Building new models of collaborative research across Europe – the IMI partnership

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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

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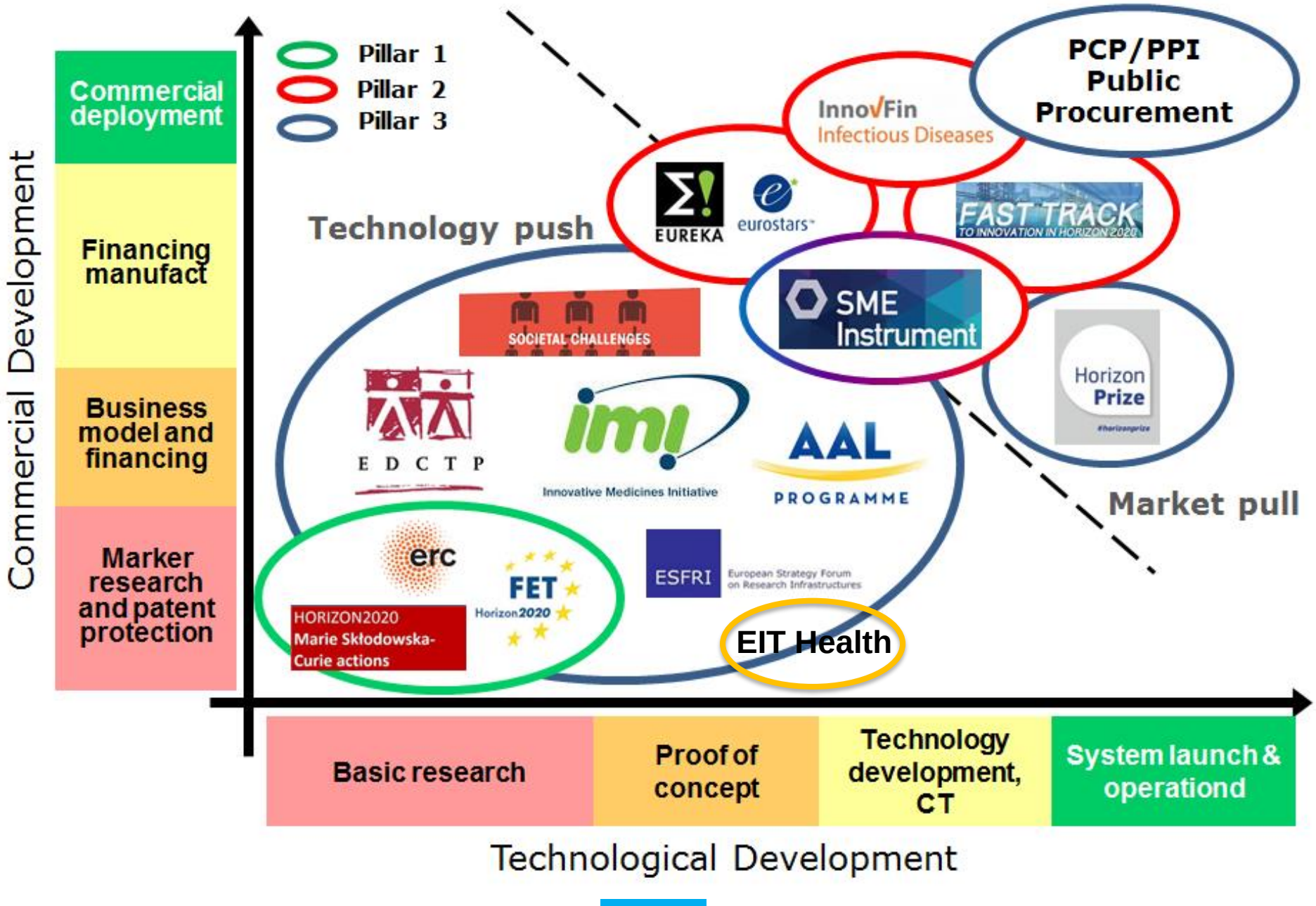
EU landscape for health research – H2020



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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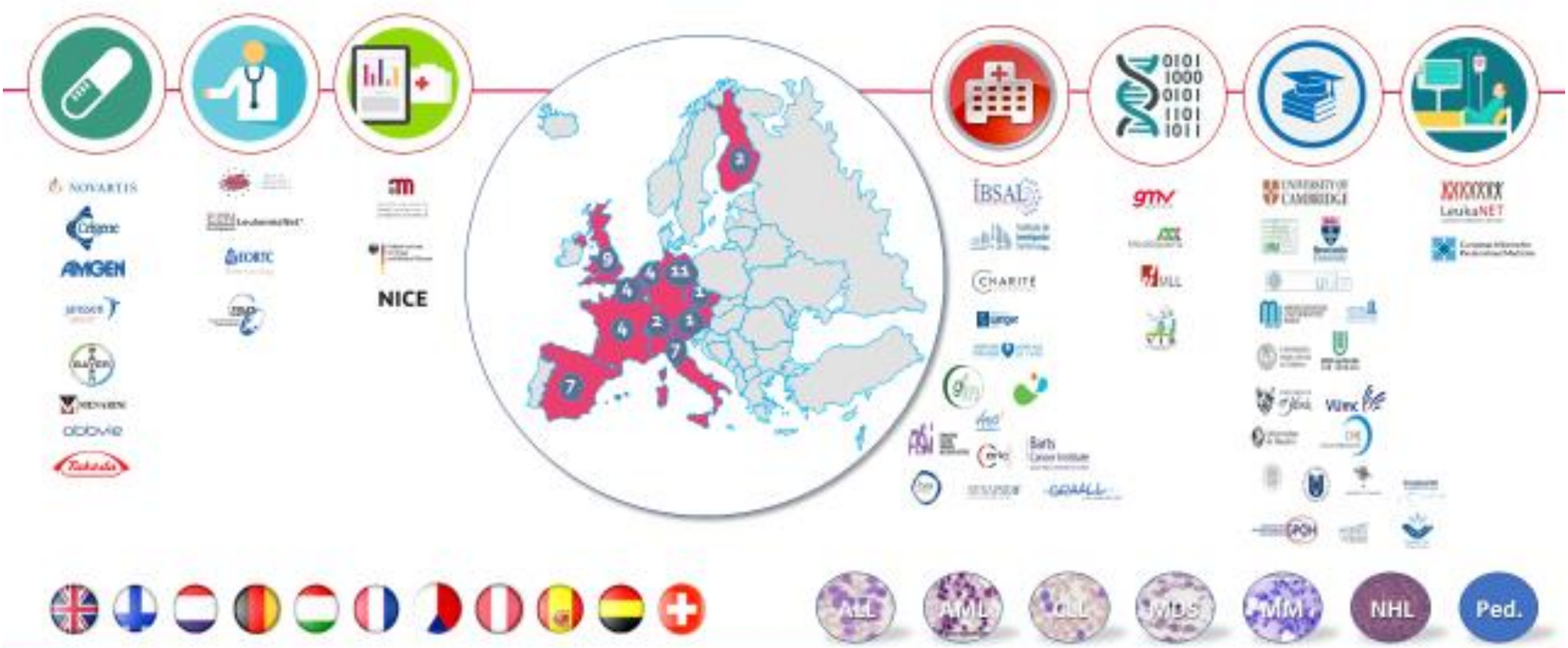
Added value of IMI

- Bringing together groups that would normally not work together, including competitors
- Attracting new partners leading to a more diverse community
- Creating new networks, maintained after projects end
- Addressing the most challenging diseases areas and cross-cutting issues
- Maximising the pooling of resources and amplifying scientific and financial investments
- Relevant outcomes for industry, direct benefits to patients, impacts on regulatory processes
- Including elements of or dedicated to education and training activities
- Increasing the number of co-authored and cross-sectors scientific publications with high citation impact

€5.3bn	121	2278	>7 000	>3 800
BUDGET	PROJECTS	PARTICIPANTS	PROJECT OUTPUTS	PUBLICATIONS

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



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…)

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Why do we want SMEs in IMI projects?

- SMEs can act as a **key interface** between latest academic discoveries and implementation in industry
- SMEs can bring **industrial grade products/services** to IMI projects
- With a commercial focus, SMEs can **drive projects to achieve** high impact results
- By developing products & services, SMEs can ensure the results of IMI projects are **widely available after the funding ends**
- Help create a **favourable ecosystem for SME innovation and growth.**

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Why should an SME participate in an IMI project?

- IMI projects are focused on **translating excellent research** into real world outcomes – an opportunity for SMEs
- SMEs can **fine-tune innovative services and products** with the actual end-user scientists
- Collaboration with large pharmaceutical companies and others allows **access to whole value chain** of drug discovery & the **building of research and business networks**
- **Enhancing reputation and visibility**. IMI project achievements often get recognised and promoted on an international level
- https://www.imi.europa.eu/get-involved/smes

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Discovery of a new cancer treatment

- French biotech CELLIPSE has been brought one step closer to a novel cancer treatment through the activities of the European Lead Factory.
- The initial work done in the ELF will be continued by CELLIPSE to prepare a package that could attract a major player to further develop first-in-class small molecules against myeloid leukemias.

Cellipse
Cell to drug discovery

Resulting from IMI EUC^{2}LID project

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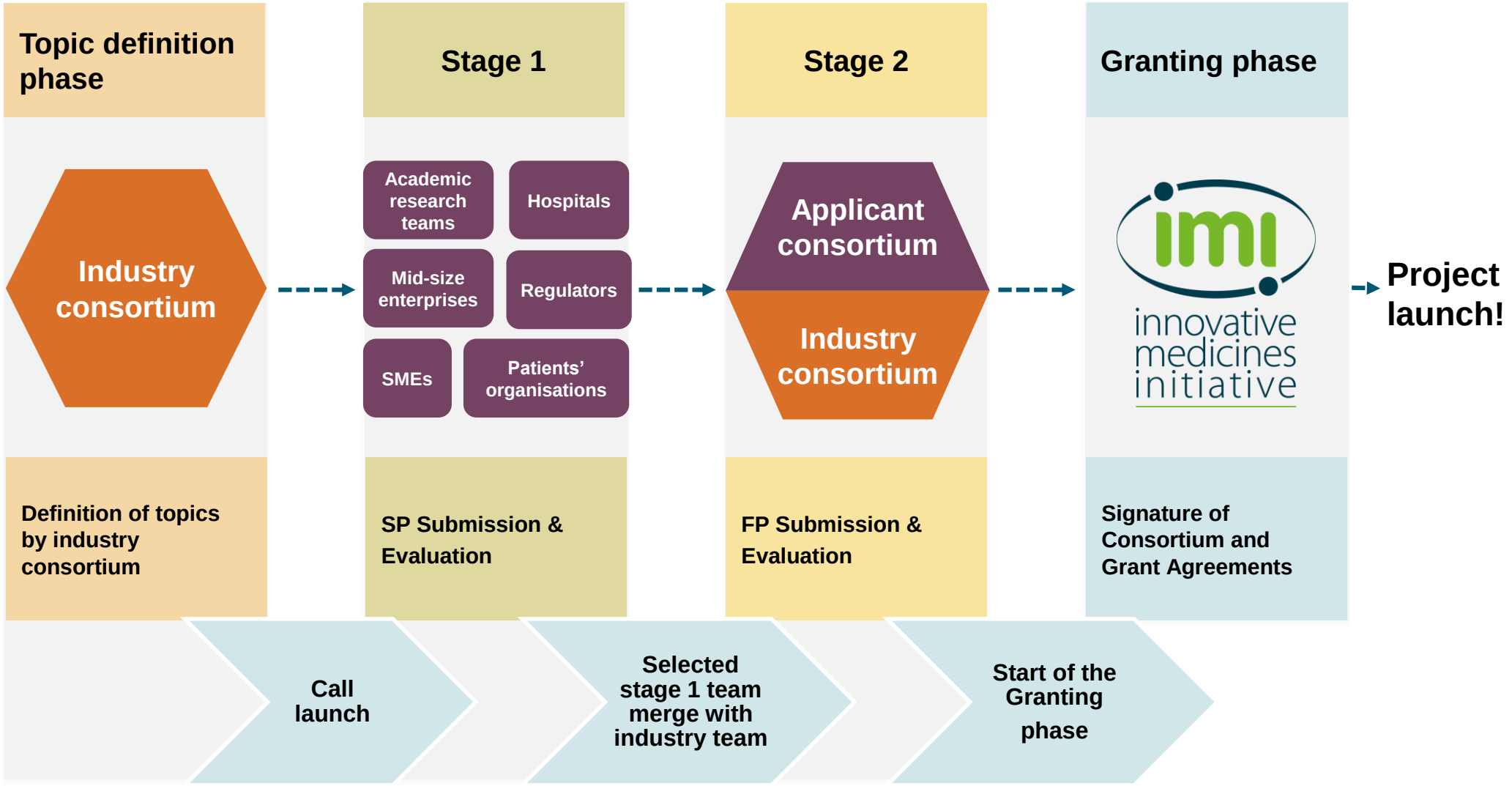
Process from Call Launch to Project Launch



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IMI2 Call 18 – 6 topics

call closure Sept 26 - project start Autumn 2020

- Translational safety: Digital pathology using AI tools
- Big data, digital health, clinical trials and regulatory research:
  - Health outcomes observatories
  - Integrated digital health information project
- Oncology: Patient Reported Outcomes in Cancer Clinical Trials
- ATMP:
  - CAR T cells development
  - Accelerating R&D for ATMP

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IMI2 Call 18 - 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.

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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

IMI2 Calls in 2020

- Two Calls currently planned: January / June
- Topics under consideration for inclusion in future IMI Calls https://www.imi.europa.eu/apply-funding/future-topics
- Draft topic texts published: +/- 2 months before official Call launch
- Webinar topic presentations organised: at official Call launch
- Deadline for submitting Short Proposals: 3 months after official Call launch

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Topics in the pipeline (indicative)

Neurodegeneration / neuroscience

- Digital endpoints and placebo effect in chronic pain

Infection control & vaccines

- Development of innovative personalized diagnostics and patient-guided therapies for the management of sepsis-induced immune suppression

Oncology

- Prospective real-world clinical implementation of liquid biopsies
- Tumour plasticity

Topics in the pipeline (indicative)

Big data, digital health, clinical trials and regulatory research

- Data lakes

Facilitating the translation of advanced therapies to patients in Europe

- Optimising patient access to new therapies for rare diseases

For more information and potential updates, see:
www.imi.europa.eu/apply-funding/future-topics

Example of indicative topic summary

Oncology

Prospective real-world clinical implementation of liquid biopsies

Liquid Biopsy is a promising concept for patient selection and disease monitoring in drug development and in clinical practice. However, as of today, few clinical studies used Liquid Biopsies to systematically and prospectively identify eligible patients for clinical studies, therapy selection, therapy monitoring or detection of first signs of efficacy. Based on outputs from IMI CANCER-ID the project will use prospective clinical trials to investigate the efficacy and robustness of the method and its ability to guide recruitment to trials and therapeutic choices

Tumour plasticity

Drug resistance in cancer is one of the greatest causes of mortality and despite increasing success with targeted therapies in the clinic (including immunotherapy) the mechanisms by which cancer cells evade cell death are still not well understood. Drug combinations are likely to be critical to overcoming drug resistance but are dependent on identifying the cellular programs that cancer cells use to resist therapeutic agents. Recent technological advances in single cell RNA sequencing (scRNA-seq) has revolutionised the study of individual cells within cancer populations. Single cell sequencing provides information that is not confounded by genotypic or phenotypic heterogeneity of bulk samples. It has led to the identification of rare cancer cells ('persister cells') able to survive drug treatment and that are able to act as a reservoir for the emergence of drug resistant cancer populations. Characterising the transcriptionally altered pathways in persister cells, the biological processes they regulate and their druggability will be critical to future drug combination strategies, with the goal of preventing or significantly delaying the development of drug resistance. The transcriptional programs employed by persister cells in response to a therapy are likely to be lineage specific. Scientific advances in single cell sequencing, cancer organoid derivation, use of patient-derived xenografts (PDX) and tissue imaging have come together to create the perfect environment to address one of the most important challenges in cancer biology today, Drug resistance.

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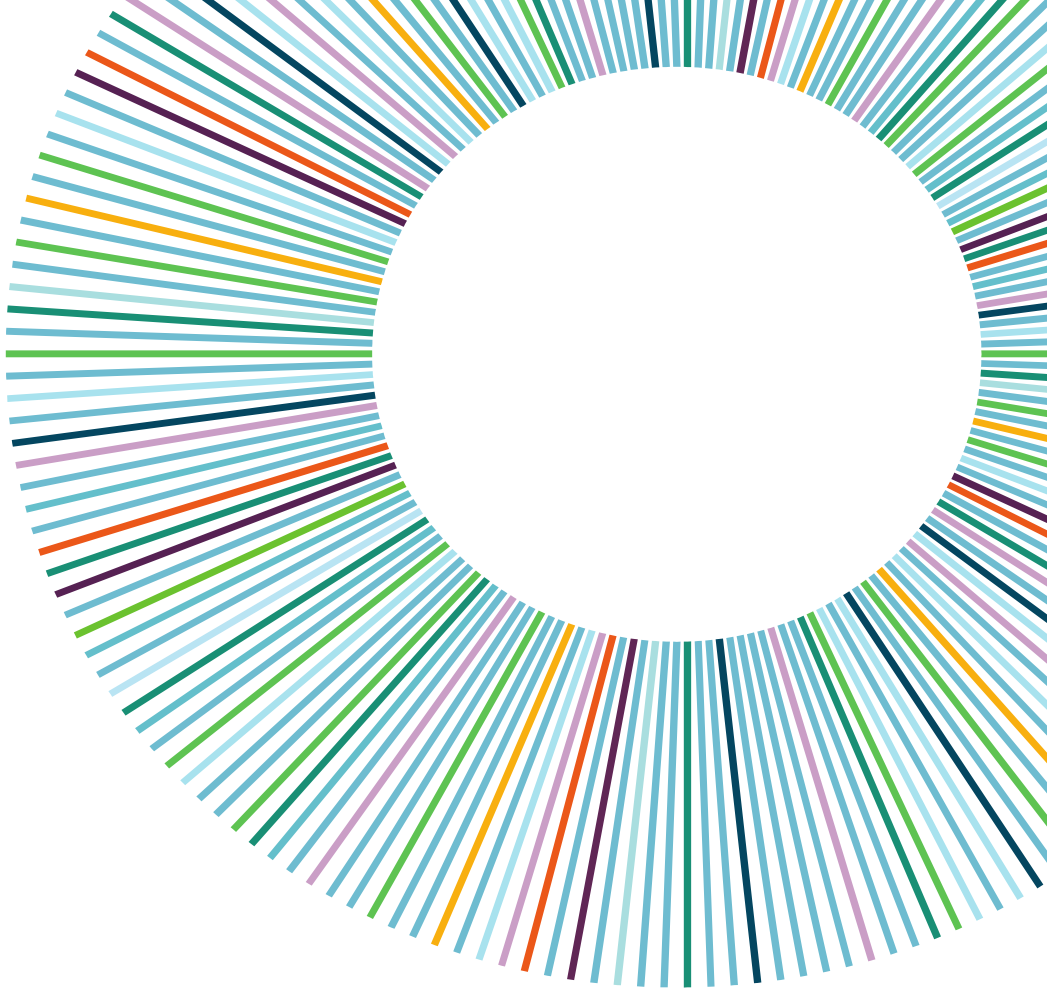

10 YEARS OF BREAKTHROUGHS
A HEALTHIER FUTURE

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