innovative health initiative

IHI 2025 In Focus

Annual Report Summary

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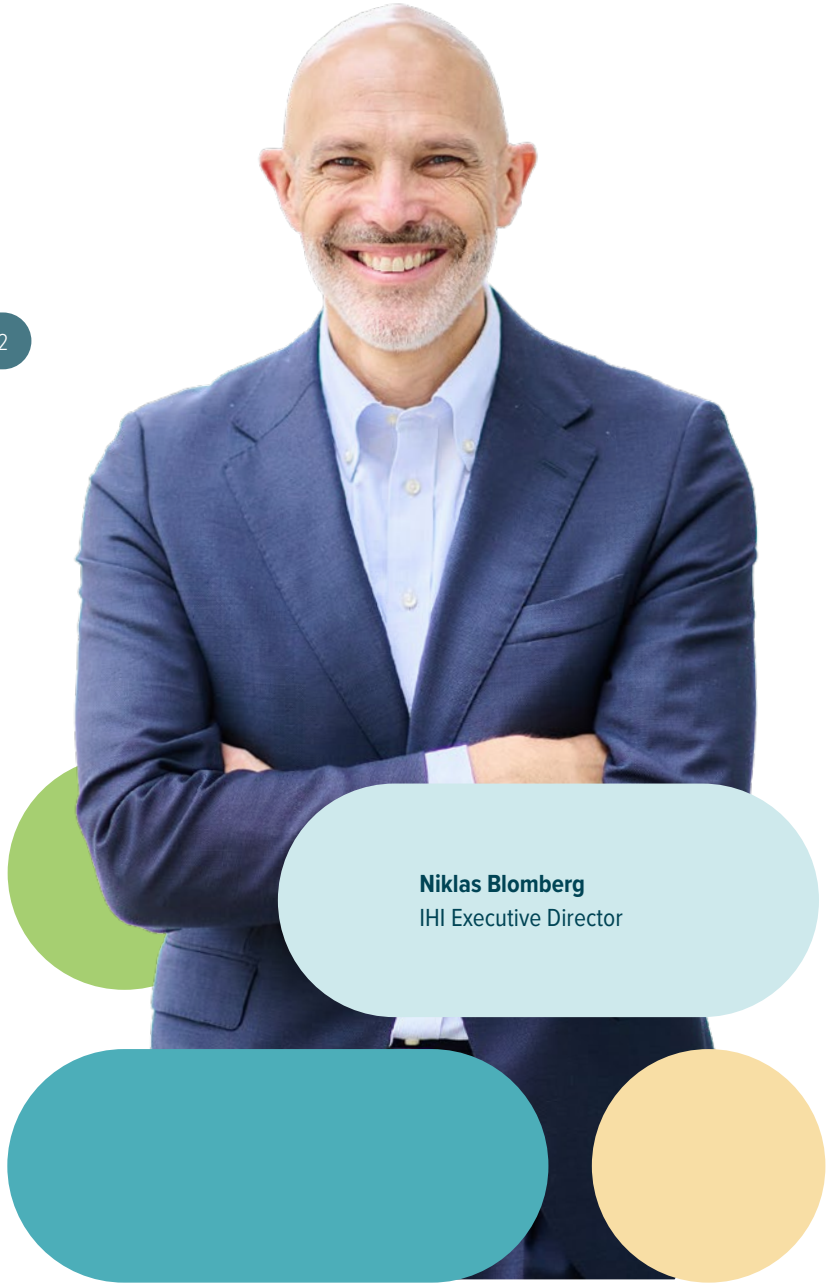


Niklas Blomberg
IHI Executive Director

1 Foreword

In 2025, the IHI portfolio hit the 50 mark, an excellent milestone to reflect on the keys to IHI's success. For me, the portfolio is a testament to IHI's strength: our ability to act as a neutral broker and create bold, transformative collaborations of diverse stakeholders.

Health innovation is a team sport. If we are serious about advancing research and transforming health care in Europe, we need to get everyone on board, from academics, big companies and SMEs to patient groups, regulators, and healthcare providers.

A key driver of our success is the nature of the industry contributions to the programme, which can be summed up as 'capabilities, not cash'. Looking at IHI and the earlier Innovative Medicines Initiative programmes, I am struck by the fact that despite the many differences between the three programmes, the breakdown of the industry contribution is remarkably consistent. This is clearly a model that works.

Personnel costs consistently account for half of the industry contribution. What makes IMI and IHI projects exciting is their ability to draw on the unique capabilities of the people working in industry. Our projects benefit from their engineering, regulatory, and innovation management skills, as well as their ability to bring innovations to patients.

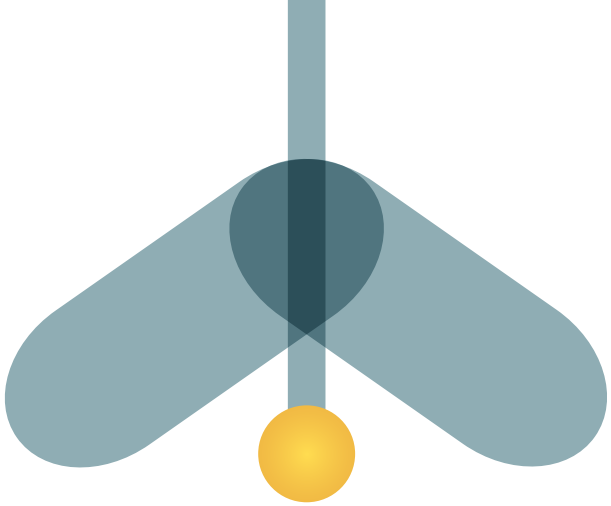
In other words, our projects consistently add value and effectively link up the European skill-base to tackle challenges that neither industry nor academia can address in isolation. Having industry experts, leading academic scientists, and health care providers and professionals working together ensures that advances in science are translated into innovative solutions for health. The close collaboration between industry, academia and other public bodies also builds skills and provides the experience of working across public and private organisations to the next generation of European scientists.

IHI is uniquely placed to address bottlenecks that slow the innovation journey. This is why we have projects on regulatory science, clinical trial design, readiness and innovation in the healthcare systems, understanding the value and impact of new diagnostics and treatments, and the manufacture of medical devices and medicines. This work is essential if we want to boost Europe's competitiveness and transform innovations into health outcomes, globally competitive companies and European jobs.

As always, this year we placed a strong focus on areas of unmet need, many of which are reflected in key EU policies. In 2025 alone, we launched four projects that will contribute to the Safe Hearts Plan, and three that will contribute to Europe's Beating Cancer Plan. More broadly, IHI projects contribute to the EU's Life Sciences Strategy, which is itself part of the wider Competitiveness Compass.

Looking to the future, public-private partnerships like IHI will have a key role to play in helping Europe's health systems adapt to the many challenges they face, from improving their ability to detect and diagnose diseases early, to getting health innovations to patients, and developing solutions to supply chain issues.

Create bold, transformative collaborations



2

IHI Highlights in 2025

In 2025, IHI embraced experimentation – trialling novel approaches and questioning the status quo. Innovation is our lifeblood, and that means exploring and trialling new approaches. With that in mind, we launched IHI's first applicant-driven call for proposals, IHI call 9. This was brand new territory for IHI – whereas usually, we outline the specific challenges to be addressed by applicants, call 9 invited potential applicants to search through IHI's strategic research and innovation agenda, identify challenges themselves and propose solutions.

The new approach was warmly welcomed by the health research community. Out of 50 proposals submitted, 39 were eligible and 13 were eventually selected for funding. Initially, the call had a budget of EUR 191 million from IHI, however, given the large number of high-quality proposals, this was increased to EUR 205 million. The call attracted a high proportion of newcomers to IHI – 38.8% of all entities in the winning proposals had never before been involved in an IHI project. The overall success of the pilot call meant that preparations could then begin for a second applicant-driven call, IHI call 12, to be launched in early 2026.

Two other calls for proposals were launched in 2025 – calls 10 and 11. Both of these were two-stage calls, covering eight topics including digital labelling for medtech, enabling and safeguarding innovation in secondary use of health data in the European Health Data Space, PFAS exposure, emissions and end-of-life management in health, and precision medicine for stratification of brain dysfunction, understanding how infections foster and induce non-communicable diseases, AI-powered signal detection in pharmacovigilance, accelerating cell therapy for type 1 diabetes and establishing ortho- and cardiology ambulatory surgical centres for Europe.

Philanthropic organisations continue to be valued partners in IHI, bringing a depth of expertise in specific areas and access to established active communities, and this was evident in call 11, with philanthropic organisations contributing significantly to the call topics on mental health, type 1 diabetes and the interplay between infectious and chronic diseases.

IHI's portfolio hit 52 projects in 2025. Between them, the new projects address all five specific objectives in the IHI Strategic Research and Innovation Agenda and cover the entire research spectrum, from early-stage drug discovery right through to clinical trial design and improvements to healthcare. They also contribute to the EU's competitiveness and to key EU policies including the Life

Sciences Strategy, European Health Data Space, AI Act, Beating Cancer Plan, and the Safe Hearts Plan.

IHI and IMI projects continue to punch well above their weight. IMI projects, which are at a more advanced stage, have completed 58 procedures for regulatory acceptance of developed assets, and 80% of IMI projects have made their outputs – including databases, biobanks and clinical trial networks – available to the wider community, serving to boost the continued development and competitiveness of the entire health sector in Europe. IHI projects, although at earlier stages, are also performing well, with 12 projects already contributing to new or improved clinical guidelines while 17 report tools and frameworks that can enable better access to and sharing of data.

Our newer, IHI JU funded projects are also on track towards a strong publication record, with **233 publications produced to date**. The impact of these publications is more than double the world average with a mean field normalised citation impact of 2.43. More than one third of papers (38.9%) are in the top 10% most cited, and there are 20 countries which have 10 or more publications funded by IHI JU.

IMI projects continue to deliver results that **demonstrate the public-private partnership's ability to support science that is both excellent and impactful**. Scientists from EUbOPEN identified a key player controlling the production of a building block of DNA – a finding that explains why some cancers are resistant to certain treatments. The work is published in the journal Science. The COMBINE project trained an AI model to improve the selection of compounds that can fight multi-drug resistant bacteria, and made the code open and accessible to others. EHDEN published the largest study to date on the global effect of drug shortages.

The study was made possible thanks to EHDEN's work on harmonising more than 350 million real-world health data records.

IMI and IHI projects are improving how clinical trials are run, which in turn will **boost Europe's attractiveness as a location for clinical trials and strengthen Europe's competitiveness in clinical research**. Over the years, IMI projects have delivered tools and resources to improve clinical trials in a variety of ways. For example, diabetes project INNODIA's adaptive clinical trial protocol allowed the project to deliver results in just 4 years; it would have taken 10 years using a classical trial design. Trials@Home generated recommendations on how to preserve scientific robustness when carrying out decentralised clinical trials and pharmaceutical companies are currently trialling a framework designed by IMI project FACILITATE to return patient data to clinical trial participants.

Although still in their early stages, **IHI projects are also beginning to bear fruit**. iCARE4CVD has delivered an innovative new AI-based tool to harmonise data in the cardiovascular disease field, a key step towards advancing more personalised care, while a PREDICTOM study of electroencephalogram (EEG) data revealed a slowdown in communication between different brain regions from the very earliest stages of Alzheimer's disease. PREDICTOM's discovery suggests that EEGs could help doctors spot signs of Alzheimer's earlier than traditional tests and examinations.

3

IHI projects continue to take flight

IHI portfolio hits the 50 mark, showing the strength of the partnership. Learn about the new IHI projects that got underway in 2025, and their goals for the future.

2025 marked the addition of 22 new projects to IHI's portfolio, raising the total number of IHI projects to 52. These projects cover the entire research spectrum, from early-stage drug discovery right through to clinical trial design and improvements to healthcare. They also contribute to key EU policies and priorities including the Life Sciences Strategy, European Health Data Space, AI Act, Beating Cancer Plan and the Safe Hearts Plan.

Contributing to the EU's Beating Cancer Plan

> In 2020, 2.7 million people in the EU were diagnosed with cancer, and cases are set to rise by a quarter by 2035. IHI's growing portfolio of cancer projects address all four pillars of the EU's Beating Cancer Plan, which focus on prevention, early detection, access to diagnosis and treatment, and improving the quality of life of patients and survivors.

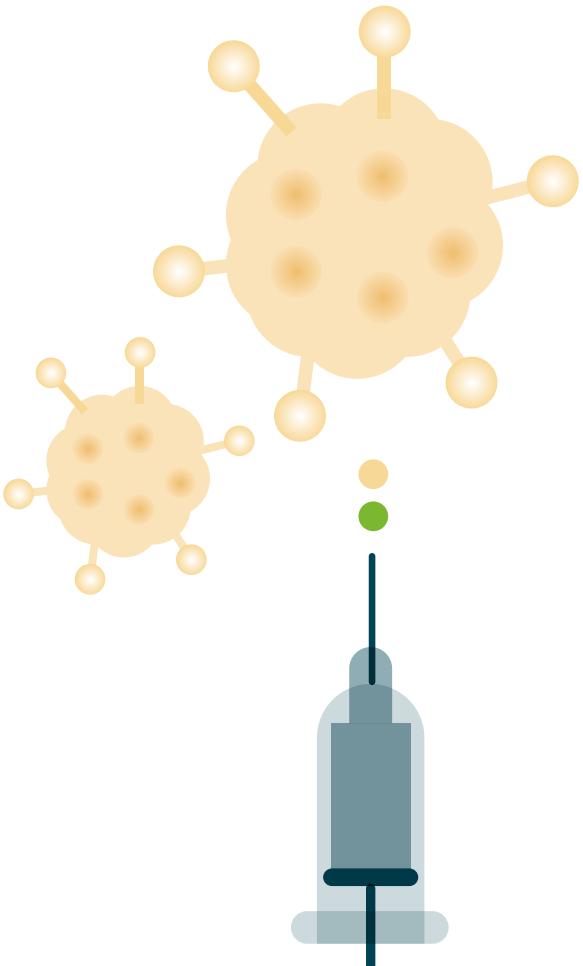
When someone is diagnosed with cancer, it is very hard to predict how their disease will progress, and which treatments are most likely to be effective. We urgently need new, clinically-validated biomarkers to provide patients with better, more personalised care, and make health systems more efficient.

BRECISE aims to deliver a framework and platform to accelerate the clinical validation of cancer biomarkers and related technologies, with a focus on prostate and bladder cancers. As a core outcome, four novel biomarkers will be tested and validated through the framework; these have the potential to dramatically transform and improve the care of people living with prostate or bladder cancer.

CAR-T (chimeric antigen receptor T) therapy is a cutting-edge cancer treatment that involves transforming a patient's own immune cells into weapons capable of identifying and destroying cancer cells. Few sites can carry out the long and complex CAR-T manufacture process, and

this limits access to the treatment. **EASYGEN** aims to revolutionise CAR-T cell manufacture by developing an automated, modular, point-of-care cell and gene therapy manufacturing platform that would allow hospitals to generate CAR-T cells on-site. The EASYGEN device would therefore make these promising treatments accessible to a much larger number of patients.

Growing numbers of cancer patients now benefit from an approach called interventional oncology (IO), in which miniaturised instruments are inserted into the patient's body via minimally invasive access routes. The miniaturised instruments are guided to the tumour with the help of imaging techniques; once there, the treatment can be applied directly and precisely to the tumour. The aim of **PreciseOnco** is to boost the interventional oncology field by integrating cutting-edge spectral imaging, motion correction technologies and robotic assistance to enhance the precision and safety of IO procedures.



Supporting the EU Safe Hearts Plan

> Cardiovascular diseases (CVD) are a leading cause of death in the EU. IHI boasts an extensive portfolio of projects addressing different CVDs; between them, they are contributing to the EU's new Safe Hearts Plan, for example by improving prevention, care and monitoring; by integrating new technologies into care; and by addressing inequalities in care.

Today, there is a lot of variation in the way CVD is diagnosed and treated, and this means that many patients may not be getting optimal care. The aim of **EuroHeartPath** is to transform the care of people with CVD in Europe by improving the entire care pathway, from early detection and diagnosis to monitoring, treatment and prevention, and by integrating cutting-edge innovations and solutions. They will focus on four diseases: heart failure, atrial fibrillation, ventricular fibrillation, and coronary disease. Ultimately, by identifying and demonstrating best practice for integrating innovations into care pathways, EuroHeartPath will trigger a paradigm shift in the management of CVDs, with benefits for patients, health systems and society alike.

Today, there are critical gaps in the early detection, diagnosis and treatment of CVDs. Innovative technologies are being developed, but managing their smooth integration into care pathways is far from easy. The aim of **GRACE** is to create a framework to improve the care pathways of people with CVD, from diagnosis to treatment and long-term management. At the healthcare system level, the framework will facilitate the seamless integration of new technologies into care pathways. At the individual level, the framework will provide tools for patients and healthcare workers to improve diagnosis and care.

Much of the EU population lives in urban areas, where the risks of developing CVD are heightened by factors such as poverty, lack of access to healthcare, and lifestyle issues. The aim of **Cities@Heart** is to deliver strategies that will help to reduce the burden of CVD in cities, close the health inequality gap, and ensure that every citizen can be reached regardless of gender, poverty, disability, background or culture. The team will focus on the four key drivers of CVD: obesity, high blood pressure, high cholesterol, and diabetes.

Atrial fibrillation (AF) describes an irregular heart rhythm that can cause severe symptoms including palpitations, fatigue, chest pain, shortness of breath, and difficulties exercising. Today, AF is diagnosed in a binary fashion – you either have it or you don't – although we know that the burden of the disease (and its impact) varies immensely from one patient to another. **AF-B-STEP** aims to define and quantify AF burden and its impact on health outcomes, and to set out standards for AF burden reporting by cardiac implanted electronics devices and consumer wearables. The hope is that this will trigger a step change in the diagnosis and care of people living with AF.

Addressing major unmet health needs

> IHI projects address diseases which place a heavy burden on patients / society due to their severity or the number of people affected; and the economic impact of the disease for patients/ society. In addition to projects on cancer and CVDs, in 2025 IHI launched new projects focusing on diseases which affect millions of Europeans, including Alzheimer's disease, Crohn's disease, osteoarthritis, and infectious diseases.

Recent years have seen the development of treatments (or 'disease-modifying therapies', or DMTs) capable of slowing the progress of Alzheimer's disease for certain groups of patients. However, getting the right treatments to the right patients remains difficult. The goal of **ACCESS-AD** is to deliver tools and strategies that will help European healthcare systems to identify solutions that will enhance the care of people living with Alzheimer's disease, from diagnostic and monitoring tools to lifestyle interventions and new DMTs, and deploy them at the scale needed.

Crohn's disease is a type of inflammatory bowel disease (IBD) that causes diarrhoea, stomach pain and weight loss as the immune system attacks the gastrointestinal tissues. Symptoms often start when patients are young, and by the time they are diagnosed, around a third of patients already have substantial damage to their bowels. Enter **INTERCEPT**, which aims to transform Crohn's disease from an incurable condition to one that could be managed and even potentially prevented. INTERCEPT plans to verify and clinically validate a panel of biomarkers and build a blood risk score capable of identifying people with a high risk of developing Crohn's disease within the following five years.

Osteoarthritis (OA) occurs when the cartilage and other tissues in our joints deteriorate, resulting in pain, stiffness, and disability. There is currently no cure, and efforts to develop treatments are hampered by several factors including the heterogeneous nature of the disease, the slow progression of the disease, our limited understanding of the underlying causes of the disease, and a lack of adequate tools to measure meaningful changes in the disease in the context of a clinical trial. The aim of **PROBE** is to use a big data approach, powered by cutting-edge artificial intelligence (AI) and machine learning (ML), to advance the care of people living with knee osteoarthritis.

Millions of people worldwide live with persistent viral infections such as HIV (human immunodeficiency virus) and hepatitis. Meanwhile people whose immune systems are weakened following stem cell transplants are also highly vulnerable to serious viral infections. Advances in treatments mean many people are able to keep the infection under control for years. However, the treatments do not work for everyone, and viruses can develop resistance. The aim of **VIROMARKERS** is to develop biomarkers that would revolutionise the care of people living with HIV and hepatitis D, as well as stem cell transplant patients at risk of cytomegalovirus (CMV) infection or reactivation.

We urgently need innovative treatments for drug-resistant infections, but developing new antimicrobials is incredibly difficult; just 3 new classes of antibiotics were brought to the market in the last 30 years. As its name suggests, **END2AMR** has set itself the ambitious goal of reinvigorating the antimicrobial drug development pipeline by delivering innovative approaches to treating resistant infections. The project will focus on both new treatment modalities and new drug delivery technologies.

Using computer power to speed up drug discovery

> IHI's SRIA includes an objective on improving our understanding of the factors that affect our health and the treatment of disease.

The earliest stages of drug discovery entail finding a "chemical probe" – a small molecule that can bind to a protein and change how that protein behaves. Today, finding chemical probes usually involves testing large chemical libraries in the laboratory to identify "hits", but this approach is slow and costly, and many human proteins still lack a probe. **LIGAND-AI** aims to draw on artificial intelligence (AI) and machine learning (ML) to hunt for promising hits, reducing the time and cost needed to explore proteins that currently have no chemical probes.

Improving clinical trials and advancing regulatory science and decision-making

> IHI aims to have a tangible impact on healthcare, and this means that many projects focus on improving clinical trials and advancing regulatory science, for example.

Clinical trials are seen as the gold standard for evaluating the safety, efficacy, and cost-effectiveness of many medical products including medicines, medical devices and diagnostic tests. However, setting up and running a clinical trial is far from easy. The aim of **GENz-trials** is to harness the power of data science and artificial intelligence (AI) to address these challenges and transform the way clinical trials are designed, carried out, and evaluated.

Real-world data and evidence (RWD/RWE) have immense potential to contribute to the development and evaluation of medicines, medical devices, and drug-device combinations. Guidance on how this could work exists, but is high level, not evidence-based, and implementing it in practice is far from easy. The aim of **GREG** is to turn this situation around by generating guidance and tools to advance the use of RWE in the development and evaluation of medicines, medical devices and drug-device combinations, and to support regulatory and health technology assessment (HTA) decision-making.

Rapid advances in research are delivering healthcare innovations and new methodologies that simply don't fit in with current regulatory frameworks. 'Regulatory sandboxes' are flexible spaces where innovators and regulators can collaborate and explore the best way to regulate a new technology in such a way that end users are protected, while innovations are not held back. They are already used in sectors such as finance, but are still in their infancy in the health field. The goal of **BRIDGE** is to develop a comprehensive set of recommendations for designing and implementing regulatory sandboxes in practice for health, including flexible, fit-for-purpose methodologies.

There are now more ways than ever to gather different types of input from patients as part of health research, innovation, and decision-making. Because these different measures are complementary, the most accurate insights into the benefits of a new treatment for patients will likely come from combining them, but doing this in practice is far from easy. Enter **UNIFIED**, which aims to generate a robust, unified framework for obtaining a holistic view of a health intervention's benefits to patients by integrating information from patient preference information (PPI), clinical outcome assessments (COAs), and digital health technologies (DHTs).

Innovations for healthcare improvement and readiness

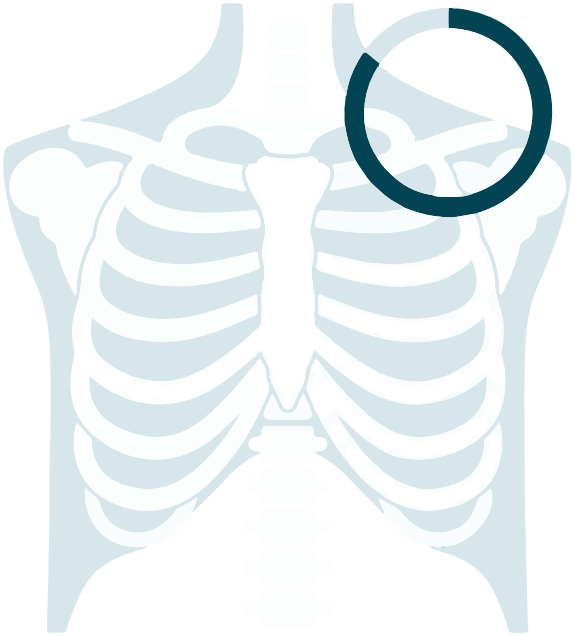
> Delivering practical improvements in healthcare that will benefit healthcare workers and patients alike is a major priority for IHI. This is reflected in the launch of projects designed to improve healthcare in diverse ways, ranging from developing support tools to ease clinicians' workloads, to novel surgical techniques.

In interventional radiology (IR), specialists use imaging technologies to guide miniature devices through a patient's body and deliver the treatment where it is needed. However, IR is highly complex, and specialists' workloads are high. **SHERPA** aims to ease the workload of interventional radiologists by providing them with assistive technologies, powered by artificial intelligence (AI). By fulfilling the role of a trusted companion (or a sherpa), these technologies will support decision-making, accelerate learning and take care of repetitive, time-consuming tasks. As a result, the IR specialist will have more time and energy to focus on the intervention itself and on their interactions with the patient.

While minimally-invasive techniques like IR are relatively common in some fields, neurosurgery still typically entails making large openings in the skull. Furthermore, attempts to integrate imaging technology into neurosurgery procedures are hampered by costs and logistics. As a result, patients are still undergoing operations where the risk of complications is high. **SEISMIC** aims to improve patient care by working out how to seamlessly integrate medical imaging technologies into minimally invasive neurosurgery techniques.

Thanks to advances in research, many chronic diseases can now be managed with treatment. However, studies show that around half of all people living with a chronic disease do not take their prescribed treatment for more than a year. The aim of **CarePath** is to deliver a 'plug and play' toolbox with resources to boost both adherence (i.e. the extent to which patients take their treatment as prescribed in terms of timing, dosage and frequency) and persistence (i.e. the length of time between the start of treatment and the last dose before stopping treatment). CarePath focuses on three common chronic conditions (obesity, type 2 diabetes, and cardiovascular diseases) and on both primary and secondary care settings.

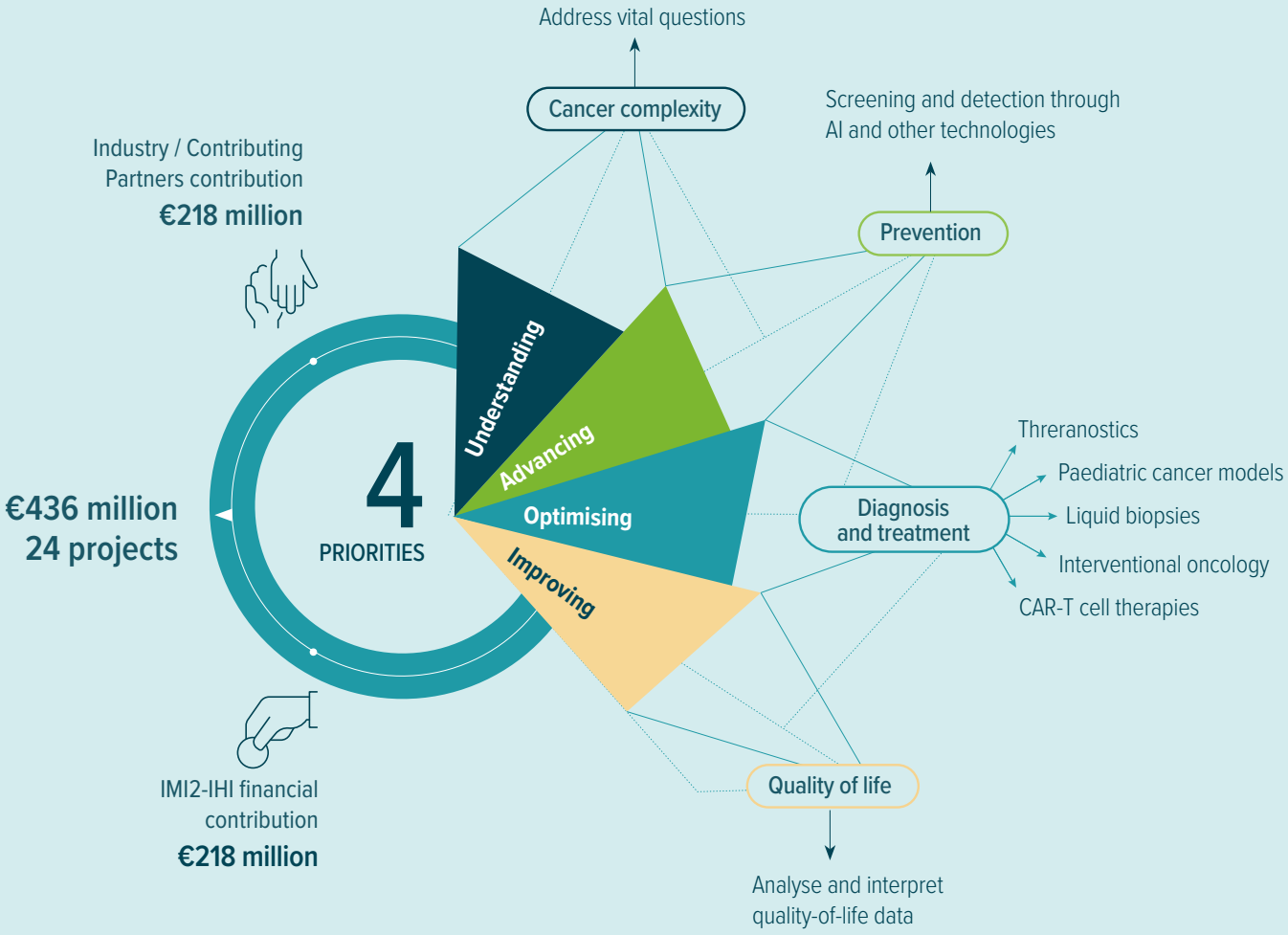
For most chronic conditions, treatment guidelines detail what medicines patients should receive and when. However, it is increasingly difficult for doctors to keep up to date with all the guidelines, and studies show that just a fraction of chronic disease patients are treated according to the guidelines for their condition. The ultimate goal of **GUIDE-AI** is to harness the power of generative artificial intelligence (AI) to boost the proportion of chronically ill patients receiving the treatments as set out in the guidelines.



Long-term health problems are responsible for two-thirds of hospital bed occupancy in Europe. But what if we could shorten or even avoid some hospitalisations entirely by moving the patient's care from the hospital to the home? **HospitalAtHome** aims to create a model where patients can receive personalised, hospital-level treatment at home, thanks to intelligent, connected systems and devices that ensure the safety, quality and continuity of care. The successful completion of the project could trigger a major transformation in health care delivery.

IHI AND IMI SUPPORTING CANCER RESEARCH AT SCALE

IHI and IMI research delivers on the EU Cancer Plan's four priorities and covers the entire continuum of care.



1

Understanding the complexity of cancer

IHI supports basic research and scientific excellence.

Projects

Our projects address vital questions such as why some patients respond to treatments and others don't, why some patients' disease spreads, or what are the underlying mechanisms driving cancer drug resistance.

Example

PERSIST-SEQ is exploring why a significant percentage of patients relapse after cancer treatment. In particular, the project is focusing on understanding how DTPs – small rare cells that can re-start tumour growth – work, so that they can be targeted in future cancer therapies.

2

Advancing prevention

IHI is taking the lead in prevention through diagnostics and data.

Projects

Our projects are using AI and other technologies to boost minimally invasive cancer screening and detection.

Example

Over half of all lung cancer patients are diagnosed when the disease has already advanced. **IDERHA** is building one of the first pan-European health data spaces, linking and analysing lung cancer data. Using that data, the project will seek to identify people that are at a high risk of developing lung cancer. If caught early enough, chances of survival are higher.

3

Optimising cancer diagnosis and treatment

IHI is contributing innovative research to the five pillars of cancer treatment (i. e. surgery, radiotherapy, chemotherapy, molecularly targeted therapy and immunotherapy), with the aim of facilitating patient access to the latest, most personalised, minimally invasive treatments for their conditions, with minimal secondary effects.

Projects

Our projects are establishing Europe as a leader in theranostics, developing better models to cure paediatric cancers, improving liquid biopsies, advancing the use of interventional oncology, and removing barriers so that CAR-T cell therapies can be delivered faster to more patients.

Examples

Improving liquid biopsies:

- **CANCER-ID** examined existing technologies for enriching, isolating and analysing three blood-based biomarkers. The project benchmarked the technologies, and then developed and validated protocols for how they should be used in laboratories in a standardised way.
- **GUIDE.MRD** are examining whether liquid biopsies could be used to identify small fragments of cancer cells that may be circulating in the blood, focusing on lung, pancreatic and colon cancers.

Better models to cure paediatric cancers:

- **ITCC-P4** developed the world's largest repertoire of freshly patient-derived models of paediatric tumours, consisting of over 400 models covering more than 20 common childhood cancers.

Leading the way in theranostics:

- **Accelerate.EU** is developing a novel radiotheranostic pair that emits alpha particles, which may be particularly effective against aggressive cancers like pancreatic, breast and brain cancers.
- **ILLUMINATE** is investigating why the theranostic treatment Lutetium-177-PSMA doesn't work for 30% of patients, and will optimise diagnostic tools so that patients who will not benefit from this treatment can be identified before trying it.

Advancing interventional oncology:

- Interventional oncology uses imaging techniques to guide miniaturised instruments through the body to attack tumours. **IMAGIO** is carrying out two clinical trials investigating whether a new hybrid 'C-arm' treatment could reduce the amount of time it takes to treat patients with liver cancer from two weeks to two hours.

Removing barriers to CAR-T cell therapies:

- CAR-T cells are engineered cells that are designed specifically to seek out and destroy cancer cells, and the therapy has proven effective for certain cancers.
- **T2Evolve** is fostering an innovation ecosystem where CAR-T cell therapy development can be accelerated in Europe, publishing recommendations on regulatory processes and providing guidance on how to integrate this treatment into European healthcare systems.
- **EASYGen** aims to dramatically reduce the manufacturing time of CAR-T cells from six weeks to 24 hours.

4

Improving quality of life for cancer patients, survivors and their families

IHI is investing in research that not only aims to find cures, but also endeavours to improve daily life for patients.

Projects

Our projects are developing recommendations on how to analyse and interpret quality-of-life data in clinical settings.

Examples

Patient-reported outcomes (PROs) provide important information on how patients feel or function in their daily lives. **SISAQOL-IMI** is developing a set of recommendations to ensure high study quality and a better comparability of PROs and quality of life measures across clinical trials.

When patients undergo cancer treatment, sometimes the medicines that made them better can have unwanted side effects on the heart. **COMPASS** aims to make the prediction of cardiotoxicity risk better so that heart problems can be identified sooner, improving patients' quality of life.

4

IHI Calls

IHI's call 8 closed in 2025, while calls 9, 10 and 11 were launched during the year.

Call 9

Call 9 was a pilot, applicant-driven one-stage call. Rather than directly proposing the challenges that applicants should seek to address, call 9 invited applicants to search through the strategic research and innovation agenda and propose solutions. The call was popular, with 50 proposals submitted. From those, 39 were eligible. The call was comprised of five topics, one topic per each of IHI's specific objectives.

Topic 1 (SO1):
Boosting innovation for a better understanding of the determinants of health

Topic 2 (SO2):
Boosting innovation through better integration of fragmented health R&I efforts

Topic 3 (SO3):
Boosting innovation for people centred integrated healthcare solutions

Topic 4 (SO4):
Boosting innovation through exploitation of digitalisation and data exchange in healthcare

Topic 5 (SO5):
Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions

The deadline for proposals was 29 April 2025.

50
proposals were submitted to this call, and

13
were selected to become IHI projects.

Applicants in eligible proposals

8.61%
are **IHI contributing partners**.

31.16%
of the participants are **IHI industry partners**

	Charity / Foundation	Payer	Health Technology Assessment body (HTA)	Healthcare	Large company	Mid-cap	Nongovernmental organisation (NGO)	Not declared	Other	Patient / citizen	Public authority	Regulator	Research / education	SME	TOTAL BY COUNTRY
Albania				1			1								2
Australia													1		1
Austria				1	2								8	3	14
Belgium	3			3	11	1	4		1	5			10	13	51
Brazil													1		1
Bulgaria														2	2
Canada				3	1								4	6	14
Colombia	1			2	1										4
Croatia					1										1
Cyprus				1						1			1	1	4
Czechia				2									1	2	5
Denmark				5	7							1	8	9	30
Estonia													2	6	8
Finland				1	5						1		1	4	12
France	2		1	13	23	1				1	2	1	16	15	75
Germany		1		10	44	4	1			1		1	37	24	123
Greece				7	6	1				1			19	7	41
Hungary					2								1	4	7
India					3					1					4
Ireland				1	1				2	3				2	9
Israel				1	4								3	3	11
Italy	1		1	10	6	1		1		1			15	7	43
Korea (Republic of)		1			1								1	1	4
Latvia				1									1		2
Lithuania													1		1
Luxembourg					1					2			1	1	5
Nepal													1		1
Netherlands	5			15	34	3	1			3	1	2	41	25	130
Norway				2	2								2	1	7
Poland				1									4	2	7
Portugal				2	1			1		1			3	5	13
Romania				1	1										2
Serbia													3		3
Slovakia					2										2
Slovenia					1					1			3		5
South Africa													2		2
Spain	2			11	20	1	1	1	1	3	6	1	26	15	88
Sweden				4	3	3							3	6	19
Switzerland				3	19		1						10	9	42
Turkey				2	3								3	2	10
Ukraine					1								1	2	4
United Kingdom	2		1	4	17	6	1			3			38	25	97
United States	1				19	4			1				2	1	28
TOTAL BY ORG. TYPE	**17**	**2**	**3**	**107**	**242**	**25**	**10**	**3**	**5**	**27**	**10**	**6**	**274**	**203**	**934**

Call 10 (two-stage)

IHI call 10 was a two-stage call with topics on digital labelling of medical technologies; the European Health Data Space; and per- and polyfluoroalkyl substances (PFAS) in the healthcare sector.

Topic 1:
Digital label: one source of comprehensive information for medical technology products

Topic 2:
Safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

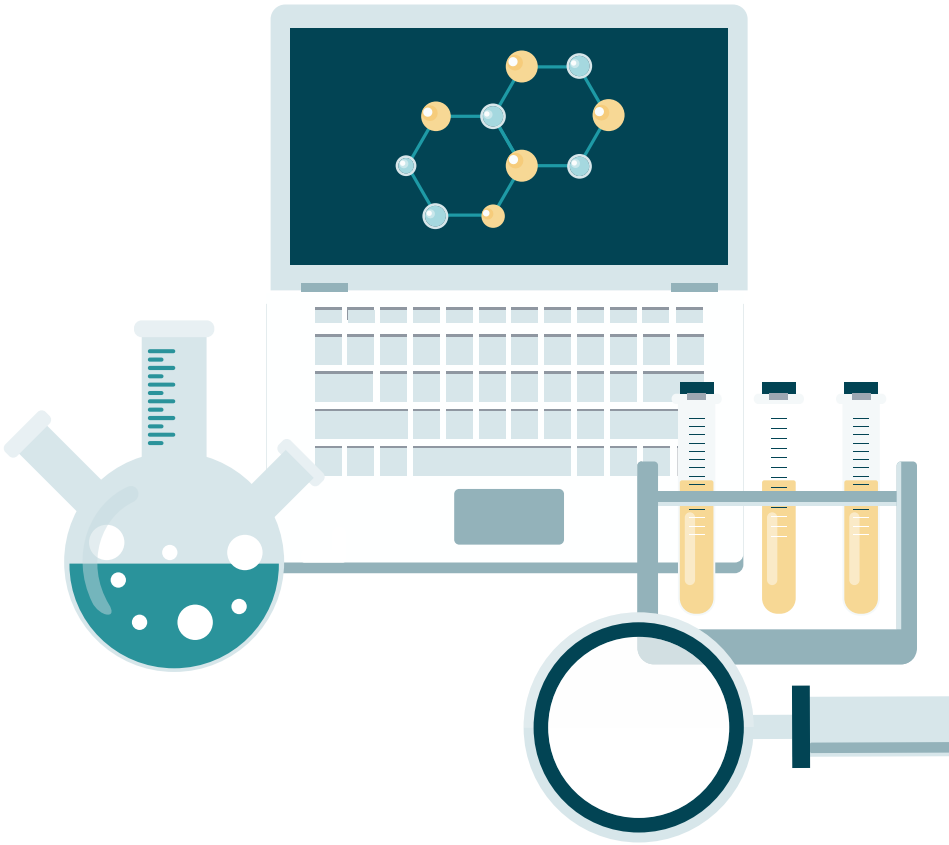
Topic 3:
Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

The deadline for short proposals was 23 April 2025 while the deadline for full proposals was 14 October 2025.

22
short proposals were submitted for this call.

The short proposals were then evaluated by independent experts and the top ranked consortium for each topic was invited to join up with the industry consortium identified in the call text and submit a full proposal.

3
full proposals were then selected to become IHI projects.



Applicants in eligible short proposals

	Charity / Foundation	Health Technology Assessment body (HTA)	Healthcare	Large company	Mid-cap	Nongovernmental organisation (NGO)	Notified Body	Other	Patient / citizen	Public authority	Regulator	Research / education	SME	TOTAL BY COUNTRY
Austria			1							1		7	2	11
Belgium	4					7	2	2	1	1		13	7	37
Bulgaria												5	2	7
Canada												1		1
Cyprus													2	2
Czechia										1				1
Denmark			1									2	1	4
Estonia													3	3
Finland			2							1		6	2	11
France								1	1	1		5	4	12
Germany			3	2	1	1				1		9	14	31
Greece					1	2						8	4	15
Hungary													1	1
Ireland				2								1	2	5
Israel			1								1			2
Italy			5			1		2		1		8	8	25
Luxembourg								1				3	1	5
Netherlands	3		3			1		1		1		9	9	27
Norway										1		3		4
Poland	1											1	1	3
Portugal												4	3	7
Romania								1						1
Slovenia										1				1
Spain	2	1	4	2		1		2	1	3		17	11	44
Sweden			1			2						3	1	7
Switzerland	1		1			5					1	5	4	17
Turkey													1	1
United Kingdom	1			1	1	1				1		9	10	24
TOTAL BY ORG. TYPE	12	1	22	7	3	21	2	10	3	14	2	119	93	309

Call 11 (two-stage)

IHI call 11 was a two-stage call with topics on brain dysfunction, the link between infections and non-communicable diseases, pharmacovigilance, type 1 diabetes, and ambulatory surgical centres.

Topic 1:
Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction

Topic 2:
Understanding how infections foster and induce non-communicable diseases

Topic 3:
AI-powered signal detection in pharmacovigilance

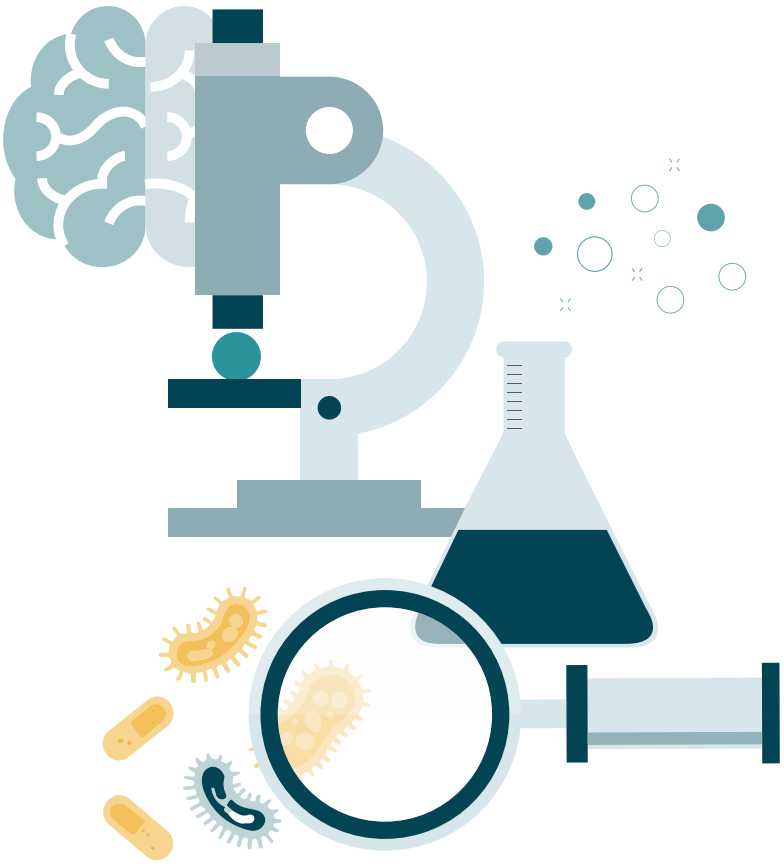
Topic 4:
Leveraging Europe's expertise to accelerate cell therapy for type 1 diabetes

Topic 5:
Establishing ortho and cardiology ambulatory surgical centres in Europe

The deadline for short proposals was 9 October 2025 while the deadline for full proposals was 29 April 2026.

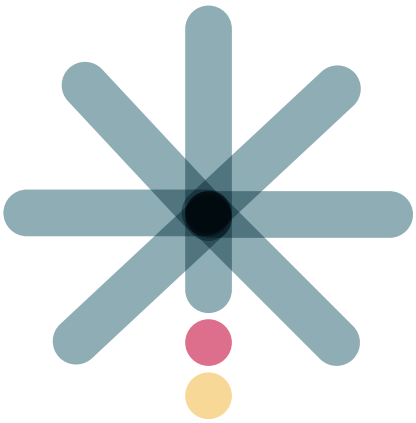
41

proposals were received in response to this call.



Applicants in eligible short proposals

	Charity / Foundation	Payer	Health Technology Assessment body (HTA)	Healthcare	Large company	Mid-cap	Nongovernmental organisation (NGO)	Not Declared	Other	Patient / citizen	Public authority	Regulator	Research / education	SME	TOTAL BY COUNTRY
Australia													2		2
Austria				3									6	1	10
Belgium	2			1		1	4		1	8			14	11	42
Bosnia and Herzegovina				1											1
Canada			2												2
Croatia												1	3	1	5
Cyprus													2	1	3
Czechia													1	1	2
Denmark				4	1					1	1	1	16		24
Estonia													5	1	6
Finland				2							2		16	3	23
France				1		1	1			2			15	2	22
Georgia				1											1
Germany				1		1	1					3	56	11	73
Greece		1		2			3				2		15	4	27
Guatemala							1								1
Hungary													1	1	2
Iceland													2		2
Ireland							2			7		1	2		12
Israel		1													1
Italy	1		1	6									27	7	42
Latvia													1		1
Lithuania													1	1	2
Luxembourg										5			2	2	9
Malta														1	1
Netherlands	4			6			2			1		3	38	13	67
Norway				4									11	1	16
Poland				1									3	2	6
Portugal				1									10	1	12
Romania								1					2	2	5
Serbia				1									1	1	3
Slovenia				1			3						4		8
Spain	2		1	9						3	2	1	31	18	67
Sweden	1			4								4	16	2	27
Switzerland													2		2
Turkey				1									3		4
Ukraine													2		2
United Kingdom	1		1	1									18	6	27
United States				1									2		3
TOTAL BY ORG. TYPE	11	2	5	52	1	3	17	1	1	27	7	14	330	94	565



5

2025 research highlights from across IHI and IMI's portfolio

Delivering impactful results to enhance EU competitiveness and address unmet health needs

The IHI Programme Office continues to manage the large number of projects launched under the IMI1 and IMI2 programmes. Here's a selection of those outputs – between them, they demonstrate how our projects are delivering results that address major unmet health needs, including infectious diseases such as tuberculosis (TB), metabolic disorders such as diabetes, and more. The projects are continuing to deliver knowledge and resources that can be used by the wider research community. In addition, the many results in fields such as health data and medical devices demonstrate how IMI paved the way for IHI by launching projects with a strong cross-sectoral element. You'll also see a number of results from projects that actually ended several years ago. The fact that the consortia are still collaborating and publishing new papers is testament to the way IMI projects are creating long-lasting, productive networks.

IMI projects are boosting Europe's attractiveness as a location for clinical trials

Clinical research is key to health and wealth, but Europe is losing ground to other regions. The Draghi report recognised the importance of boosting Europe's attractiveness as a location for clinical research. Over the years, IMI projects have delivered tools and resources to improve clinical trials in a variety of ways.

Faster, innovative clinical trials for type 1 diabetes treatments proven possible by INNODIA

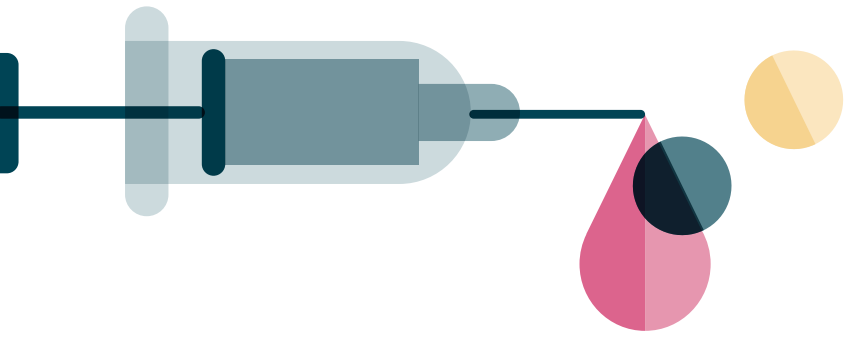
Some years ago, the INNODIA project delivered a master protocol designed to facilitate and speed up the launch of clinical trials using drugs designed to arrest type 1 diabetes in those who have been diagnosed recently. The project then used the protocol to run clinical trials and the results of one trial were released in 2025. The aim of the trial was to test different dosages of a drug called anti-thymocyte globulin (ATG) on children and young adults with new onset clinical type 1 diabetes. If the team had used a classical trial design (testing one dose versus a placebo), it would have taken them 10 years to get a result. Thanks to the adaptive trial design, the team were able to test four doses and a placebo at once, meaning it took just four years to get a result, enhancing Europe's competitiveness.

Read more

Industry embraces return of patient data framework for clinical trials

Every patient taking part in a clinical trial has the right to request their own data back, under the EU Clinical Trials Regulation. However, many patients don't know that they can do this, and receiving data back is not straightforward. IMI project FACILITATE developed a white paper setting out a framework for returning patients' data, in a way that builds trust and fosters collaboration, and benefits the patient without hindering the trials. The project championed a proactive approach, advising sponsors to proactively offer to return patient data via a process developed by the project. GSK and Sanofi have launched pilots trialling how the framework works in practice within clinical trials, while several other companies have expressed interest in using the framework in upcoming trials.

Read more



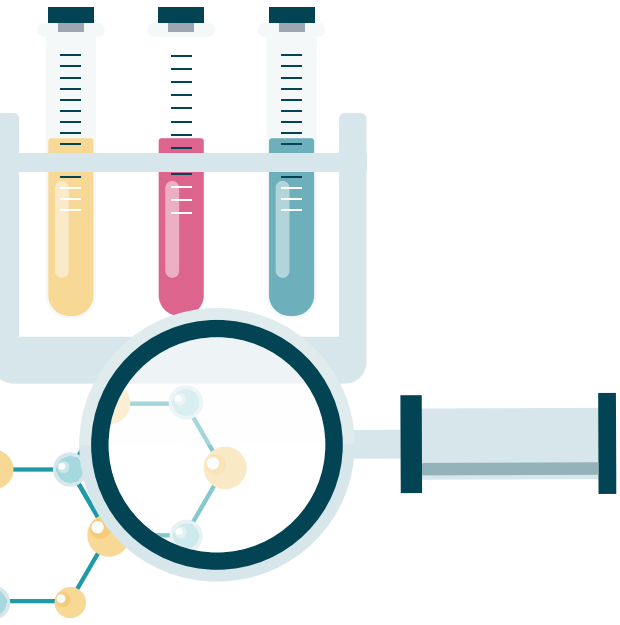
Trials@Home delivers recommendations on decentralised clinical trials

Decentralising clinical trials, and allowing people to take part in clinical research from the comfort of their homes, has a lot of advantages for both patients and those running trials. However, decentralisation is not as simple as it sounds. IMI project Trials@Home explored how decentralisation could be achieved and what research needed to be carried out.

By the end of the project, Trials@Home had compiled a robust set of recommendations to help clinical researchers design trials that participants can engage in from their own homes. These include engaging stakeholders during trial design; testing and selecting technologies early; offering responsive support to trial participants; and ensuring digital infrastructures are fully secure.

Although the project has come to a close, the work of Trials@Home will continue via the Trials@Home Interest Network.

Read more



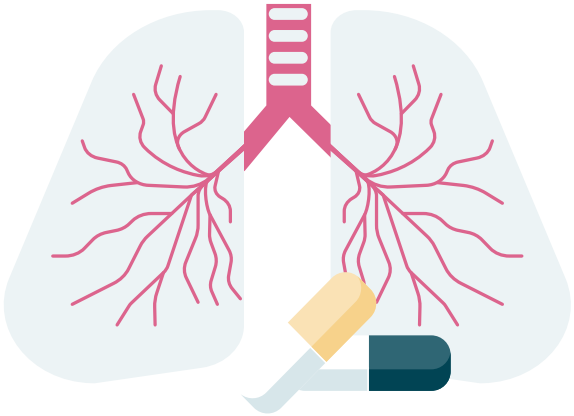
SISAQOL-IMI releases recommendations on patient-reported outcomes

In drug development, it is important to find out how treatments affect how patients feel and function in their daily lives. This information is also essential when weighing up the benefits and risks of a medicine. In practice, it is rather difficult to obtain this information and communicate it clearly and simply. Now the SISAQOL-IMI project has released recommendations and resources to support the design, analysis, interpretation, and presentation of patient-reported outcomes (PROs) in cancer clinical trials.

Alongside the SISAQOL-IMI recommendations, which are published in The Lancet Oncology, the SISAQOL-IMI team has delivered practical, interactive online tools to help users easily apply the recommendations, including a table to help stakeholders to identify relevant recommendations for their specific trial, a glossary providing scientific and plain language definitions of key terminology, and a guidebook to help users navigate the tools.

Ultimately, the tools and resources developed by SISAQOL-IMI should ensure that cancer clinical trials accurately capture how patients feel or function during treatment. This in turn will aid decision making for regulators, health technology assessment bodies and, crucially, improve patients' quality of life. The findings may also be applicable to clinical trials in other disease areas.

Read more



Tale of potent anti-TB treatment highlights power of partnerships

We urgently need new and innovative approaches to treating tuberculosis (TB), and one promising potential TB treatment is advancing through clinical trials thanks to support from IMI and the European and Developing Countries Clinical Trials Partnership (EDCTP). Alpibectir boosts the activity of existing TB drug ethionamide. Ethionamide has to be taken in high doses that often cause severe side effects. Alpibectir could allow doctors to cut the dose of ethionamide by two thirds, reducing the risk of side effects. Early-stage trials in IMI project **TRIC-TB** and EDCTP project bEto-TB have shown the alpibectir-ethionamide combination to be safe and good at killing TB bacteria. Now, alpibectir-ethionamide combination (called AlpE) is in a further trial through IMI project **UNITE4TB**, which is working to accelerate the development of novel TB drugs and drug combinations via innovative trial designs deployed across a global clinical trial network.

The team hopes that the data from the bEto-TB and UNITE4TB studies will provide further insights into the safety, tolerability, and TB-killing ability of AlpE. The data will also help them pin down the optimal doses of alpibectir and ethionamide in the combination, information that will be key to moving AlpE into phase 3 clinical trials. Meanwhile the fact that alpibectir has been able to move seamlessly from IMI2 to EDCTP and then back to IMI2 highlights the synergies between the two health partnerships.

Read more

Foundation to support paediatric clinical trials up and running

IMI project **conect4children** set up the c4c-Stichting to build on the project's work and provide a sustainable, integrated platform for the efficient and swift delivery of high-quality clinical trials in children and young people in Europe. In 2025, the foundation became fully operational, offering services to both non-commercial and commercial sponsors. c4c-S provides comprehensive trial support services as well as expert advice services through access to over 450 experts in more than 25 medical specialties, including Young Persons Advisory Groups and participants and parent groups (PPI). By the end of the year, the project had received 50 requests for services.

Meanwhile, the project published the results of studies conducted to test the viability of the c4c paediatric trial network. One study focussed on the effectiveness of paracetamol in premature babies with a serious heart defect called patent ductus arteriosus. Another study investigated the use of steroids in children with Kawasaki disease, which mainly affects children under 5 and is characterised by a high temperature, rash, swollen glands in the neck, dry, cracked lips, and red eyes, fingers or toes. The successful conclusion of the studies demonstrates that the networks, protocols and systems set up by the project do work in practice.

IMI project results showcase scientific excellence and impact in multiple fields

Meanwhile IMI projects continue to deliver results that demonstrate the public-private partnership's ability to support science that is both excellent and impactful. Results cover the entire spectrum of research, from early-stage drug development right through to implementation science – the branch of science that helps smooth the way towards the uptake of health innovations in the real world.

Cellular 'handbrake' controls cancer drug response, study shows

Purines are molecules that are one of the building blocks of DNA. Cells can create purines by recycling old materials or by manufacturing them from scratch via a process that requires a lot of energy and is driven by an enzyme called PPAT. If this manufacture process is not controlled, purines can build up in the cell. This becomes a problem if someone is taking a cancer treatment that mimics purines; the purines manufactured by the cell effectively out-compete the drug, stopping it from working.

Now, scientists have worked out how an enzyme called NUDT5 acts as a 'handbrake' on PPAT, preventing it from triggering excess purine production. The work, published in the prestigious journal **Science**, was funded in part by the IMI project **EUbOPEN**.

While NUDT5 was known to be involved in cells' energy metabolism and signalling, the fact it plays a role in purine production is a revelation. The discovery came about when EUbOPEN scientists developed a molecular degrader called dNUDT5 that removes NUDT5 from cells entirely. They found that eliminating NUDT5 from cells in this way removed the brake on purine synthesis, allowing it to spiral out of control. Further experiments revealed that NUDT5 works by physically attaching itself to the PPAT enzyme, stopping it from driving purine production.

The result could inform the development of new and better cancer treatments, and result in new biomarkers to guide therapy involving drugs that target DNA.

Read more

Directing the power of AI towards finding compounds to combat antimicrobial resistance

Although many companies individually store databases detailing whether various compounds are effective against drug-resistant bacteria, to date, there has been no synchronised effort to collect this data and use it to better direct antimicrobial drug discovery.

The **COMBINE** project decided to leverage machine learning and big data to train a new AI model that can help to select the most effective antimicrobial activity of compounds. The model is described in a paper in the **Journal of Chemical Information and Modeling**. The model improves the efficiency of the drug development process by predicting how a molecule can be optimised, and by indicating what actually works.

This whole pipeline has been deposited on GitHub, which makes the code open and accessible to others.

Read more

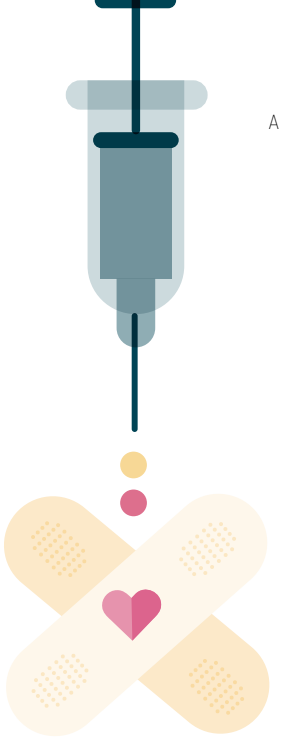
EHDEN publishes largest study to date on the global effect of drug shortages

The European Health Data and Evidence Network (EHDEN), which started out as an IMI project, has harmonised over 350 million pseudonymised health records to the OMOP common data model, making robust real-world data available to answer key questions for health research.

A team of scientists used **EHDEN** to assess the impact of drug shortages on patient care across Europe and North America. The study analysed data on the incidence and prevalence of medicine use after shortage announcements, focusing on 16 drugs, and found that eight drugs saw a 33% drop in incidence and nine drugs had a 33% or higher drop in prevalence. The findings were published in the **Lancet Public Health**.

With more than 50 data partners and many European countries represented, this study is the largest real world evidence study ever conducted. The study demonstrates the value of the EHDEN network and the public-private partnership to improve preparedness and health resilience by leveraging real world data from many healthcare settings to inform the impact of drug shortages on patient care.

Read more



Improving the rates at which patients take their treatments properly

More than half of all patients don't take their treatment as planned, which results in one in every ten hospitalisations. The BEAMER project explored why people don't always follow treatment plans and found that while some of the factors were immutable, others were behavioural and could be modified.

BEAMER analysed who wasn't taking their treatment and why. The project successfully divided the patient population into four main groupings, and then devised a strategy for healthcare professionals on how to deal with each group to maximise patient adherence to treatment plans.

The team developed a questionnaire, B-COMPASS, which consists of just six questions designed to group patients by their needs. The idea is that while in the waiting room for a doctor's appointment, or before an interview with a patient support team, patients fill out the questionnaire and the result is given to the doctor just before the appointment. The healthcare professional can quickly see which style of information delivery or support would work best for the patient and adapt accordingly.

To test out this hypothesis, pilot studies for BEAMER are kicking off. The pilots will take the form of randomised control trials, with patients divided into two groups; one group will receive the current standard of care, and the other group will use the B-COMPASS questionnaire system.

Read more

VITAL new tools to promote vaccination amongst the elderly

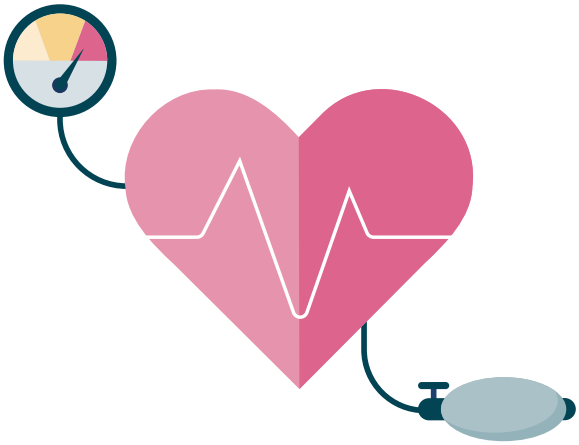
As we get older, our immune system becomes less effective, meaning that we become more susceptible to infectious diseases. At the same time, vaccine uptake in the elderly population is not as high as it should be. IMI project VITAL has delivered a suite of tools to boost vaccination uptake amongst the elderly. These include an educational platform for healthcare professionals to help improve communication about vaccines with elderly patients. The platform offers educational resources in five languages – English, Italian, Dutch, French and Hungarian – and is integrated with academic programmes so that the next generation of healthcare professionals can also benefit from it.

The project also dove into how the economic impact of the current methods for managing infectious diseases in ageing adults could best be measured and reported on. Based on their findings, VITAL developed a toolkit to help decision-makers to figure out how best to organise national vaccination programmes. The tools include a framework to help lay out how to analyse hot spots and patient flow, as well as economic models that can illuminate different aspects of disease dynamics. These tools will help policymakers to visualise the long-term benefits of vaccinating the elderly, and provide a robust evidence-base to support policy decisions.

Read more

IHI projects are delivering their first results

Although they are still in their early stages, many IHI projects are starting to deliver results that highlight the added value of bringing a cross-sector, public-private approach to health research challenges.



IHI heart disease project devises AI-based tool to standardise health data

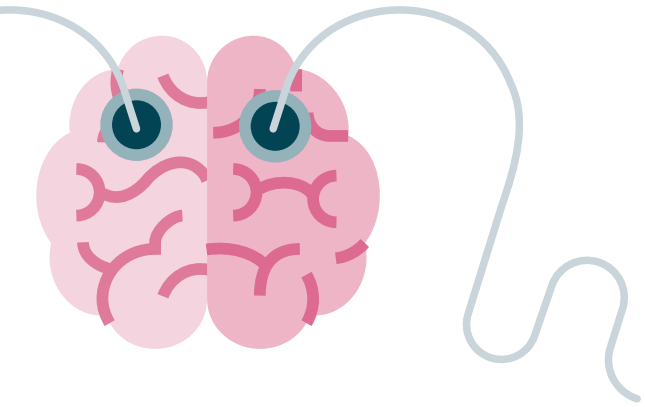
iCARE4CVD aims to personalise and improve the care of people living with cardiovascular disease (CVD). As a first step, they plan to analyse data from over a million patients to gain new insights into the diseases. The problem is that this data is currently stored in multiple locations and in multiple different ways.

The challenge for iCARE4CVD was to find a way of harmonising these diverse data types so that they can be reliably used for research. To do this, the team developed a CDE (common data element) mapper which, as its name suggests, maps data elements including medical terms, measurements and even complex data entries to existing, internationally recognised medical vocabularies.

The CDE-Mapper, which is described in a paper in Computers in Biology and Medicine, draws on artificial intelligence (AI) and is designed to learn and improve over time by involving human experts who review and confirm its choices.

The iCARE4CVD team tested the CDE-Mapper on different data sources, and compared its performance against other widely used AI systems. They found that it outperformed existing methods by 11% when it comes to identifying and translating health concepts. It did especially well when dealing with complex or multi-part data. The CDE-Mapper could help researchers studying CVD by making it easier to spot trends and develop new therapies. The CDE-Mapper also contributes to the implementation of the European Health Data Space (EHDS).

Read more



Simple brain scan reveals early signs of Alzheimer's disease

PREDICTOM aims to boost our ability to detect people at risk of developing dementia (including Alzheimer's disease) before the first symptoms appear. Now, the project has demonstrated that a type of brain scan called an EEG (electroencephalogram) can distinguish between healthy people and people with very subtle symptoms of the disease. The findings are published in the Journal of Dementia and Alzheimer's Disease.

Most previous studies of Alzheimer's disease using EEG data focused on things like the speed of the brain rhythms. In contrast, the PREDICTOM team turned to graph theory to analyse the data. Graph theory is a branch of mathematics used to model complex networks – like the brain's communication patterns and functionality among different brain regions. The analysis revealed clear differences in how electrical signals moved between brain regions in people with different levels of cognitive symptoms. People with Alzheimer's disease showed the slowest brain activity and seriously reduced communication between the different regions of the brain. Crucially, changes in brain network activity were also clearly visible in people with very subtle memory concerns.

The discovery suggests that EEGs could help doctors spot signs of Alzheimer's earlier than traditional tests and examinations; this is important because EEGs are low-cost and widely accessible, and could even be used in the home.

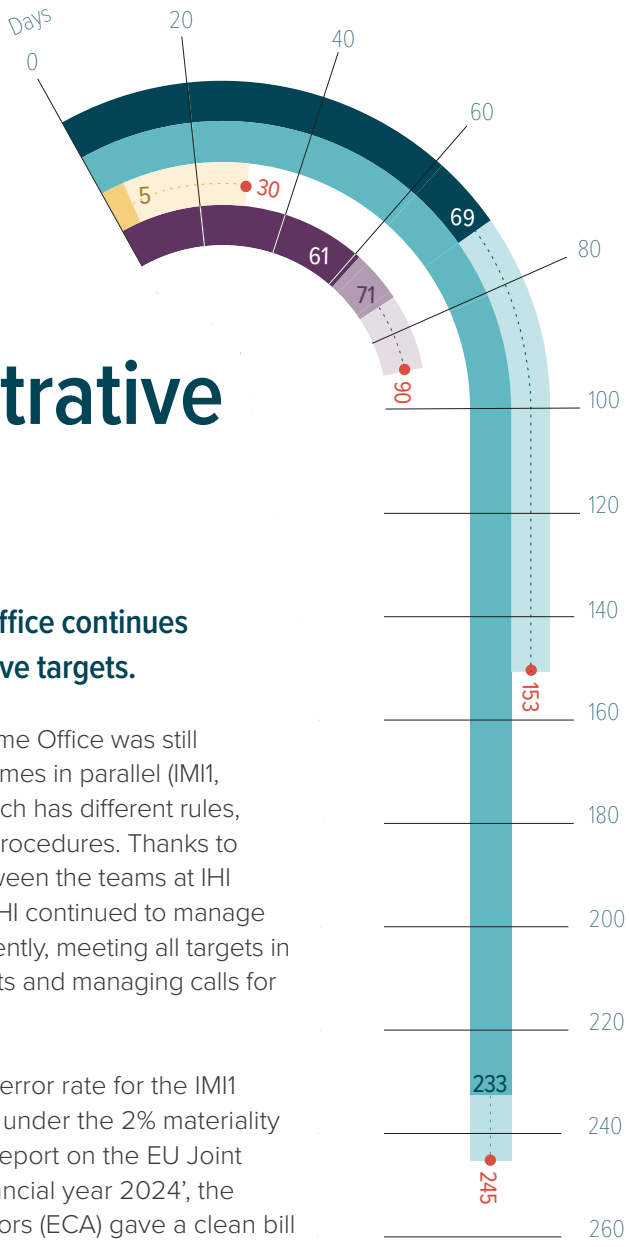
Read more

EDENT1FI pinpoints best approach for identifying those at early stages of type 1 diabetes

EDENT1FI aims to establish a European screening platform to identify children and adolescents at early stages of type 1 diabetes; evaluate the clinical, economic, psychological, and practical aspects of screening; and develop strategies that can be implemented across healthcare systems. In 2025, the project published a lexicon initiative which provides a terminology for type 1 diabetes with the goal of standardising how disease stages, biomarkers, risks, and clinical terms are defined and used across research and care. This lexicon, published in The Lancet Diabetes & Endocrinology, should improve clarity, consistency, and comparability across studies and clinical practice, enabling more reliable data integration and communication.

The project also evaluated strategies for identifying people with presymptomatic type 1 diabetes. The findings, published in Diabetologia, show that repeated islet autoantibody screening remains the most effective stand-alone approach. Screening at ages 2, 6 and 10 years identifies up to 80% of children who will develop type 1 diabetes. The paper also highlights the importance of public engagement and robust infrastructure for early detection programmes.

6 Administrative targets



The IHI Programme Office continues to hit key administrative targets.

In 2025, the IHI Programme Office was still managing three programmes in parallel (IMI1, IMI2 and IHI), each of which has different rules, management tools and procedures. Thanks to strong collaboration between the teams at IHI and robust procedures, IHI continued to manage these programmes efficiently, meeting all targets in terms of making payments and managing calls for proposals.

The cumulative residual error rate for the IMI1 and IMI2 programmes is under the 2% materiality threshold. In its 'Annual report on the EU Joint Undertakings for the financial year 2024', the European Court of Auditors (ECA) gave a clean bill of health for IHI JU, issuing an unqualified ('clean') opinion on the reliability of the accounts as well as on the legality and regularity of the revenue and payments underlying the annual accounts.

On the budget front, the Programme Office achieved budget execution rates of 98.4% and 98.5% for commitment and payment appropriations % respectively. This represents an outstanding performance for 2025, underpinned by rigorous planning, proactive management and diligent monitoring. Furthermore, 100% of administrative payments and payments to experts were made on time.

7

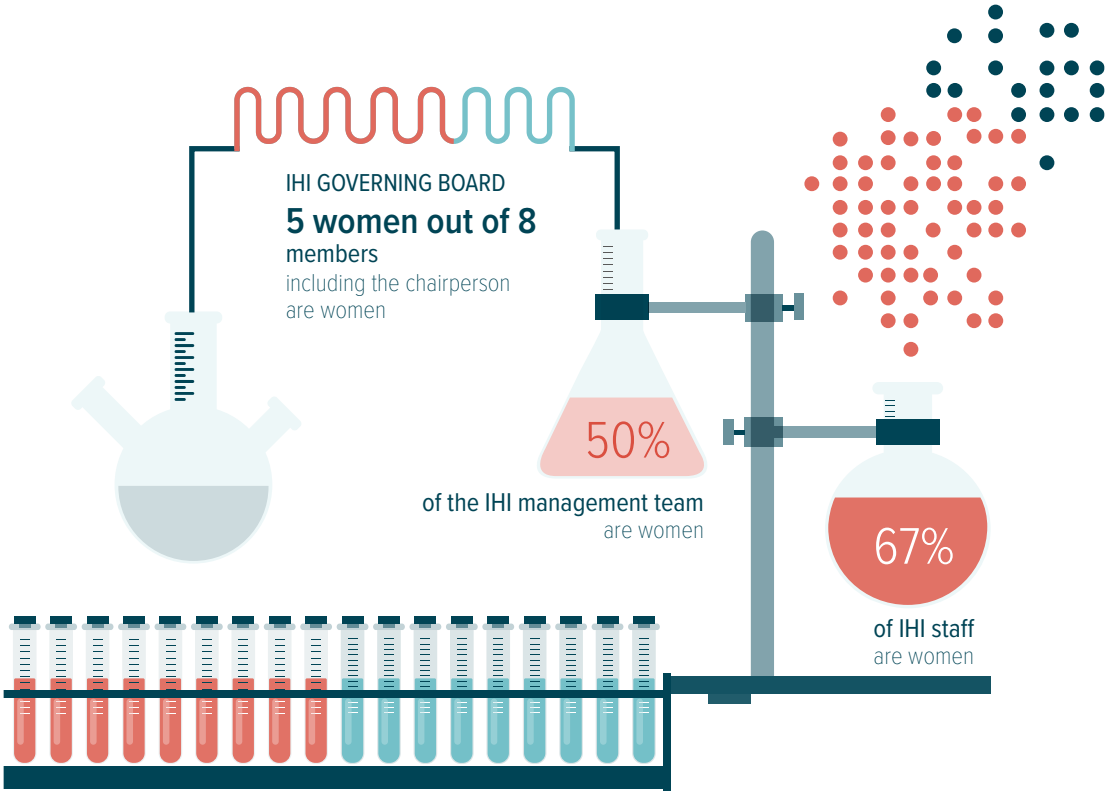
Gender balance

Women are well represented at all levels of IHI's work.

Women are well represented at all levels of IHI's work, including in leadership roles, as the following statistics (valid as of the end of 2025) demonstrate:

STATES REPRESENTATIVES GROUP (SRG)

57 of the 77
representatives
including the chairperson are women



IHI GOVERNING BOARD

5 women out of 8
members
including the chairperson are women

50%
of the IHI management team
are women

67%
of IHI staff
are women

SCIENCE AND INNOVATION PANEL (SIP)

9 of the 18
members
including the chairperson are women

innovative health initiative

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