

Driving the future of healthcare in Europe



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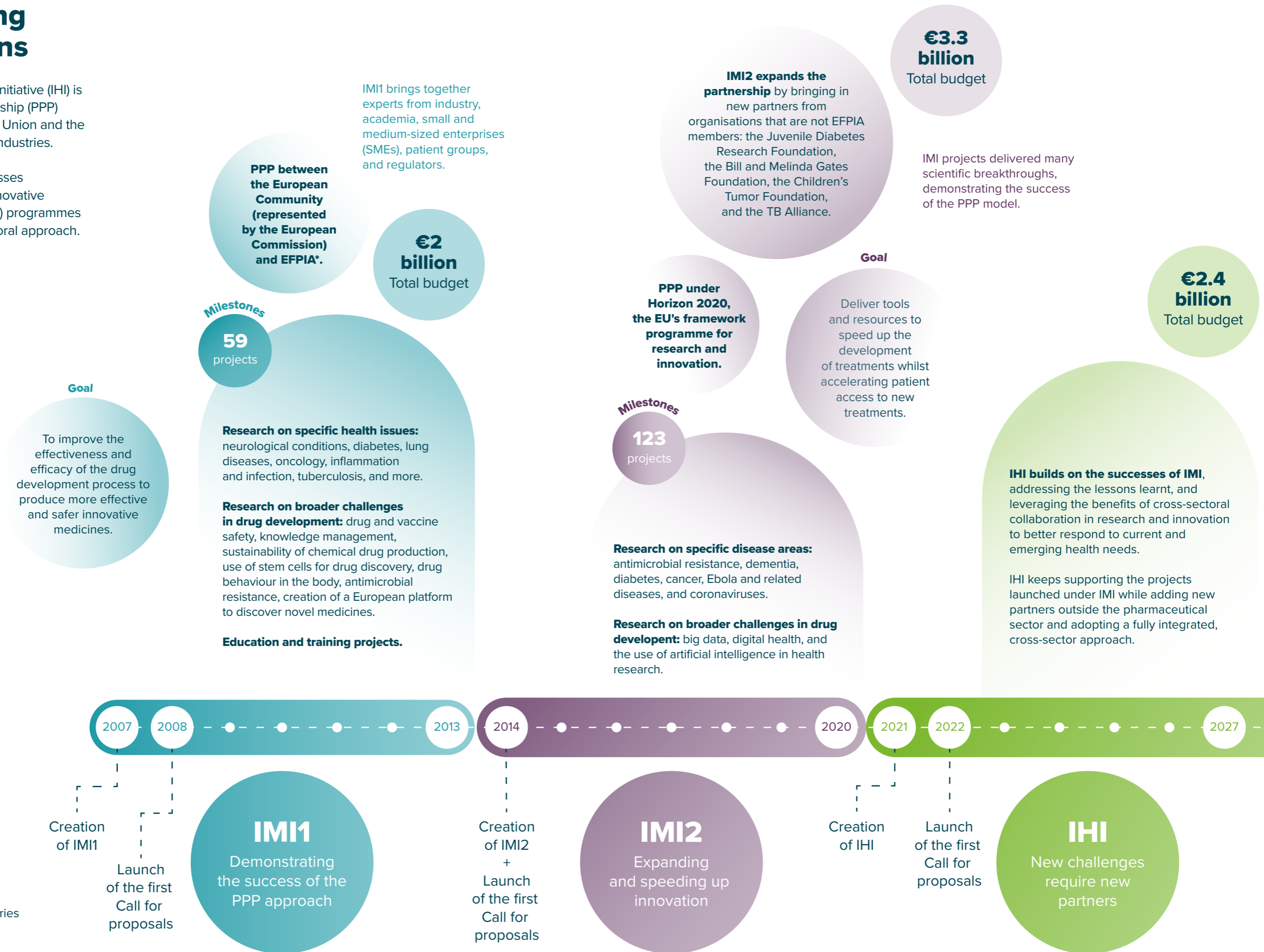
This brochure presents the Innovative Health Initiative (IHI) and contains a snapshot of the Innovative Medicines Initiative (IMI) project achievements, many of which are recorded in the Annual Activity Report (AAR) 2021.

The AAR 2021 is available [here](#).

Celebrating IHI's origins

The Innovative Health Initiative (IHI) is a public-private partnership (PPP) between the European Union and the European life science industries.

IHI builds on the successes and expertise of the Innovative Medicines Initiative (IMI) programmes with a more cross-sectoral approach.

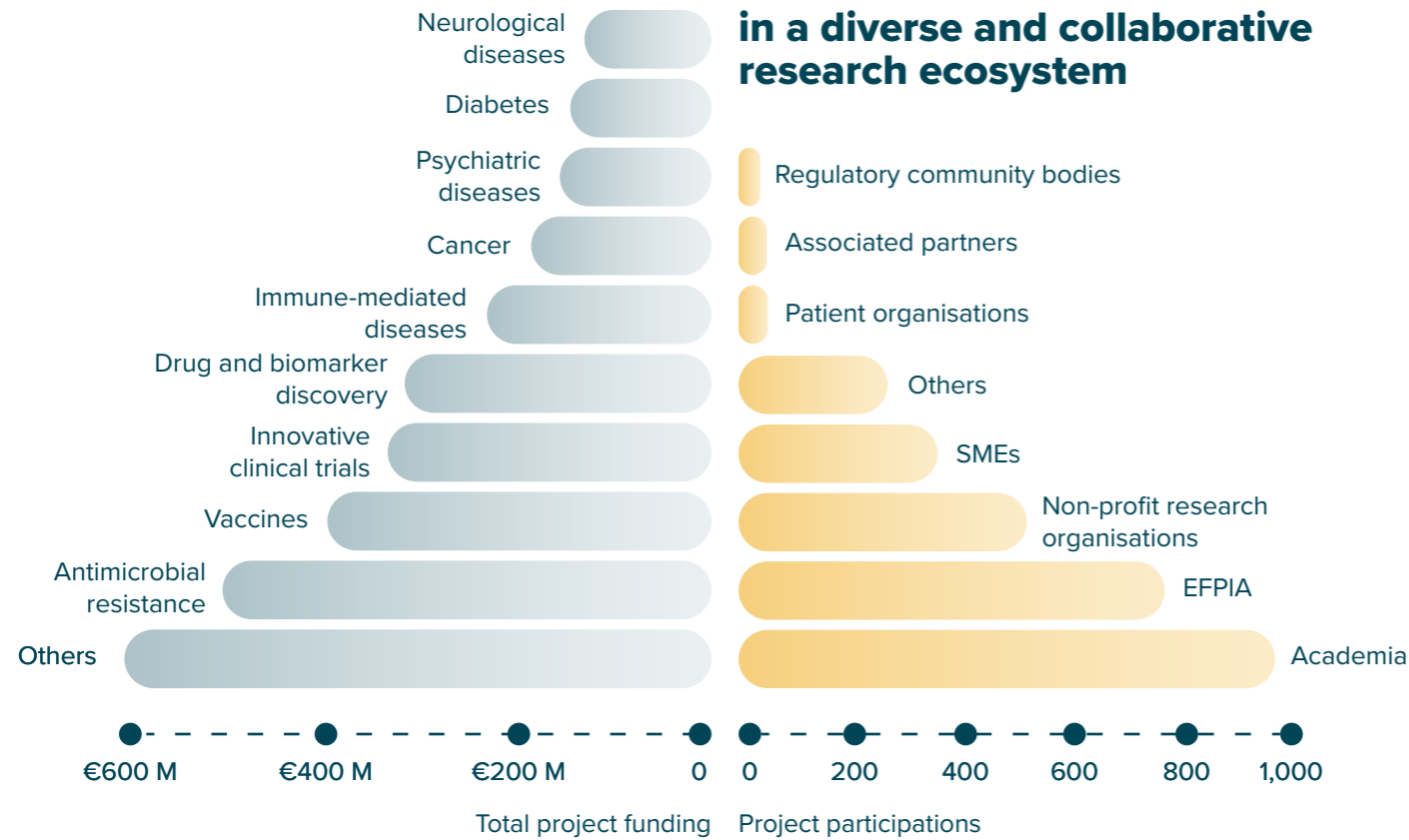


*European Federation of Pharmaceutical Industries and Associations

Bringing diverse sectors together to transform health care

IMI projects cover the full spectrum of drug discovery and development.

IMI: funding strategic areas

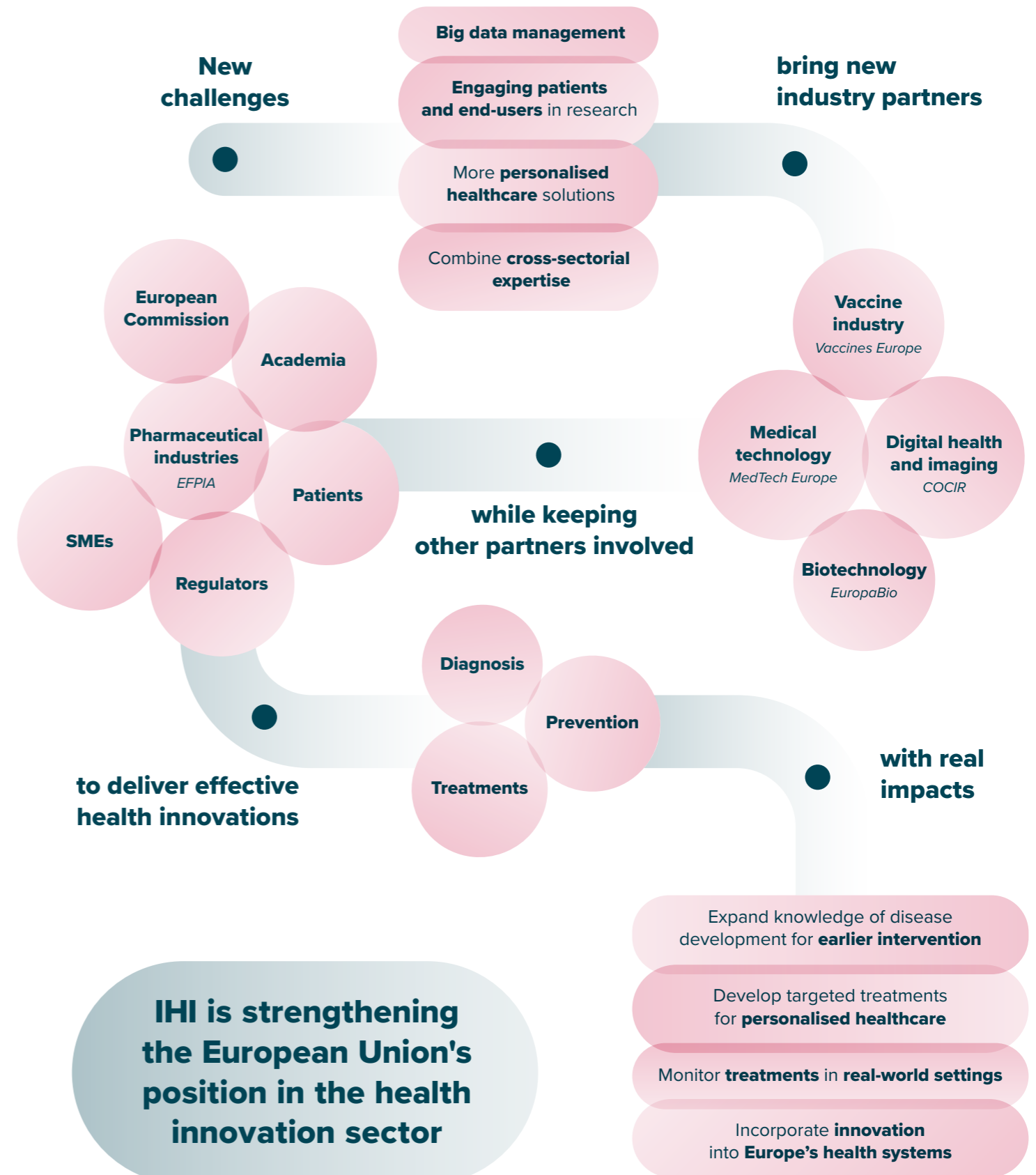


Projects outputs

- New tools, biomarkers, and resources:**
 - for drug discovery and preclinical drug development
 - to predict clinical outcomes
 - to test vaccine candidates' efficacy and safety
- New taxonomies of diseases and new stratifications of patient sub-populations**
- Education and training tools**
- Improved protocols, processes, and clinical networks for clinical trial design and processes**
- Big data solutions** to leverage knowledge and improve data standards implementation
- Impacts on the regulatory framework**

From disease care to health care: an integrated, people-centred approach

In 2021, IHI is set up to improve the translation of health research into real benefits for patients and society.



Continuing the path towards personalised oncology

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020. The fight against cancer is a top priority for the European Commission.

Our projects are contributing to this fight in diverse ways, like understanding why tumours are resistant to therapies or how to accelerate pre-clinical and clinical cancer drug development processes.



€187 million
Total funding

15
Projects

Laying the foundations to move paediatric cancer research forward

Childhood cancers are different from adult cancers. Therefore, innovative treatments specifically developed for children are required. A challenge in this quest is the lack of tumour models relevant to children, needed to understand better the emergence and evolution of tumours and why they resist treatments.

ITCC-P4 is creating a platform with childhood cancer tumour models that can be used to test promising drugs. These models allow the pre-clinical testing of drugs to generate more accurate data on whether these are safe and effective to use in children with cancer.

Impacts & outcomes

- **Paper published in *Molecular Cancer Therapeutics*** with recommendations to guide the use of models for paediatric malignant tumours, and to inform the clinical development of promising agents
- **+600 patient-derived models** registered covering all major paediatric tumour types
- Testing of **+100 models**

A healthcare alliance against blood cancer

Blood cancers account for $\sim \frac{1}{3}$ of cancer cases in children and $\sim \frac{1}{3}$ of cancer deaths. Many blood cancers are rare, and the lack of data on them poses a challenge for clinicians, researchers, and decision-makers.

HARMONY aims to use big data to improve the care of patients with blood diseases. The project gathers, integrates, and analyses anonymous patient data to help define endpoints and outcomes for these cancers. This information can help in providing the patients with the right treatment at the right time.

- **Big data platform** to share data on blood cancers
- **Delivered insights** into various forms of blood cancer

Impacts & outcomes

A unique chemical library to advance drug discovery

The **ESCuLab** project makes available a collection of over half a million compounds and a screening centre to support drug discovery programmes and boost drug discovery in various fields. Researchers with drug targets can have them screened against the collection and get help developing any resulting hits.

Impacts & outcomes

- **Two drug candidates** for cancer treatment have progressed to human clinical testing

COVID-19: encouraging collaborative research during pressing times

IMI responded quickly to the COVID-19 outbreak and launched a Call for projects aimed at tackling the emergent needs posed by the COVID-19 crisis.



€117 million
Total funding

94
Organisations

8
Projects

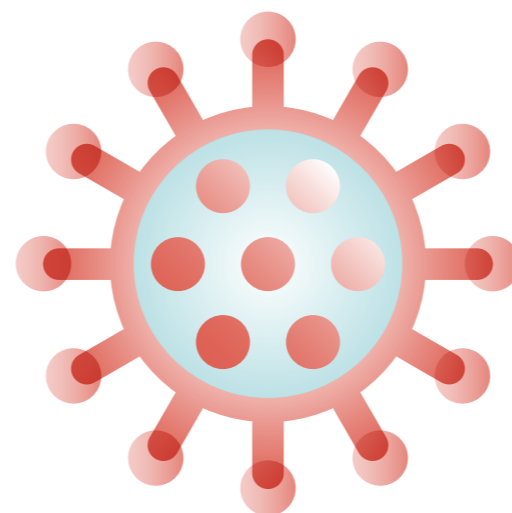
Drug repurposing, a smart race against time

Drug repurposing is the research process of using existing drugs to treat diseases other than the originally intended ones. The drug's safety has already been tested and the additional clinical trials are easier and faster to perform.

MAD-CoV-2 uses computational biology and machine learning approaches to identify existing approved antiviral drugs that could be repurposed to treat COVID-19 and future coronavirus outbreaks.

Impacts & outcomes

- Identified **200 approved drugs** that could be appropriate for repurposing against COVID-19, **40** of which were already in clinical trials
- Identified a **potential combined therapy** (using 2 drugs) for the treatment of COVID-19



Accelerating research to neutralise the coronavirus

The **CARE** consortium is the largest scientific research initiative addressing the challenges of COVID-19 supported by IMI. CARE is focused on drug repurposing for faster delivery of treatments against COVID-19, but also intends to deliver treatments for future coronavirus outbreaks.

- Identification of an **antibody that neutralises SARS-CoV-2**, able to protect patients for 4–6 months
- Discovery of a **genetic link** to the likelihood of someone developing severe disease
- Insights on **how SARS-CoV-2 indirectly damages** the endothelial cells that line the blood vessels, lymph nodes, and heart
- New **assay for understanding antibody response** in natural infection versus vaccination
- Insights into the **durability of different antibodies** against the spike protein

Impacts & outcomes

Faster diagnoses for more targeted treatments

Reducing the time of diagnosis of COVID-19, but also other infections, ensures that COVID-19 patients can be quickly isolated, limiting the spread of the disease. An early diagnosis is also key to ensuring patients receive the right treatments and reducing the unnecessary use of antibiotics.

The **RAPID-COVID** consortium is developing a diagnostic kit able to detect SARS-CoV-2 and additional viruses and bacteria, to support the differential diagnosis of patients with similar symptoms.

Impacts & outcomes

- Two CE-marked* diagnostic panels** which can detect the causative pathogens in patients with COVID-like symptoms and differentiate SARS-CoV-2 alongside 17 common causes of upper respiratory tract infections and 11 common causes of pneumonia

*CE-marking (required for products marketed in the EU) indicates that a product meets EU safety, health, and environmental protection requirements.

Antimicrobial resistance: a silent global tsunami

The misuse and overuse of antibiotics have been linked to the emergence and spread of microorganisms which are resistant to them.

Antimicrobial resistance (AMR) makes treatment ineffective, leading to infections that are more difficult to treat, and death. New antibiotics, as well as a change in people's behaviour, are crucial to face this major global threat to human and animal health.

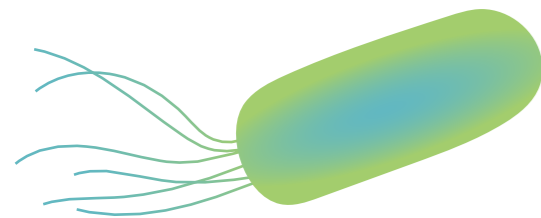


€507 million
Total funding

17
Projects

Impacts & outcomes

- European network of +1,200 hospitals and +900 labs ready to participate in clinical trials and studies
- ECRAID: entity set up to ensure the legacy of COMBACTE projects



Taking action against antibiotic resistance

COMBACTE projects aim to boost antibiotic drug development by pioneering new ways of designing and implementing clinical trials for new antibiotics.

Advancing the development of promising new antibiotics

Despite the crucial need for new medicines to treat resistant microorganisms, the development of new drugs is still quite limited.

ENABLE set up a drug discovery platform for testing and optimising potential drug candidates that are still in the earlier stages of drug discovery. The project guides researchers and connects experts to help advance their molecules through the drug development process until it is ready for testing in patients.

- Contributed to the development of **two potential antibiotics**, from discovery and pre-clinical stage to clinical trials

Impacts & outcomes

Enhancing diagnostics for a more personalised and evidence-based antibiotic prescription

Greater use of diagnostic tests could help ensure antibiotics are used only when necessary. But the wider use of diagnostic tests is hindered by a lack of insight into their medical, technological, and economical value.

VALUE-Dx aims to determine the value of diagnostics to help doctors deliver personalised and evidence-based antibiotic prescriptions. By helping optimise antibiotic use, the project will contribute to limiting AMR and improving patient outcomes.

- Development and improvement of **health economic models and policy recommendations** to reduce AMR
- VALUE-Dx **E-learning platform** to support the adoption of diagnostics in community care settings

Impacts & outcomes

Other disease areas

Further disease areas are also represented in the IMI portfolio, from neurodegenerative and autoimmune diseases to rare diseases, among others.



12

Autoimmune disease projects

24

Neurodegenerative disease projects

4

Rare disease projects

Shortening the path to rare disease diagnosis

Rare diseases will affect 1 in 17 people during their lifetime - many of these severe and long-lasting. Still, their diagnosis can take years and result in misdiagnoses and ineffective treatments.

Screen4Care aims to dramatically shorten the time taken to diagnose and treat rare diseases. It does so by exploring how genetic screening of newborn babies and digital technologies could help to identify rare diseases early on.

Development of **new artificial intelligence tools** to speed up the diagnosis of rare diseases

Open platform that enables continuous data collection and information exchange; its goal is to aid in the development of new diagnostics and provide advice and faster access to effective treatments to patients and relatives, as well as engaging them in the diagnosis process

Expected impacts & outcomes

Speeding up psoriatic arthritis diagnosis to improve patient life quality

Over 80 autoimmune conditions affect millions of people worldwide. Psoriasis is an example. Around 20-30% of people with psoriasis develop psoriatic arthritis, which is hard to diagnose.

HIPPOCRATES aims to speed up the diagnosis of psoriatic arthritis and pave the way for personalised treatments, to ultimately enhance the life quality of people with psoriatic arthritis.



Expected impacts & outcomes

Deliver **knowledge and tools** to facilitate the identification of psoriasis patients who are greater risk of developing psoriatic arthritis and diagnose them faster

Together, accelerating biomarker discovery for neurodegenerative diseases

Millions of people worldwide are affected by neurodegenerative diseases, but there are very few treatment options. Many research efforts have focused on expanding the knowledge on biomarkers to identify people in the early stages or measure the effects of a potential treatment. Yet, this data is not always accessible and easy to use.

EPND aims to establish a collaborative platform that links existing European research infrastructures. This will facilitate access to biological samples and data, accelerating biomarker discovery and supporting the development of therapeutics for neurodegenerative diseases.

Expected impacts & outcomes

European network of research infrastructures to speed up the discovery of new biomarkers for neurodegenerative diseases

Development of principles to enable access to samples and data and establish fair and transparent governance and processes

Tackling cross-cutting challenges in health research

Medical research faces many challenges beyond drug development. These cross-cutting issues include, for instance, big data, medical technologies, medicines safety, and sustainability.



Data brings us together

Medical research generates vast amounts of high-quality data. But the research landscape is often fragmented. Closer collaboration is needed to increase our understanding of diseases and help advance drug development.

NEURONET brings together information on IMI projects researching neurodegenerative disorders. The project makes it easier to identify gaps, multiply impacts, and enhance the visibility of the many projects, boosting coordination and collaboration.

Knowledge Base with information on over 20 IMI neurodegenerative disorders projects, providing an overview of the portfolio and the diverse projects' outputs and assets

Expected impacts & outcomes

Using big data to improve patients' outcomes

Massive amounts of medical data are generated every day by researchers, clinicians, and patients. If linked, this 'big data' can help to rapidly deliver new insights and advance medical research.

The **Big Data for Better Outcomes (BD4BO)** programme brings together all stakeholders to generate the knowledge, data, and methodologies needed to support that transition. Through its projects, BD4BO focuses on many key therapeutic areas, such as cardiovascular disease, Alzheimer's disease, and certain types of cancer.

Expected impacts & outcomes

- Published recommendations** to inform EU decision-makers on how to make the European Health Data Space really work for patients, doctors, and researchers
- More efficient research,** advancing knowledge into diseases, treatments, and patients' experiences, thereby accelerating the development of new medicines
- Tools, resources, and expertise** facilitating the identification of which treatments work best for different patients
- Design and selection of treatments** based on outcomes that matter to patients



Engaging patients to enhance treatment adherence

Approximately 50% of the patients do not take their treatment as prescribed. This can impact their health and quality of life, and result in avoidable hospitalisations and 200,000 deaths in the EU every year.

BEAMER aims to increase the understanding of the factors influencing patient adherence across disease areas. This will allow stakeholders to develop solutions that boost treatment adherence.

Expected impacts & outcomes

Model of the main factors affecting patient adherence to treatments to test it in 18,000 patients in 6 countries

Placing patients at the centre of health

Patients' contribution is key to shaping medicine development. Their involvement in the process improves the relevance, quality, and validity of drug research and development from the patient perspective, making it more effective and more oriented to patient needs.



57% of projects involve patient and healthcare professionals' associations

Impacts & outcomes

Advancing patient-centric research

IMI recognises the vital contribution of patients and works closely with them throughout all stages of the health process. Patients are continuously engaged and involved in projects and activities both at strategic and operational levels.

IMI created the **pool of patient experts**, an initiative to provide patients' perspectives, needs and priorities within IMI. Patients have been engaged in:

- **evaluating proposals** submitted for the Calls for proposals
- **monitoring of projects**
- attending **project close-out meetings**
- participating in **patient-centred activities** organised by the projects
- joining the **webinar with the EMA** on the European regulatory process
- participating in the **event dedicated to IMI's impact on patient engagement**
- **continuous communication** on the latest project developments and highlights

Going above and beyond in health research

APPROACH aims to facilitate more personalised treatments for osteoarthritis, a debilitating condition affecting joints. To do so, APPROACH set up a Patient Council with people from across Europe with osteoarthritis.

"... patient involvement [...] is an enriching experience for patients and researchers involved, and has broad benefits that range beyond the scope of the research project."

Taylor, J. et al. (2021) "Making the patient voice heard in a research consortium: experiences from an EU project (IMI-APPROACH)," *Research involvement and engagement*, 7(1), p. 24.

- **Paper published in *Research Involvement and Engagement*** describing the process of involving patients in research, its challenges, and benefits
- **Integrated bioinformatics platform** functioning as a data and bio-tissues repository
- Implementing **patient screenings** that will help identify biomarkers of disease progression to develop personalised treatments

Impacts & outcomes

Patient co-creation: the key to success

Prostate cancer is the second most common cancer in males. Early screening and diagnosis may lead to a better prognosis, but improvements in this process are still needed.

PIONEER is using big data approaches to address key knowledge gaps related to the screening, diagnosis, and treatment of prostate cancer patients.

- **Core Outcome Sets (COS)** for prostate cancer that involve and are relevant for all stakeholders, including patients. COS are an agreed minimum set of outcomes that should be measured and reported in all clinical trials

- **Paper published in *European Urology Focus*** with recommendations for patient engagement in COS development

Impacts & outcomes

Improving decision-making one project at a time

The medicine development sector is one of the most regulated across the world. This ensures that only high-quality, proven safe, and effective products reach the market and the public. Therefore, having an impact on the regulatory framework is considered a major achievement.



Anticipating potential harmful effects of drugs

Predicting which medicines could be potentially harmful to certain vital organs is a major challenge during drug development. Biomarkers can be used to predict injury in major organ systems.

The **TransBioLine** project is developing biomarkers that will reliably indicate liver, kidneys, pancreas, blood vessels, and central nervous system (CNS) injury. The project has been in close contact with regulatory authorities to ensure the biomarkers can be widely used in drug development.

Biomarkers for damage to the vascular system, CNS, kidney, and liver accepted **into the Biomarker Qualification Program*** of the U.S. Food and Drug Administration (FDA)

Impacts & outcomes

*This qualification allows the biomarker to be used during drug development to support the regulatory approval of a new drug.

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Completed regulatory procedures

From real-life to the lab

Real-world evidence (RWE) is needed to assess the value of a new drug. In practice, this means data obtained outside the context of controlled trials, such as that generated during routine clinical practice. However, there is little guidance on how to generate RWE and integrate it into drug development.

The IMI projects **GetReal** and **GetReal Initiative** brought together all the relevant stakeholders to work towards a consensus on best practices in the use of RWE in drug development, as well as regulatory and reimbursement decision-making.

- GetReal Institute:** ensures access, further development, and adoption of new tools, methods and best practices in the generation and use of RWE
- GetReal Trial Tool:** provides guidance on options and implications of introducing real-world elements in clinical trial design
- GetReal Academy:** delivers courses on RWE
- Aggregate Data Drug Information System (ADDIS) upgrade:** educational tool focusing on benefit-risk assessment, preference elicitation, and shared decision-making

Impacts & outcomes

Patients' preferences boost research

Patients' perspectives can make the process of drug research and development process more effective and more oriented to patient needs. However, there's limited experience with patient preferences studies, and many research questions still need to be addressed in this area.

PREFER is investigating and testing the best ways to let patients have an active voice in medicine development and decision-making. The project has developed a set of recommendations for the industry, regulatory authorities, and health technology assessment (HTA) bodies on how to use patient perspectives in medicine development.

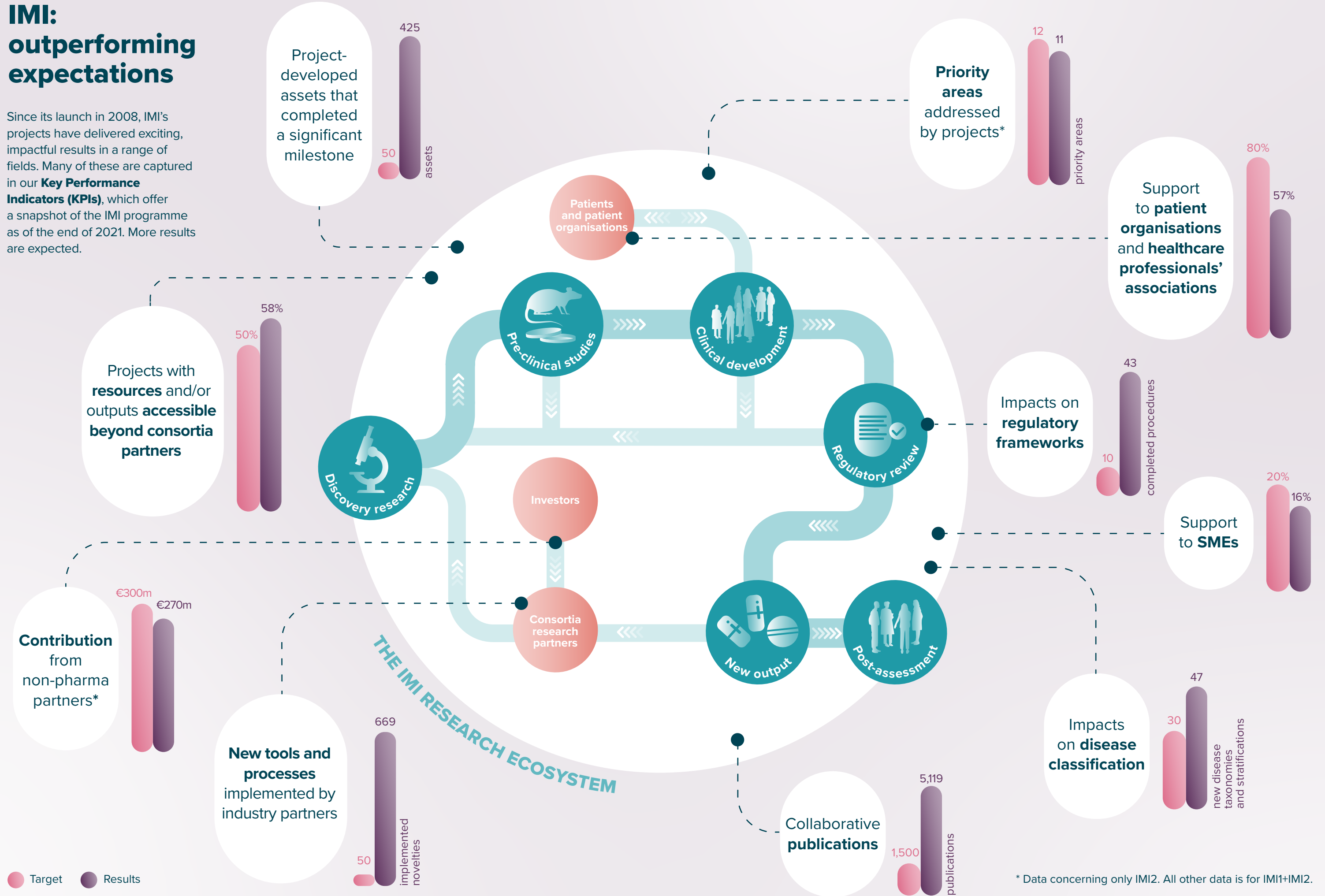
Positive qualification opinion from the European Medicines Agency's (EMA) committee, endorsing the project's framework

Greater **collaboration between scientists and industry with patients** to plan and design patient preference studies and allow regulators and HTA bodies to gain experience in reviewing data from these studies

Impacts & outcomes

IMI: outperforming expectations

Since its launch in 2008, IMI's projects have delivered exciting, impactful results in a range of fields. Many of these are captured in our **Key Performance Indicators (KPIs)**, which offer a snapshot of the IMI programme as of the end of 2021. More results are expected.



* Data concerning only IMI2. All other data is for IMI1+IMI2.

Project dissemination

IMI projects are delivering diverse tools, resources and methods that are helping to change and improve the way new medicines are discovered and developed.

It is crucial that these resources, and information on them, are disseminated by the project partners and IMI.

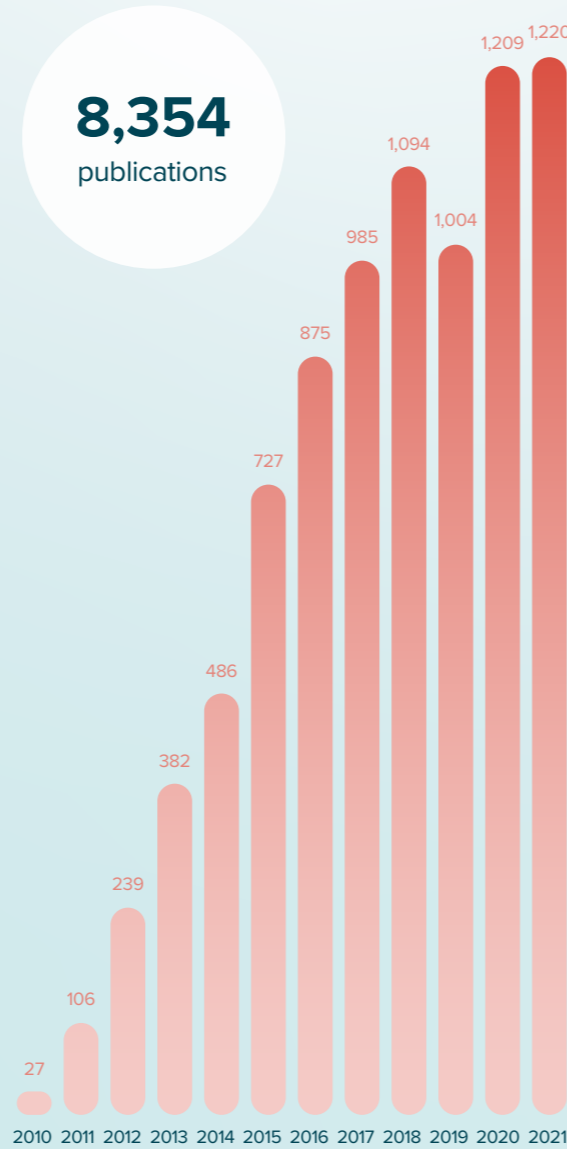
Published outputs of IMI-funded research projects

Scientific publications are the key communication and dissemination channel for scientific results.

The published outputs point to the sheer volume and high quality of research taking place in IMI projects.

The statistics speak for themselves:

+1,000 publications per year since 2018

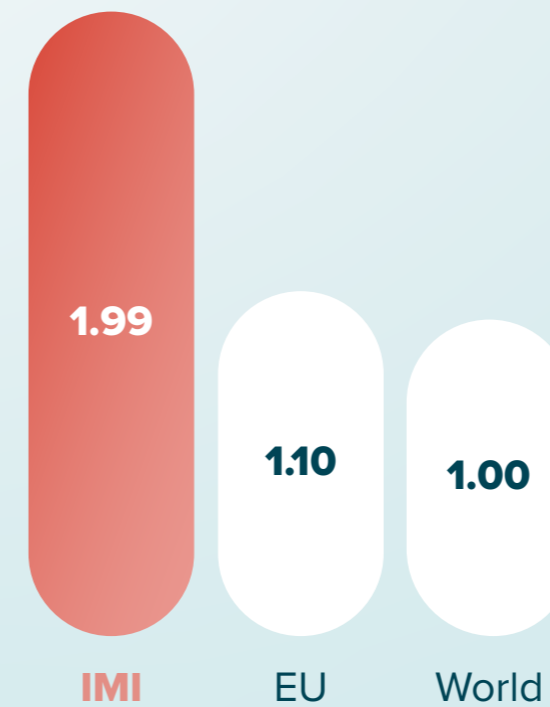


Papers published in +1,000 different journals

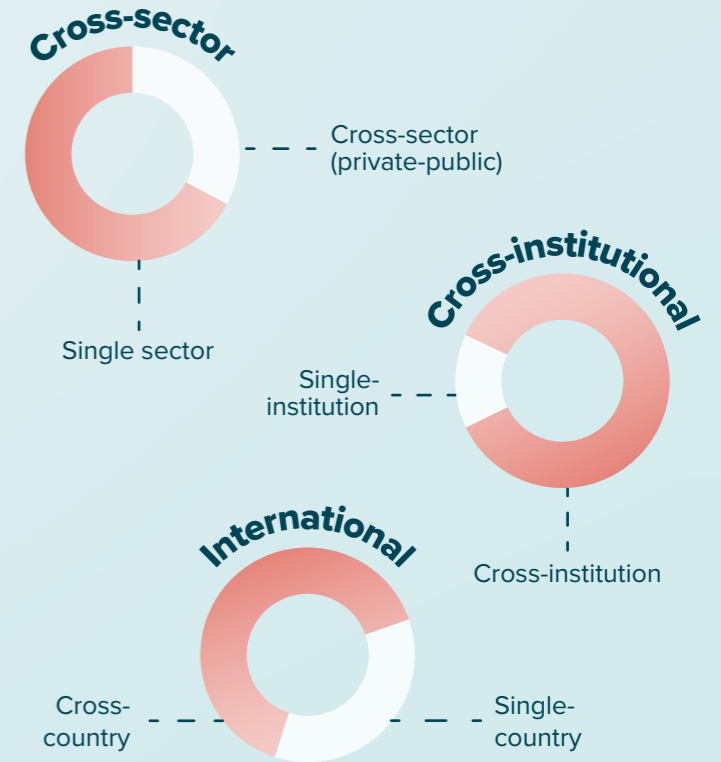


High citation impact

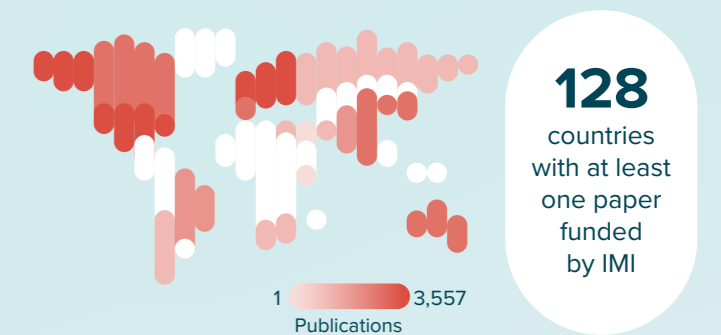
IMI's citation impact compares favourably with similar organisations and the EU and world averages. This shows that IMI is maintaining a high standard even as its output increases.



Highly collaborative



Activities are funded all over the world



Robust and efficient granting processes

IMI2 average results in 2021



The future is IHI

Looking to the future, it is clear that new breakthroughs will involve cross-sectoral discoveries, such as artificial intelligence diagnostics and medical devices-drugs combinations, or new therapeutic approaches like gene therapy and image-guided cancer therapies.

A growing number of people already use medical devices, digital technologies, and e-health services to monitor and manage their health. This means there is a need for the various sectors working in health research and innovation to collaborate and bring end-users to the path for a real transformation in health care.

IHI was launched in 2021 to advance a more cross-sectoral approach to health research and innovation.

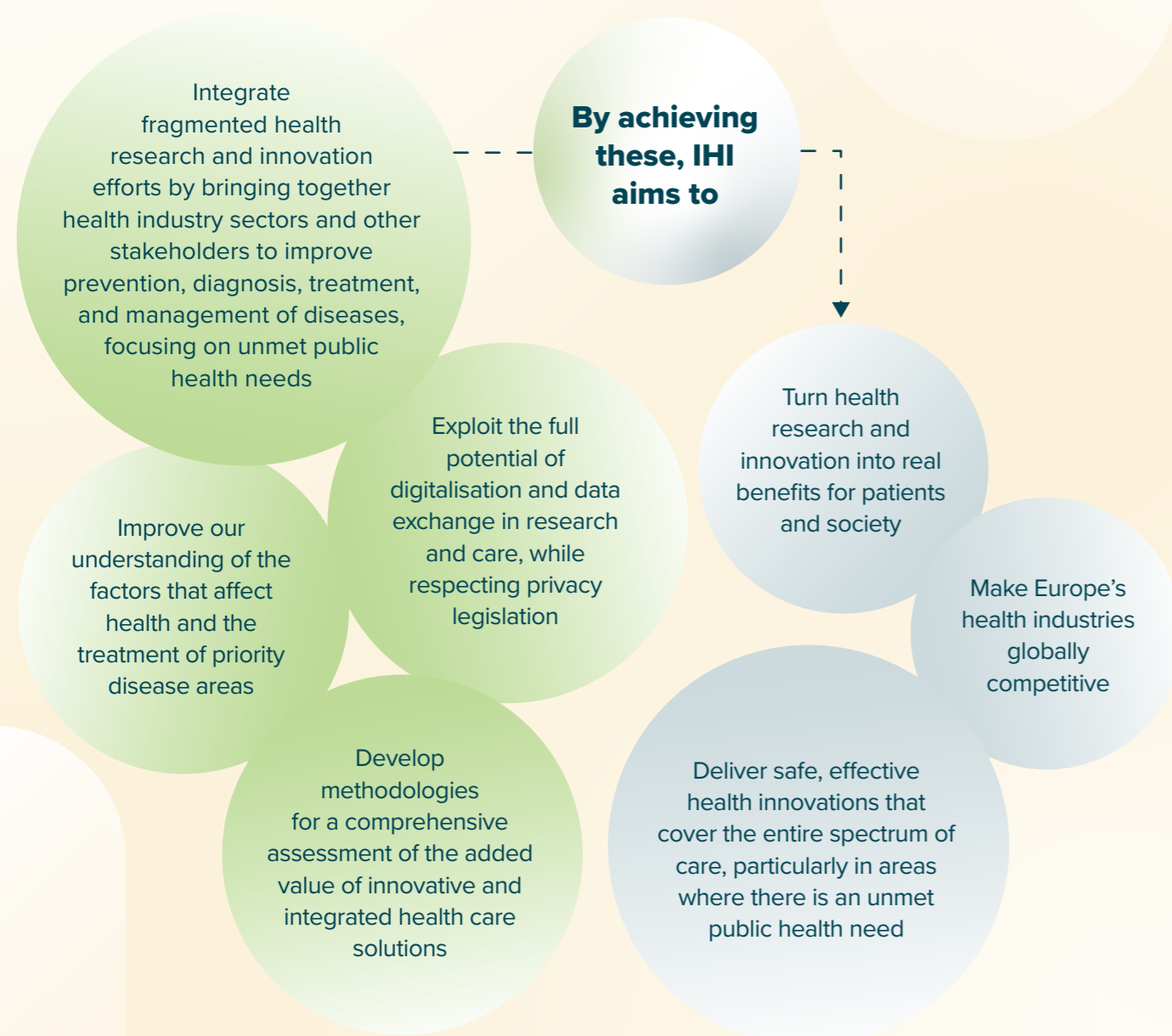
Our research focus

Under IHI, we plan to support truly cross-sectoral projects involving the biopharmaceutical, biotechnology, medical technology, and digital sectors, aiming to pioneer a more integrated approach to health research.

Our vision

We move the focus from disease care to health care, starting with disease prevention, and covering diagnostics, personalised treatments, and disease management to transform people's lives.

Our objectives



Our governance bodies

Our governance bodies work together to ensure IHI benefits from the inputs of the wider scientific and health community, the European Union Member States, and countries associated with Horizon Europe.

Governing Board

Main decision-making body

It consists of four representatives of the EU and four representatives of the European life sciences industry partners.

States Representatives Group (SRG)

Advisory body

It is a vital link between IHI and relevant national and regional research and innovation programmes. It consists of representatives of the EU Member States and countries associated with Horizon Europe.

Executive Director and Programme Office

Responsible for the daily running of IHI, including launching new calls for proposals and monitoring projects launched under IMI.

Science and Innovation Panel (SIP)

New advisory body for science-based advice

Brings together representatives of the European Commission, industry partners, SRG members, the scientific community, the wider health sector, and patients to ensure that IHI projects adequately address public health issues and the needs of end users.

Calls for proposals are open

Our objectives are at the core of our call topics. IHI calls for proposals represent an opportunity for organisations involved in healthcare and research to be part of the cross-sector PPP with multiple benefits, including:

- access to funding
- networking and partnerships
- access to knowledge, resources, and expertise
- reputation
- improving products and services
- new business and funding opportunities
- influencing and contributing to advance research

This first IHI calls for proposals represent an excellent opportunity for researchers, patients and all health stakeholders to get involved in exciting new projects that will transcend the boundaries of the different sectors active in health research and healthcare.

Dr Hugh Lavery
IHI Interim Executive Director



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