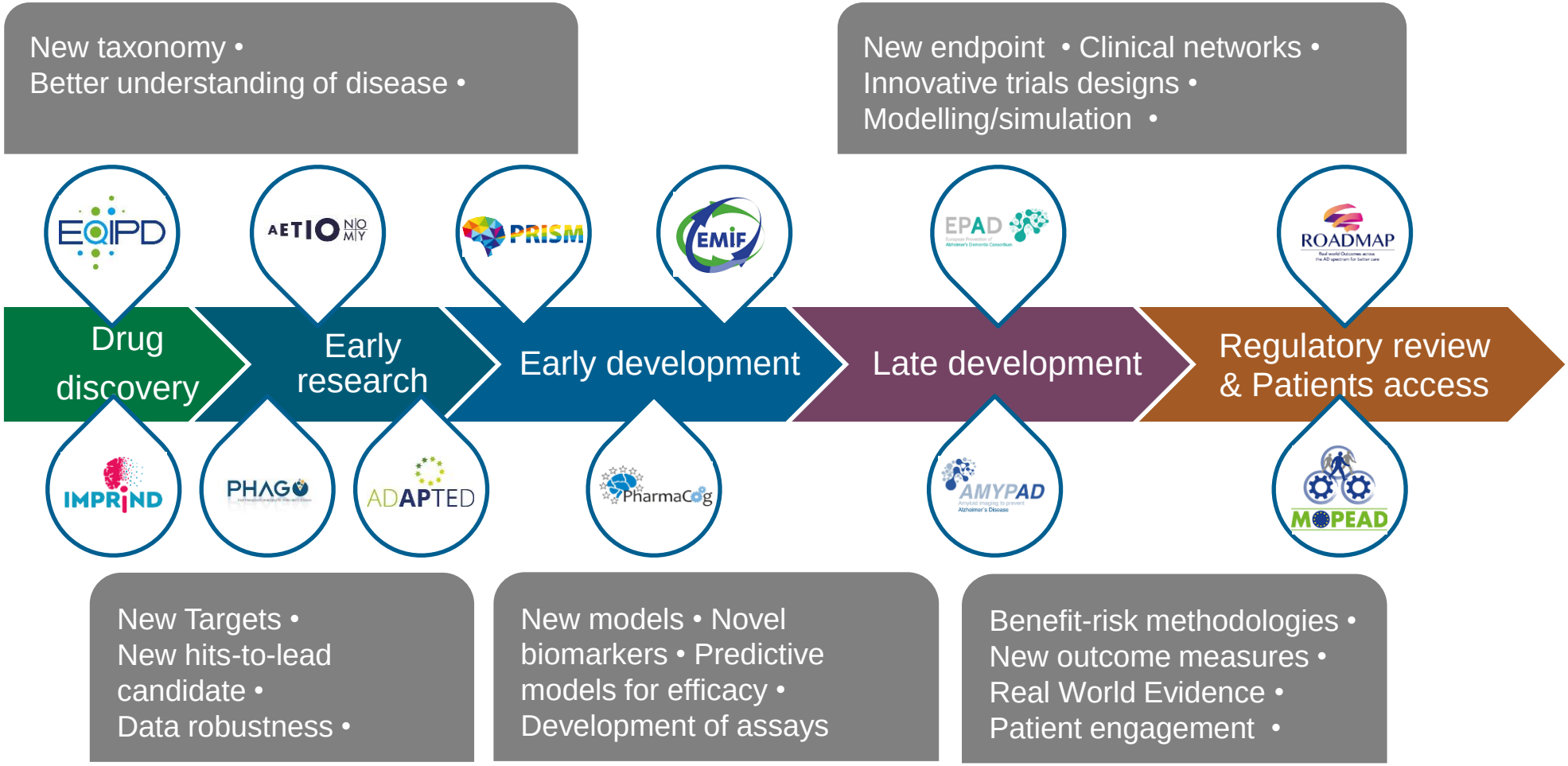
The IMI dementia portfolio: covering the whole value chain



- **End-to-end approach**
- Vision of **personalised medicines**

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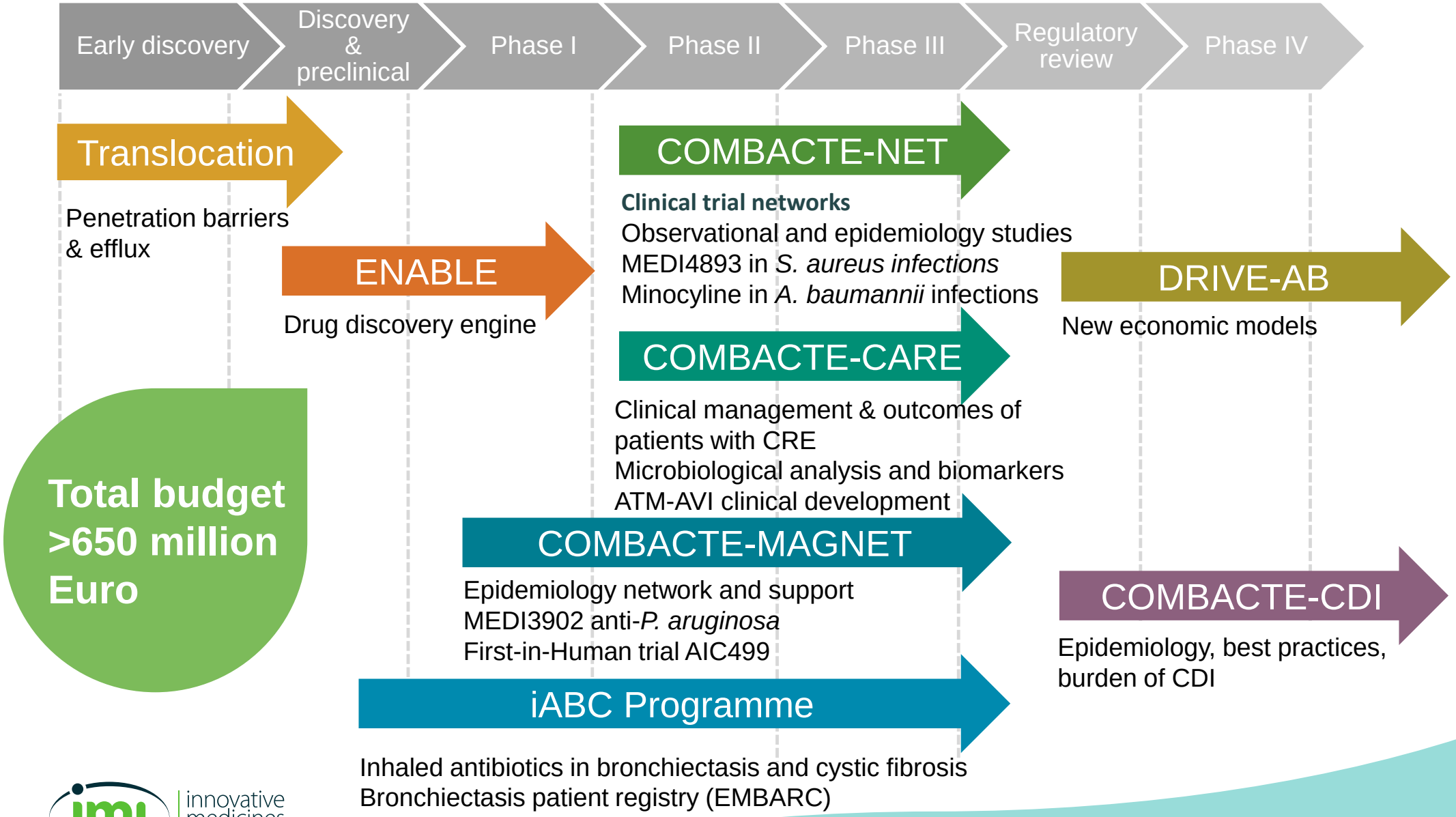
New Drugs for Bad Bugs (ND4BB)



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AMR Accelerator programme

PILLAR A:

Capability Network Basic science to build knowledge

- Coordination & support of projects across Accelerator
- Projects focused on improving success of AMR R&D

PILLAR B:

Tubercolosis (TB) Drug Discovery

Progress novel TB programmes to end Phase 1

- Build preclinical capabilities, explore basic science to support TB drug discovery and progress TB assets through end of Phase 1

IMI Associated partners contribution:

- Bill & Melinda Gates Foundation
- TB Alliance;
- University of Dundee

PILLAR C:

Portfolio Network Incubate early drug discovery programmes

- Novel framework to discover, study, and advance potential new treatments for AMR infection

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Ebola+ programme overview IMI2

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

Pipelines	Development	Manufacturing	Deployment	Diagnostics
PEVIA APHP Vaxeal	VSV-EBOVAC Sclavo Vacc. Assoc.	EBOMAN Vibalogics, Janssen	EBODAC LSHTM, Janssen	EbolaMoDRAD Public Health Institute Sweden
	EBOVAC 1 LSHTM, Janssen			FILODIAG GNA Biosolutions
	EBOVAC 2 Inserm, Janssen			Mofina Public Health England, Altona
	VSV-EBOPLUS Sclavo Vacc, MSD			VHFMoDRAD FHM, Cepheid
	EBOVAC 3 LSHTS Janssen			

Total budget: > € 300 million

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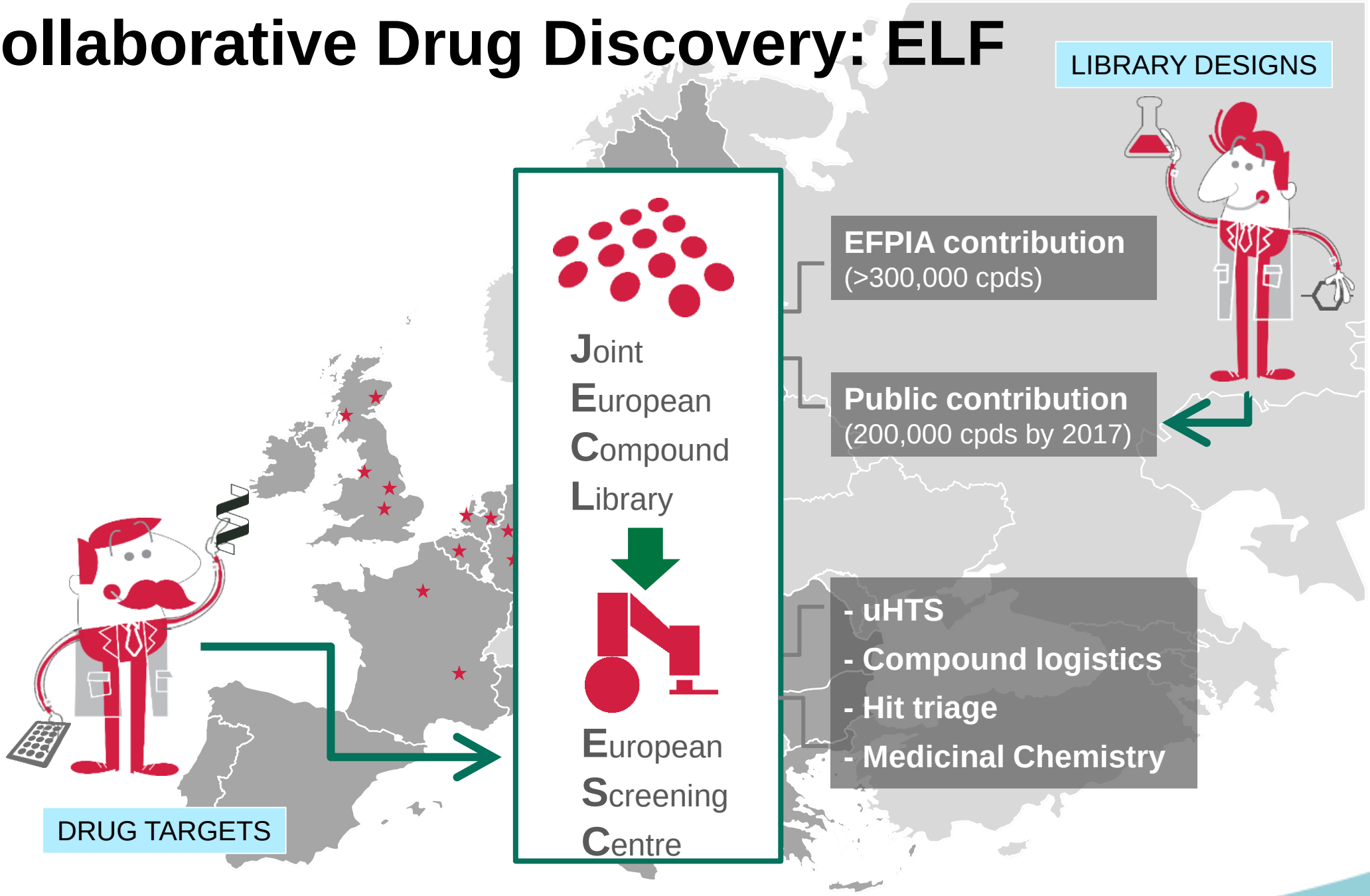
Collaborative Drug Discovery: ELF



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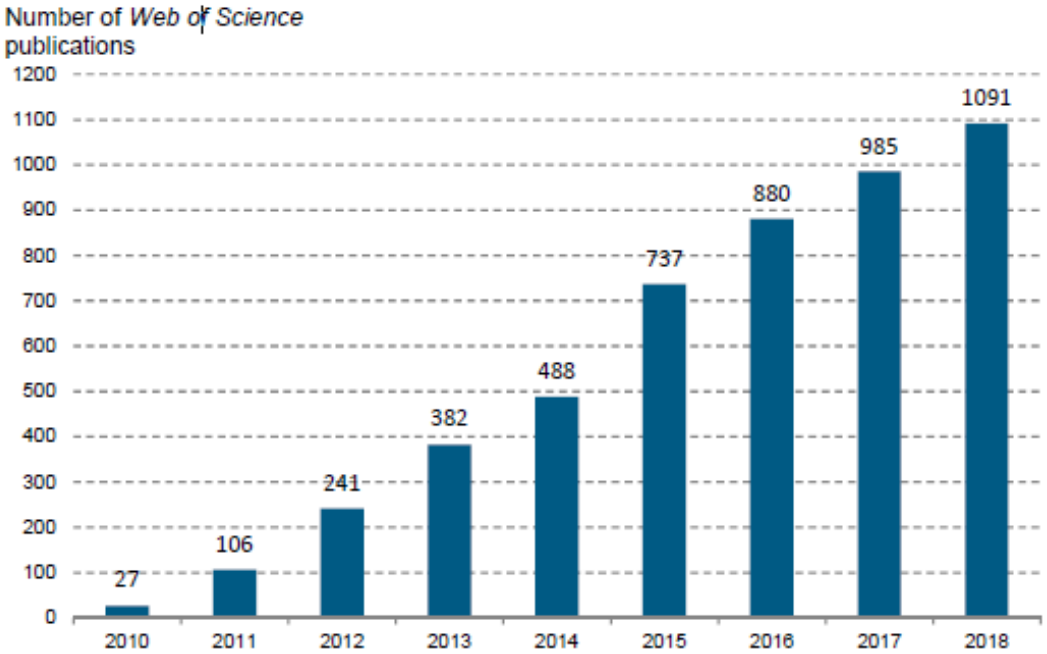
Bibliometrics

IMI publications increase year-on-year

4,937 IMI publications



(Courtesy IMI2 JU 2019)

Bibliometrics report 2019 (data up to December 2018). Total number of publications produced by IMI projects between 2010 and 2018

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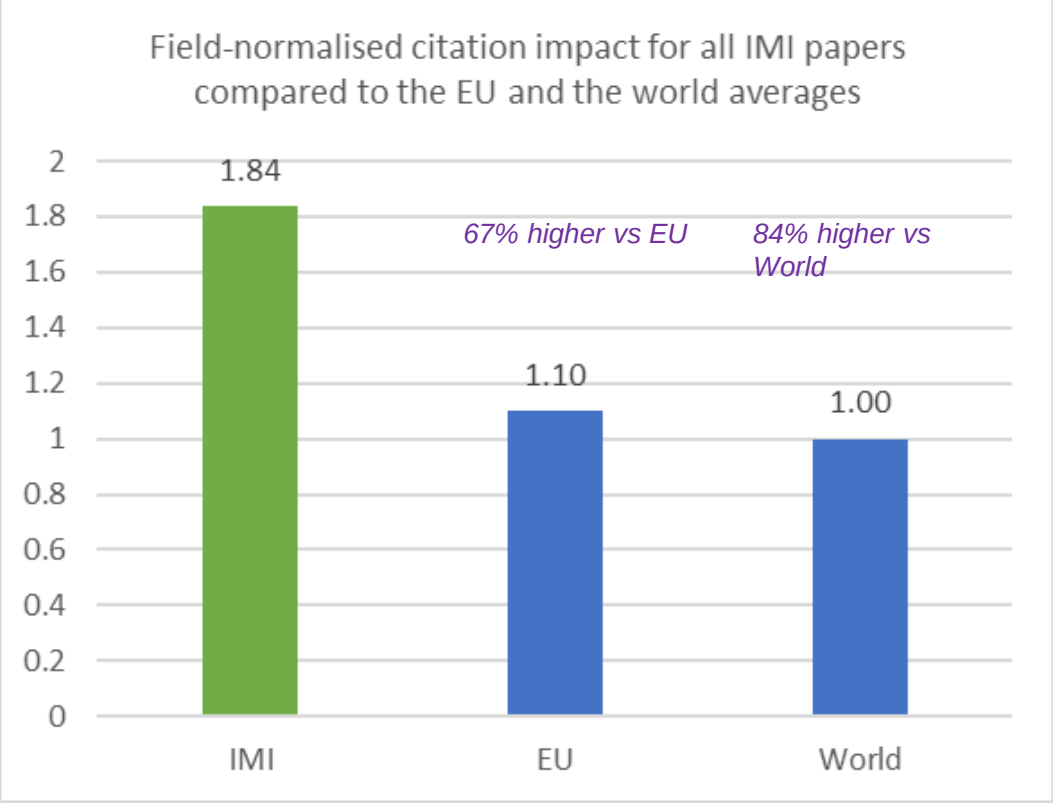
IMI's Citation Impact vs EU and world average



The field-normalised citation impact of IMI project research is nearly twice the world average (84% higher), which indicates the research was internationally Influential and 67% higher than EU average.

Bibliometrics report 2019 (data up to December 2018).

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IMI research is highly collaborative

	Number of papers	% of papers
Cross-sector	2,836	62.2%
Single-sector	1,717	37.7%
Cross-institution	3,841	84.3%
Single-institution	712	15.6%
International	2,793	61.3%
Domestic	1,760	38.6%

Over 62% of cross-sector publications

Over 84% of cross-institution publications

Over 61% of internationally collaborative papers

(Courtesy IMI2 JU 2019)

Bibliometrics report 2019 (data up to December 2018). Co-authorship of papers is used as a measure of collaboration between different sectors, institutions and countries.

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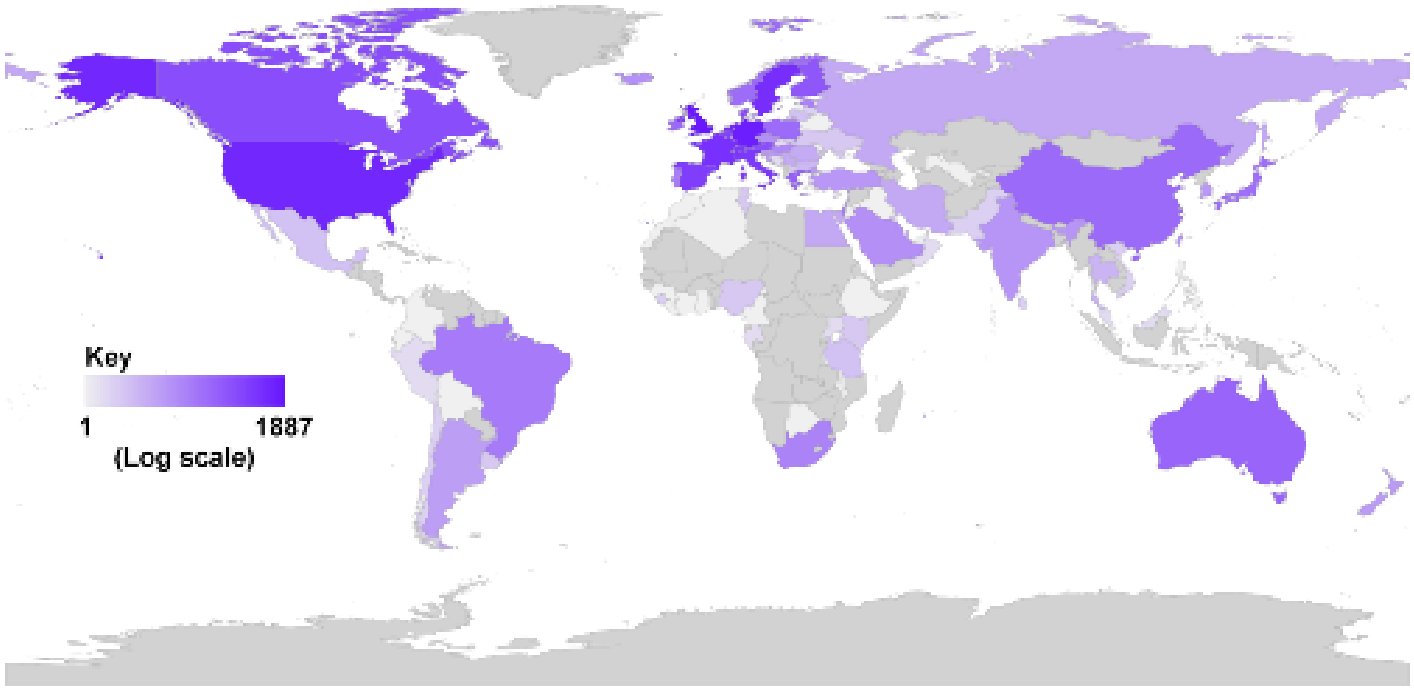
98 Countries have at least 1 IMI-funded publication



The Global reach of IMI activities

(Courtesy IMI2 JU 2019)

Bibliometrics report 2019 (data up to December 2018).
Log scale: It is a scale that shows countries having from 1 publication to 1887 publications (U
being the top end with 1887 publications).

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The Innovative Medicines Initiative – Application process

Hugh Laverty, Head of Scientific Operations
IMI2 Information Day Bulgaria, 17th January 2020

A single set of rules

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

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

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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

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Minimum conditions for an applicant consortium

- 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

- Formation of the applicant consortium usually one of the challenges faced in applying to IMI
  - Start early
  - Establish international network
  - Applicant consortia should be balanced in terms of expertise and operational capacity and avoid redundancies between partners

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IMI2 JU Funding model

- **IMI2 JU is a PPP, actions are normally co-funded by:**
  - JU funding to BRFs (**b**eneficiaries **r**eceiving **f**unding = legal entities eligible for funding)
  - In-kind/cash contribution from BNRFs (**b**eneficiaries **n**ot **r**eceiving **f**unding):
    - EFPIA constituents and affiliates
    - IMI2 JU Associated Partners
    - (future other IMI2 members)

Other legal entities may also participate as BNRFs at their own cost

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One single funding rate per project - BRFs

One project = One rate

For all beneficiaries and all activities

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

JU contribution to BRFs covers:

- **Personnel**
  - Wider acceptance of average personnel costs
  - Acceptance of supplementary payments

    For non-profit organisations of up to 8000 euros/year/person
  - Less requirements for time records
- **Equipment, consumables, travels…**
- **Subcontracting**

Considering BRFs accounting and management principles

- **BRFs (only) may also receive Financial contribution from EFPIA/APs**
  - to be reported as receipts

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EFPIA and Associated Partners contribution - BNRFs

- EFPIA companies
- Other industries and partners (= Associated Partners to IMI2)
  - In-kind (actual direct and indirect costs or average FTE) and/or financial contributions (FC)*
  - Based on the usual management principles and accounting practices
  - Contributions from affiliated entities as part of in-kind

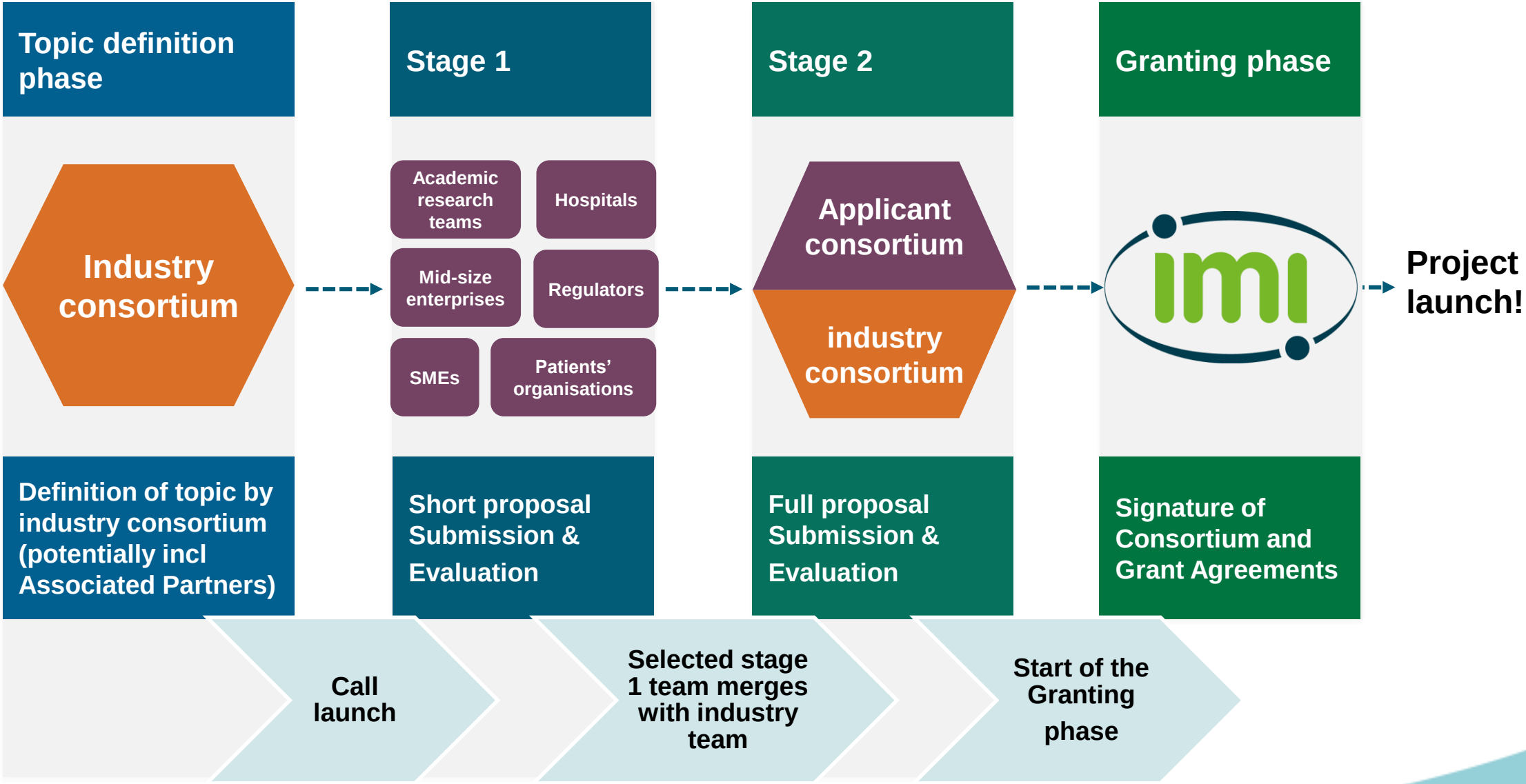
  * Recipient of FC must be BRFs, i.e. eligible for JU funding

When relevant to IMI2 JU objectives: non-EU in-kind contribution (up to 30% at programme level)

Annual financial reporting is disconnected from GA periodic reports

From Call to grant award

How does IMI work? Two stage procedure



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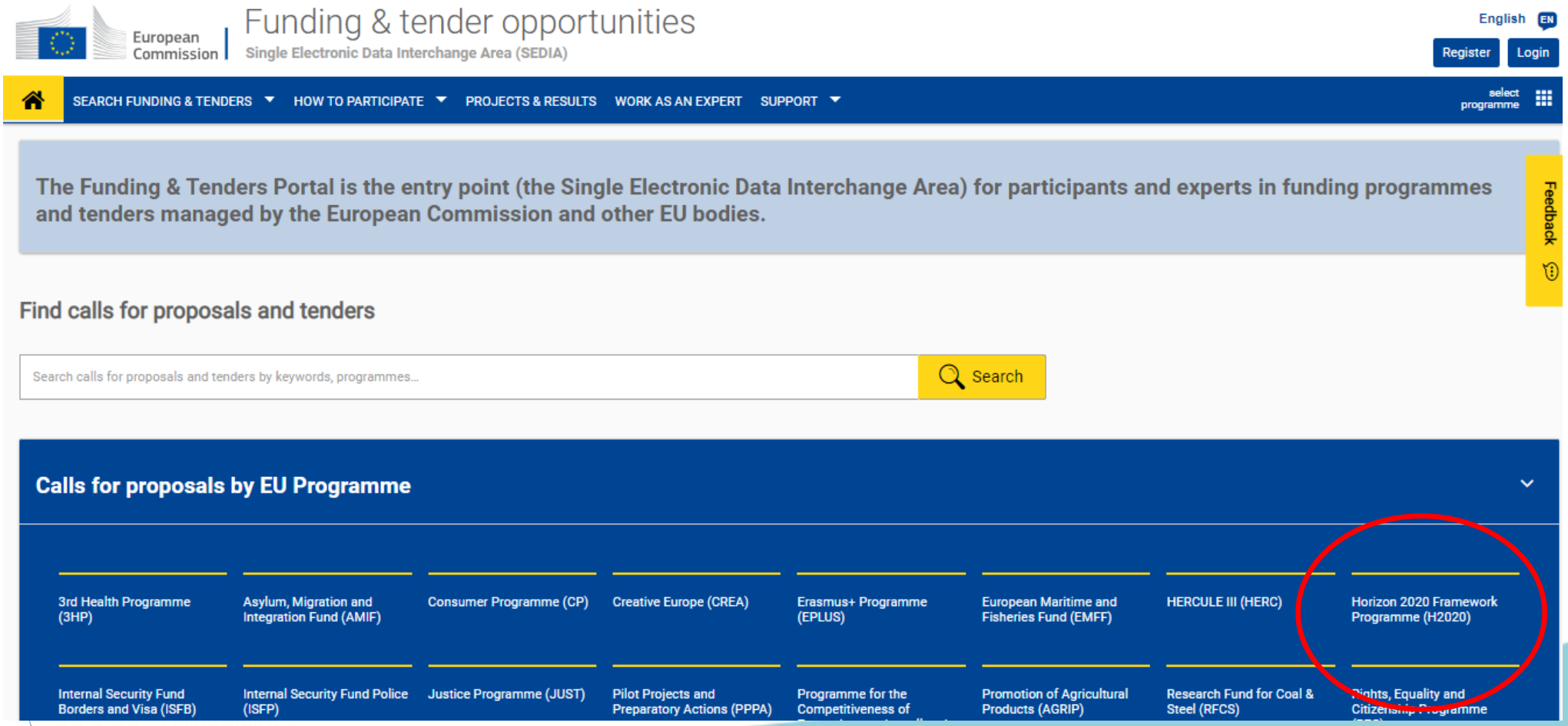
Submitting a proposal

Via the **new** Funding and Tenders Portal

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home



A single set of evaluation criteria

Standard criteria

Excellence	Impact	Quality & efficiency

- Two-stage evaluation: all three criteria considered at both stages

- Thresholds and weighting in the **Call documents** depending two-stages/single stage
- Minimum of **3 independent experts**

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

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The review process: consensus evaluation

- Panel of independent experts
- The aim is to reach a consensus on comments and scores
  - Hearing with applicant consortium to aid discussion
- **Criteria**
  1. Excellence
  2. Impact
  3. Quality and efficiency of the implementation
- Separate ethics panel assessing the ethical aspects of the FP at stage 2

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Consortium agreement

- Contractual arrangement **between all participants** to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the **IMI2 JU Model Grant Agreement**
- To be agreed before the signature of the GA, IMI2 JU is not a party
- **To be adapted to the specific needs of each IMI action!**
- A template prepared by EFPIA shows what a consortium agreement might look like:

  http://efpia.eu/documents/229/141/EFPIA-Consortium-Agreement-Template-for-IMI2-actions

  Consortia may also use alternative templates if they wish.

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IMI2 Grant Agreement

- A new IMI2 JU MGA (v.5) has applied from Call 18
- It follows H2020 Model Grant Agreement (v.5) with IMI2 specificities.
- IMI2 JU Annotated Model Grant Agreement v.2.1 (based upon H2020 AGA v.5.1)
- It is e-signed between IMI2 JU and Coordinator only. Other beneficiaries e-sign Accession Forms
- EFPIA and Associated Partners are beneficiaries not receiving funding (BNRFs, Art.9) - their financial report occurs outside the GA, for more info please consult '*IMI2 JU guidelines for reporting in kind and financial contributions by Members other than the Union and Associated Partners*'

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The Innovative Medicines Initiative – Funding opportunities, 2020

Call 20 key facts

- Call 20 Launch date: **21st January 2020**
- SP submission date: 21st April 2020
- Around the time of call launch topic-specific webinars are held giving the opportunity to ask questions directly of the topic writers
- You can register for the webinars on this page:

https://www.imi.europa.eu/news-events/events/imi2-call-20-webinars

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Topic 1: Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in Psoriatic Arthritis

- Around 20-30% of people with the immune disease psoriasis go on to develop arthritis.
- However, all too often, patients experience symptoms for many years before they are diagnosed with psoriatic arthritis. Furthermore, the treatments for psoriatic arthritis do not work for all patients.
- The aim of this topic is to deliver tools that will allow doctors to diagnose psoriatic arthritis earlier, and even predict which psoriasis patients are at greatest risk of developing arthritis.
- It will also shed new light on factors that could indicate how a psoriatic arthritis patient's disease will progress over time, and this will allow the development of personalised treatments.

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Topic 1: Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in Psoriatic Arthritis

Applicants:

- Researchers, SMEs, patients, regulatory agencies and HTA in the areas of PsA and psoriasis
- Clinical characterisation expertise and access to patients, analytical platforms, strong data management

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Topic 1: Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in Psoriatic Arthritis

Key facts

- Industry consortium: Novartis, UCB, BMS, Pfizer
- Expected duration of the action 60 months

Budget:

- IMI2 JU contribution: EUR 10 211 000
- EFPIA in kind contribution: EUR 13 880 000

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Topic 2: Innovations to accelerate vaccine development and manufacture

Vaccines are a huge public health achievement, but developing a new vaccine is very costly, time consuming and risky. Recent years have seen advances in academia and biotech companies in the fields such as immunology, big data and artificial intelligence.

The aim of this topic is to incorporate these advances into the vaccine industry, and to develop biological and mathematical models that are better at predicting how well a vaccine will work. Ultimately, the hope is that this will accelerate and de-risk the development of new vaccines.

Topic 2: Innovations to accelerate vaccine development and manufacture

4 sub-topics

- In silico platform for knowledge management and mathematical modelling of the immune system
- Novel controlled human infection models (CHIMs)
- Next generation human in vitro systems and assays
- In silico platform for modelling vaccine substance and product attributes in biomanufacturing

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Topic 2: Innovations to accelerate vaccine development and manufacture

At stage 1, applicant consortia should submit short proposals to one of the four subtopics (1–4). An applicant consortium can submit a short proposal for more than one subtopic, on condition that a separate short proposal is submitted for each subtopic.

To achieve the project objectives, maximise cross-learning and enable data sharing, **a single full proposal** should be submitted at stage 2.

This full proposal will include activities covering all four subtopics and their specific work packages.

Thus, at stage 2, the full proposal will be submitted by the consortium composed by the successful applicant sub-consortia of all four subtopics and the industry consortium.

Topic 2: Innovations to accelerate vaccine development and manufacture

Applicants

- In silico platform for knowledge management and mathematical modelling of the immune system:
  - Expertise in computational modelling, immunology, front end and back end in silico platform generation
- Novel controlled human infection models (CHIMs)
  - Expertise in microbiology, virology and microbial genetics, clinical expertise in ethics, immunology, big data, establishment of large databases and regulatory science
- Next generation human in vitro systems and assays
  - Expertise in next generation in vitro systems, novel immunological assays, novel reagents for interrogating immune responses, prospective clinical cohort studies
- In silico platform for modelling vaccine substance and product attributes in biomanufacturing
  - Bio pharmaceutical process knowledge, process modelling expertise, front end & back end development, knowledge management systems for data integration, evaluation, curation of open-source data

Topic 2: Innovations to accelerate vaccine development and manufacture

Key facts

- Industry consortium: GSK, Sanofi Pasteur, Takeda (subtopic 3 only), CureVac AG (subtopic 3 only)

- Expected duration of the action 66 months (60 R&I activities + 6M dissemination and sustainability)

Budget:

- IMI2 JU contribution: EUR 18 600 000 for the four subtopics and open calls
- EFPIA in kind & financial contribution: EUR 19 870 000 for the four subtopics and open calls

ATTENTION There is a specific budget allocated to each subtopic! Read carefully the topic text

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Topic 3: Academia and industry united innovation and treatment for tuberculosis

AMR Accelerator

PILLAR A:
Capability Network
Basic science to build knowledge

1. Projects focused on improving success of AMR R&D
2. Coordination & support of project across Accelerator

PILLAR B:
TB Drug Discovery
Progress novel TB programs to end Ph 2

Build preclinical capabilities, explore basic science to support TB drug discovery and progress TB assets through end of Ph2

PILLAR C:
Portfolio Network
Incubate early drug discovery programs

Novel framework to discovery, study, and advance potential new treatments for AMR infection

Topic 3 of Call20 is launched under Pillar B (**TB Drug Discovery Network (TBDDN)** to complement the actions funded under IMI2 JU Call 15 and IMI2 JU Call 16.

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Topic 3: Academia and industry united innovation and treatment for tuberculosis

Tuberculosis is the leading infectious cause of death worldwide, killing around 1.5 million people annually. Treatment consists of a combination of drugs taken for at least six months, or even longer in patients whose disease is resistant to frontline treatments.
The long treatment time, coupled with the side effects of some drugs, lead some patients to stop taking their antibiotics, and this contributes to drug resistance. Identifying new treatment combinations that could shorten the treatment time and tackle drug resistance is difficult and time-consuming.

The goal of this topic is to develop and carry out innovative clinical trial designs to identify new treatment combinations using drugs that have already undergone initial studies in humans.
The topic will also develop and evaluate new technologies to monitor and enhance treatment adherence.

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Topic 3: Academia and industry united innovation and treatment for tuberculosis

Applicants:

Expertise in: Innovative clinical trials , Innovative Biomarkers. Clinical trial simulation. Artificial Intelligence/Machine Learning (AI/ML) , Digital Health Technologies Pharmacogenomics

NCEs portfolio.

To ensure a working portfolio of ten assets, it is anticipated that EFPIA and Associated Partners will contribute a substantial number of assets to the pipeline to mitigate potential compound attrition.

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Selection of molecules will be subject to due diligence by the governance bodies of the consortium. For further information on the existing portfolio of TB assets please refer to the working group on new TB drugs (www.newtbdrugs.org).

Applicant wishing to include their own NCE(s) will be subject to the same governance and acceptance criteria as other assets in the existing portfolio as determined by the decision-making bodies within the consortium.

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Topic 3: Academia and industry united innovation and treatment for tuberculosis

- **Key facts**
- Industry consortium: GSK, BioMérieux, Janssen, Otsuka.
- Associated Partners: Deutsches Zentrum für Infektionsforschung (DZIF), Klinikum of the Ludwig-Maximilians-Universität München
- Expected duration of the action 84 months

Budget:

- IMI2 JU contribution: EUR 92 500 000
- EFPIA & APs in kind contribution: EUR 92 500 000

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Topic 4: Tumour plasticity

Once a cancer has spread to other parts of the body, it is very hard to cure it. Often, patients respond well to a drug for a time before the cancer becomes resistant to it, and this drug resistance is a major cause of cancer mortality.

The source of this drug resistance lies in rare cancer cells called ‘drug tolerant persister’ cells, or DTPs. Studies show that DTPs survive drug treatments by altering the activity of certain genes.

The goal of this topic is to add to our understanding of DTPs, including their genetic sequences and microenvironment, and to develop tools to collect and analyse them.

It will focus on non-small cell lung cancer, breast cancer, and colorectal cancer but may also carry out studies on other adult and childhood cancers.

Topic 4: Tumour plasticity

Applicants

- Relevant technology companies, SMEs in addition to researchers and clinicians
- Expertise to carry out single cell sequencing, the development of new versions of single cell technology, parallel single cell sequencing technologies that capture epigenome-transcriptome interactions, bioinformatics and computational approaches,
- access to relevant human samples and animal models

Topic 4: Tumour plasticity

- **Key facts**
- Industry consortium: AstraZeneca, Bayer, Eli Lilly, Transgene SA, Merck KG, Charles River

- Expected duration of the action 60 months

Budget:

- IMI2 JU contribution: EUR 7 058 000

- EFPIA in kind contribution: EUR 8 500 000

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Topic 5: Proton versus photon therapy for oesophageal cancer- a trimodality strategy

Radiotherapy plays a key role in the treatment of many cancers. However, as it can cause side effects in surrounding organs, the dose is limited meaning that treatment takes longer and can be less effective.

In contrast proton therapy delivers a higher dose of radiation that is more focused on the tumour itself, limiting damage to other, healthy organs.

The goal of this topic is to assess the usefulness of proton therapy as a treatment compared to radiotherapy, using oesophageal cancer as a case study.

Radiation therapy boosts survival rates for oesophageal cancer, but the disease still kills 500 000 people worldwide every year, meaning further improvements in treatment are urgently needed. In the long term, the results of this topic should also prove useful for other types of cancer.

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Topic 5: Proton versus photon therapy for oesophageal cancer- a trimodality strategy

Applicants

- Experience in the application of radiotherapy and PT
- Clinical expertise in oesophageal cancer
- Proven ability to co-design and conduct relevant clinical studies to obtain high quality clinical data
- Experience in the legal and ethical challenges associated with multi-centre data management
- Access to HTA expertise and oesophageal cancer patient expertise

Topic 5: Proton versus photon therapy for oesophageal cancer- a trimodality strategy

Key facts

- Associated Partners: Ion Beam Applications, Varian Medical Systems Particle Therapy

- Expected duration of the action 60 months

Budget:

- IMI2 JU contribution: EUR 1 500 000

- in-kind and financial contribution APs: EUR 1 500 000, which includes a financial contribution of EUR 1 000 000.

Path finder project looking towards the future programme in health under Horizon Europe

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Topic 6: Handling of protein drug products and stability concerns

Many new medicines are based on proteins, and these have dramatically improved the lives of people with a range of diseases.

However, ensuring the quality of protein drug products both during and after manufacture is far from easy. If stored or handled inappropriately during transport, or at the hospital, pharmacy or patient's home, the proteins can break down, compromising the safety and efficacy of the product.

This topic has two objectives: firstly, to improve our understanding of how protein drugs are handled in the real world and the effect this has on product quality; and secondly, to develop guidelines, processes and training to improve the way protein drug products are handled by different stakeholders.

Topic 6: Handling of protein drug products and stability concerns

Applicants:

- A global understanding of protein DP handling providing first hand knowledge
- Capacity to investigate real world handling procedures in hospitals, pharmacies and homes and assess the impact on stability of the DP
- Expertise in the methods of communication and training and handling of protein DPs
- Ability to implement new technologies to achieve relevant data for handling conditions and also to produce novel and efficient training materials and methods

Topic 6: Handling of protein drug products and stability concerns

Key facts

- Industry consortium: Sanofi, AbbVie, AstraZeneca, Boehringer Ingelheim, Lonza, Merck, Pfizer, Roche, Teva

- Expected duration of the action 48 months

Budget:

- IMI2 JU contribution: EUR 3 140 000

- EFPIA in kind contribution: EUR 3 959 500

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Webinars for Call 20 topics

- IMI will hold webinars on IMI2 – Call 20 topics from Wednesday 22 January to Tuesday 31 January inclusive.

- All webinars on the Call topics will feature a presentation by the EFPIA topic coordinator and time for questions and answers. The webinars represent an excellent opportunity to learn more about the Call topics, interact directly with the topic coordinators, and get in touch with other potential applicants.

- The webinar on IMI's rules and procedures will include presentations of IMI's intellectual property policy and tips on the preparation of proposal submissions.

- IMI will also hold a dedicated webinar for SMEs. This will cover elements of the different Call topics that may be of particular relevance for SMEs, as well as a presentation of IMI's rules and procedures with a focus on aspects that are most important for SMEs.

- The slides presented will be published on the IMI website, along with recordings of all webinars and lists of participants who agreed for their details to be published.

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Webinar Schedule for Call 20 topics

- IMI rules & procedures - Wednesday 29 January | 11:00
- Opportunities for SMEs in IMI2 - Call 20 - Thursday 30 January | 11:00

Topic-specific webinars

- Early diagnosis, prediction of radiographic outcomes and development of rational, personalised treatment strategies to improve long-term outcomes in psoriatic arthritis - Wednesday 22 January | 11:00
- Academia and industry united innovation and treatment for tuberculosis (UNITE4TB)- Thursday 23 January | 11:00
- Tumour plasticity - Friday 24 January | 11:00
- Innovations to accelerate vaccine development and manufacture - Monday 27 January | 11:00
- Proton versus photon therapy for oesophageal cancer – a trimodality strategy - Tuesday 28 January | 15:00
- Handling of protein drug products and stability concerns - Friday 31 January | 11:00

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Tips for success

Common Mistakes

- **Admissibility/Eligibility criteria not met:**
  - submission **deadline** missed
  - proposal **out of scope**
    (if you have doubts on how to respond to the Call contact us)
  - Not involving at least **three independent legal entities** (RIA) from **three** different **MS/AC**

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Common Mistakes

- The proposal does not address all the **objectives** (in some cases proposals have nothing to do with the topic!)
- Submitted text does not respect the proposal template (sometimes received even slides!)
- Applicants do not have the **capabilities** to address all of the objectives or there is redundancy between partners
- A proposal is scientifically excellent but will have **limited impact**
- **Budget**, either over-estimated or not fully justified
- **Ethical issues** not addressed

Writing a successful proposal

- **Read all the Call-relevant material that is provided on the IMI website** – **www.imi.europa.eu**
- **Understand IMI 2 rules** and respect them
- **If in doubt, ask** a member of the Programme Office
- A proposal should provide **reviewers** with all the information requested to allow them to evaluate it
- Start working early (pre-materials available before)
- Dedicate sufficient time to submit the proposal: create an EU login account, obtain a PIC number - don't wait until the last day to start the submission process
- Facilitated by having an established network of collaborators

Writing a successful proposal

Ensure:

- Consider the PPP dimension of the action (e.g. Governance, industry contribution vs IMI2 JU funding)
- Applicants must have the **expertise** and **capabilities** to address **all** of the objectives and there is no redundancy between partners
- In addition to being scientifically excellent the output of proposed project will have a **significant impact**
  - More tips: **www.imi.europa.eu/content/tips-applicants**

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Final Calls of IMI2

- Call 21 and 22 launch foreseen for 26 June 2020

- This is the final year of call launches under IMI2
- IMI2 projects will continue and follow the usual project lifecycle until completion

- Future calls beyond 2020 will be launched under a future partnership in health….

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Remaining scientific priorities 2020 (TBC)

- **Neurodegeneration and other neuroscience priorities**
  - Rare neurodegenerative and neurocognitive diseases clinical platform development
  - Complement in neurodegenerative diseases
- **Infection control including vaccines**
  - Development of innovative personalized diagnostics and patient-guided therapies for the management of sepsis-induced immune suppression
  - Modelling the impact of monoclonal antibodies and vaccines on the reduction of antimicrobial resistance
- **Big data, digital health, clinical trials and regulatory research**
  - Data lakes
  - Personalised endpoints
  - Returning clinical trial data to patients: The proactive return of clinically relevant information to study participants during and after a clinical trial
- **Oncology**
  - Real-world clinical implementation of liquid biops
  - Microbiome
- **Translational safety**
  - Pharmacodynamic drug-drug interaction predictive testing by learning algorithms to enhance safety
  - Digital vivarium
- **Facilitating rare disease therapies (including Advanced Therapy Medical Products) reaching patients in Europe**
  - Clinical outcomes assessments for rare diseases
  - Defragmenting and shortening the path to rare disease diagnosis by using genetic screening and digital technologies

More information

Stay in touch

- Visit our new website **www.imi.europa.eu**
- Sign up to our newsletter **via the website**
- Follow us on Twitter **@IMI_JU**
- Join our LinkedIn group **bit.ly/LinkedInIMI**
- E-mail us **infodesk@imi.europa.eu**

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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

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Thank you

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