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Foreword

Health is one of society's greatest shared priorities, yet it has never faced more complex challenges. Ageing populations, the growing burden of chronic disease, persistent health inequalities, emerging infectious threats and increasing pressure on healthcare systems are reshaping how we think about health across Europe and beyond. Addressing these challenges demands more than scientific excellence alone. It requires collaboration across disciplines, sectors and borders to transform research into solutions that improve lives.

As this special health edition of *Projects Magazine* demonstrates, that collaboration is already delivering remarkable progress. Across Europe, researchers, clinicians, engineers, data scientists, public health experts and policymakers are working together to develop the knowledge, technologies and innovations that will define the future of healthcare.

Within these pages, we see projects taking a proactive approach to health, shifting the focus from treating illness to preventing it before it begins. Others are advancing next-generation vaccines, immunology and diagnostic technologies to strengthen preparedness for future health threats, while pioneering new approaches to personalised medicine, digital healthcare and rehabilitation are bringing more effective, accessible care closer to patients. Elsewhere, ambitious initiatives are improving our understanding of brain health, harnessing artificial intelligence and advanced analytics to unlock new insights, and developing more resilient, sustainable healthcare systems capable of meeting the demands of future generations.

Running through every one of these initiatives is the power of partnership. None of these advances are being achieved in isolation. They are the result of organisations bringing together complementary expertise, sharing knowledge openly and working collectively towards common goals. It is this collaborative spirit that allows ideas to move beyond the laboratory, informs policy and clinical practice, and ultimately delivers meaningful benefits for patients and society.

That is why, at Insight Media, we are proud to help tell these stories. By connecting researchers, projects, policymakers, industry and the wider public, we can ensure that innovation reaches the audiences who can build upon it, adopt it and maximise its impact. The discoveries featured throughout this edition remind us that the future of healthcare will be shaped not only by scientific breakthroughs, but by the strength of the partnerships that bring them to life.

William Davis
Managing Director, Insight Media

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NEWS

Algae microbots could transform bladder cancer treatment

Researchers have developed tiny algae-based robots capable of delivering chemotherapy drugs deep into bladder tumours, a breakthrough that could significantly improve the effectiveness of bladder cancer treatment while reducing side effects.

Developed by scientists at the **University of Edinburgh and Xiamen University**, the biohybrid magnetic microbots are engineered from natural microalgae and loaded with the chemotherapy drug doxorubicin. Guided by externally programmed magnetic fields and tracked using real-time ultrasound imaging, the microscopic robots can be directed precisely to tumour sites, where they release their therapeutic payload.

Bladder cancer is one of the ten most common cancers worldwide and is often treated by delivering drugs directly into the bladder through a catheter. However, conventional treatments frequently struggle to penetrate deeply into tumour tissue, limiting their effectiveness and often requiring higher doses or longer treatment times.

In laboratory tests involving mice with bladder tumours, the algae microbots achieved drug penetration levels more than ten times greater than those seen with standard treatment approaches. After just one week of therapy, tumour burden was reduced to less than three per cent of that observed in animals receiving conventional treatment.

Researchers also found that the treatment could be completed in around 30 minutes while minimising damage to healthy tissue. The technology takes advantage of the natural properties of single-celled algae, which are

biocompatible, biodegradable and well suited to carrying and releasing drugs. Using real-time imaging feedback, researchers can control the movement of swarms of microbots, enabling them to navigate through the bladder and target tumours with remarkable precision.

Published in the journal Nature Nanotechnology, the study represents a promising step towards more effective and less invasive bladder cancer therapies.

While further preclinical validation and regulatory review are required, the research team is already discussing translational follow-up studies with hospitals as it works towards future clinical trials.

EMA reports another strong year for medicine approvals

The European Medicines Agency (EMA) recommended 104 human medicines for marketing authorisation in 2025, including 38 new active substances, alongside 30 veterinary medicines – the highest annual total for a second consecutive year. The approvals include first-in-class treatments, advanced therapies and medicines for rare diseases, reflecting continued innovation across the life sciences sector. The agency says the figures demonstrate Europe's strong pipeline of new medicines and its ongoing commitment to accelerating access to safe, effective therapies for both people and animals.

Unlocking the full potential of cancer immunotherapy

A new €2.5 million project is set to advance a promising form of personalised cancer immunotherapy by improving the way tumour-fighting immune cells are produced for patients with solid cancers. The three-year Repro-TIL project, funded through the European Innovation Council (EIC) Transition programme, will help move the technology closer to clinical application.

Led by Swedish biotechnology company **Asgard Therapeutics** in collaboration with Lund University and Herlev Hospital, the project is developing a first-in-class platform to enhance tumour-infiltrating lymphocyte (TIL) therapy. TIL therapy harnesses a patient's own immune cells to attack cancer but has so far achieved its greatest success in only a limited number of cancers because producing sufficient numbers of highly effective tumour-reactive cells remains a major challenge.

The Repro-TIL project addresses this limitation by combining TIL therapy with Asgard Therapeutics' proprietary dendritic cell reprogramming technology. The approach is designed to selectively expand neoantigen-specific, tumour-reactive T cells, increasing the number of activated immune cells capable of recognising and destroying cancer cells. By adding a single step to the existing manufacturing process, researchers hope to create a more potent and consistent cell therapy for patients with solid tumours.

Over the next three years, the consortium will complete preclinical validation and CTA-enabling studies, advancing the technology to Technology Readiness Level 6 and laying the foundations for future clinical development. The funding also broadens the application of Asgard's cell reprogramming platform beyond its lead therapeutic programme, demonstrating its potential as a versatile technology for next-generation immunotherapies.

If successful, Repro-TIL could help overcome some of the key barriers that have limited wider adoption of TIL therapies, including inefficient cell expansion, T-cell exhaustion and poor tumour reactivity. By improving the quality and effectiveness of personalised cell therapies, the project aims to bring more powerful immunotherapies closer to patients with difficult-to-treat solid cancers, offering new hope for more effective and durable cancer treatment.

ERC awards €721 million for frontier research

The European Research Council (ERC) has awarded €721 million through its latest Advanced Grants competition, supporting 281 leading researchers across Europe to pursue ambitious, high-risk, high-reward research projects. Covering fields from health and climate science to artificial intelligence and fundamental physics, the grants are designed to enable established scientists to push the boundaries of knowledge and explore groundbreaking ideas. The funding is expected to create around 2,700 jobs for postdoctoral researchers, PhD students and research staff, further strengthening Europe's scientific excellence and innovation capacity.

NEWS IN BRIEF

Gene editing

Researchers at Children's Hospital of Philadelphia have successfully corrected disease-causing genetic mutations in laboratory studies, bringing new treatments for inherited disorders closer to clinical reality.

Cancer vaccines

Scientists at RCSI University of Medicine and Health Sciences have reported promising results from an experimental mRNA vaccine designed to target neuroblastoma, one of the deadliest childhood cancers.

Cancer atlas

Researchers from VIB and Vrije Universiteit Brussel have created a detailed atlas of tumour-associated dendritic cells, providing new insights for future cancer immunotherapies.

Heat protection

The World Health Organisation Regional Office for Europe has released updated guidance to help countries prepare for extreme heat events as climate-related health risks continue to increase.

Workforce warning

World Health Organisation Regional Office for Europe has warned that Europe could face a shortage of nearly one million health workers by 2030 without sustained investment in recruitment and retention.

Vector surveillance

The European Centre for Disease Prevention and Control and European Food Safety Authority have updated maps tracking disease-carrying mosquitoes, ticks and other vectors across Europe.

NEWS

New EU guidance on safety of blood, tissue and cell donations

The **European Centre for Disease Prevention and Control (ECDC)** has published new scientific guidelines designed to harmonise hepatitis B and hepatitis C screening for blood, tissues and cells donated for medical use across Europe, helping to improve patient safety and reduce the risk of infection transmission.

The updated recommendations establish a single, evidence-based approach for screening donors of substances of human origin (SoHO), including donated blood, stem cells, reproductive cells and tissues used in transplantation and medically assisted reproduction. They underpin the implementation of the EU's new Regulation on standards of quality and safety for substances of human origin, replacing a patchwork of older national practices with a consistent European framework.

Hepatitis B and hepatitis C remain significant public health concerns because both viruses can be transmitted through donated biological materials. Although existing screening programmes have made medical procedures extremely safe, previous legislation resulted in variations in testing protocols between EU and EEA countries. The new guidance provides harmonised laboratory screening requirements, risk-based donor assessment criteria and recommended deferral periods for donors with potential exposure to infection.

Developed by ECDC with input from infectious disease specialists and experts from across Europe, the guidance is based on extensive reviews of the scientific evidence. It aims to ensure a consistently high level of protection for recipients of donated blood, organs, tissues and cells, while also safeguarding children conceived through medically assisted reproduction.

The recommendations are expected to support healthcare providers, blood services, tissue banks and national authorities as they implement the new SoHO Regulation. By introducing common standards across Europe, the guidelines should improve consistency in donor screening, strengthen public confidence in donation programmes and help reduce the risk of hepatitis transmission during medical procedures.

The hepatitis B and hepatitis C guidance forms part of a wider programme of ECDC technical guidelines covering communicable diseases that may be transmitted through substances of human origin, supporting a modern, science-led approach to patient safety across the European Union and European Economic Area.

Study highlights need for better mental health data

A new study from the World Health Organisation (WHO) Europe has revealed significant gaps and inconsistencies in how mental health is measured across the European region, making it difficult to accurately assess needs, track progress and compare outcomes between countries. Researchers found that many existing indicators focus on illness and service use rather than broader aspects of mental wellbeing and quality of life. The findings underline the need for more comprehensive and harmonised monitoring systems to support evidence-based policymaking and improve mental health outcomes across Europe as demand for services continues to grow.

NEWS IN BRIEF

Vector watch

The European Centre for Disease Prevention and Control has highlighted continued surveillance of measles, West Nile virus, chikungunya, Nipah virus and Ebola in its latest Communicable Disease Threats Report, reinforcing Europe's focus on outbreak preparedness and rapid response.

Digital health

World Health Organisation Regional Office for Europe and Healthcare Denmark have agreed to strengthen cooperation on digital health, artificial intelligence and health data innovation.

Pain Research

Researchers at University of Arizona have identified cannabis-derived aroma compounds that may relieve pain without producing the intoxicating effects associated with THC.

Heart health

Research presented through the European Society of Cardiology suggests several commonly used food additives may be linked to increased blood pressure and cardiovascular risk.

Exercise benefits

A study reported by the BMJ Group suggests that as little as 90–120 minutes of strength training per week may deliver significant long-term health benefits.

Cartilage repair

Scientists at Stanford Medicine have restored cartilage in ageing mice by targeting a protein linked to ageing, raising hopes for future osteoarthritis therapies.

European Health Data Space enters implementation phase

The European Union has taken a major step towards creating a more connected, data-driven healthcare system with the European Health Data Space (EHDS) now officially in force. Following its publication in the Official Journal of the European Union in March 2025, the Regulation has entered its implementation phase, laying the foundations for a secure framework that will transform how health data is accessed, shared and reused across Europe.

The EHDS is designed to give citizens greater control over their personal electronic health records while making it easier for healthcare professionals to access essential patient information across borders. At the same time, it establishes a trusted framework allowing anonymised or pseudonymised health data to be reused for research, innovation, public health, policymaking and regulatory activities under strict governance and privacy safeguards.

Although the Regulation is now in force, its implementation will be gradual. Over the coming years, Member States will establish national digital health authorities and adopt the technical standards and governance structures needed to support the new system.

The first major operational elements, including cross-border exchange of patient summaries and e-prescriptions, are scheduled to become mandatory from 2029, with additional health data categories such as medical imaging, laboratory results and genomic data following in later phases.

For researchers and innovators, the EHDS represents a significant opportunity. By enabling secure access to high-quality health datasets from across Europe, the framework is expected to accelerate medical research, support the development of new diagnostics and treatments, strengthen preparedness for future health emergencies and advance personalised medicine. At the same time, harmonised rules for electronic health record systems will improve interoperability across the EU, creating a more integrated digital health ecosystem.

The EHDS is widely regarded as one of the cornerstones of the European Health Union. While considerable work remains before the framework is fully operational, its entry into force marks the beginning of a long-term transformation in how health data supports patient care, scientific discovery and healthcare innovation across Europe.

EMA recommends updating COVID-19 vaccines

The European Medicines Agency's Emergency Task Force (ETF) has recommended that COVID-19 vaccines for the 2026–27 vaccination season be updated to target the XFG variant, which has become one of the dominant circulating strains. The recommendation aims to ensure vaccines continue to provide the best possible protection against severe disease and hospitalisation as the virus evolves. The guidance will support vaccine manufacturers and regulators in preparing updated formulations ahead of the next vaccination campaign, helping European health systems maintain preparedness for future waves of infection.

NEWS IN BRIEF

Kidney discovery

Researchers at Mayo Clinic have identified a previously unknown mechanism used by the kidney to conserve water, opening new avenues for disease research.

Alzheimer's research

Scientists at ETH Zurich have identified a new target for Alzheimer's disease and developed an experimental compound that slowed nerve cell loss in mice.

Lung screening

Researchers from the University of Glasgow and collaborators have found that lung cancer screening is generally well tolerated, although inequalities in patient experience remain.

Liver health

World Health Organisation Regional Office for Europe has designated a new collaborating centre focused on liver disease to strengthen prevention, diagnosis and treatment efforts across the region.

Heat action

The World Health Organisation Regional Office for Europe has published updated guidance to help countries strengthen Heat/Health Action Plans, supporting governments in protecting vulnerable populations as extreme heat events become more frequent across the region.

Ebola preparedness

The European Centre for Disease Prevention and Control has issued new guidance to help European countries prepare for the potential importation of Ebola virus disease cases.

Insight Feature

Building a fairer health future

Why do health inequalities persist despite decades of innovation and investment? ***Alison Maassen*** of EuroHealthNet argues that the answer lies beyond hospitals and clinics, in the social, economic and environmental conditions that shape health long before people enter a healthcare system.

Europe's health systems are facing a convergence of challenges like never before. Populations are ageing, chronic diseases are increasing, health inequalities remain deeply entrenched, and public services are under growing pressure. At the same time, scientific advances, digital technologies and new approaches to care are creating unprecedented opportunities to improve lives.

Yet, despite decades of innovation and investment, one fundamental question remains: why do so many health inequalities persist? For Alison Maassen, Programme Manager at EuroHealthNet, the answer lies in a common misconception about where health is actually created.

EuroHealthNet is the European Partnership for Health Equity and Wellbeing, bringing together more than 80 public health agencies, ministries, research organisations, universities and civil society groups from across Europe. Working at the intersection of policy, practice and research, its mission is to reduce health inequalities by addressing the factors that

shape health long before people enter a healthcare setting.

For EuroHealthNet, health is shaped not only by healthcare services, but by the economic, environmental, social and political conditions that influence people's lives. Housing, employment, education, financial security, community connections and the environments in which people live all play a role in determining health outcomes.

"Our work focuses on health inequalities," explains Maassen. "How can we reduce health inequalities within and between European states? And the way that's done isn't by necessarily just tweaking the health system. It's looking at all the determinants of health, those great big levers and drivers that are underpinning how well we're doing."

It is this broader, systemic understanding of health that underpins the partnership's work and explains why improving health outcomes requires action far beyond hospitals and clinics.

"We really consider ourselves a catalyst and convener," Maassen explains. "What we do try to do is bring people together and in doing so we look to act as a catalyst – to make a spark."

Looking beyond healthcare

Central to EuroHealthNet's thinking is the belief that health is created far beyond the healthcare system itself. The conditions in which people live, work and age often have a greater influence on health outcomes than the medical care they eventually receive.

Never underestimate the value of being competent.

The evidence increasingly supports this view. In a recent analysis of ten years of European Social Survey data, EuroHealthNet examined how health inequalities have evolved across the continent and whether progress is being made in narrowing the gap between different groups. The findings were sobering. "What we found was basically that we're stagnating," Maassen explains. "And in many cases, we're actually even declining."

Perhaps most concerning was that reductions in health inequalities were not always the result of healthier populations. "What happened is that people who had been better off actually reported worse health outcomes than they did before, whereas people who were the worst off continued to report not great health outcomes.

So you had reduced the inequalities between the best off and

the least well off. But nobody benefited from that reduction."

When EuroHealthNet examined the factors driving poor health outcomes, the results pointed well beyond traditional healthcare. "The number one driver that people indicated was financial insecurity. The second was a lack of feeling of control over their lives. And then the third and the fourth were unhealthy diets and housing."

These findings reinforce a growing body of evidence showing that health is closely linked to education, employment, income, housing quality, environmental conditions and social participation. For EuroHealthNet, improving health therefore requires a much broader societal response. "It's really working through more of a health promotion approach," says Maassen. "And that's why we are working across health and social."

This thinking also underpins EuroHealthNet's growing focus on the concept of a wellbeing economy, an approach that asks whether economies should serve people and the planet, rather than the other way around. "Why is it that people are working in service of the economy and the economy is not working in service of the people and the planet?" she asks. "How can we actually flip this around?"

Prevention

If there is one area where rhetoric and reality continue to diverge, it is prevention.

Few policymakers would argue against the value of preventing disease rather than treating it. Yet investment patterns tell a different story. "Health promotion and disease prevention have a lot of rhetorical prominence," says Maassen. "Everybody loves to talk about them, and they say they are important, but you don't see that reflected in budgets.

"For 20 years now, we've seen health promotion and disease prevention at around 3% of total health expenditure across OECD countries. It jumped in 2021 to 5%, but that was because of COVID-19 vaccine purchases."

For Maassen, the challenge is structural. "It's almost a design flaw in the way that the public sector works, that it is by its nature reactive. To be health-promoting, you have to be forward-looking. You have to be proactive."

The issue becomes even more pressing as Europe's population ages. By 2050, the number of Europeans aged 65 and over is expected to increase by more than 40%, while the number aged over 80 could almost double. Yet, as EuroHealthNet's recent policy work highlights, the real challenge is not ageing itself but ageing in poor health. "There is a huge economic argument to be made for investing more in health promotion and disease prevention," says Maassen. "If we age in poor health, then the system faces so many more demands."

Healthy ageing is not simply about extending life expectancy but extending healthy life expectancy. The challenge facing Europe is not that people are living longer, but that too many people spend later life in poor health, placing greater pressure on healthcare, long-term care and support services.

Healthy ageing, she argues, should not be viewed as a cost but as an investment that helps people maintain independence, wellbeing and quality of life for longer.

A changing Europe

As EuroHealthNet develops its strategy for the coming years, the organisation has adopted a powerful metaphor to describe the forces shaping Europe's future. "We see that there are currents," Maassen explains. "The big immovable trends. You can't turn this boat."

These currents include climate change, digitalisation, demographic change and growing inequalities. "The climate transition is one of them. The digital transition is one of them. The demographic transition is one of them. And then we would also say that this increase in health and social inequalities is one of them."

Above these currents sit what Maassen describes as "waves" – the challenges emerging from these deeper shifts. Mental ill health, growing corporate influence over health-related behaviours, misinformation and social fragmentation are among these pressures now confronting policymakers.

One area of particular concern is the growing influence of commercial determinants of health. "It's very common that people will say obesity is an individual choice," says Maassen. "But if 50% of your population is obese, that's not an individual choice anymore. So much of the choices we think are individual choices are obviously influenced by our environments."

The implication is clear. Improving health outcomes requires more than encouraging individual responsibility. It requires addressing the systems and environments that shape behaviour in the first place.

Digital innovation

Few developments have generated as much excitement in healthcare as digital innovation. Artificial intelligence, remote monitoring, telemedicine and personalised care technologies are increasingly seen as solutions to many of healthcare's biggest challenges, and Maassen acknowledges their potential.

"Digital can be a huge asset," she says. "Telemedicine, for example, could play a transformative role in addressing rural health inequalities by connecting patients with healthcare professionals regardless of location.

"What is one of the most promising tools that we have to help address rural health inequalities and access? Telemedicine. It's a fantastic tool."

She also points to initiatives that allow people with chronic conditions to monitor their health from home, reducing hospital visits and improving quality of life. Yet she is equally clear that technology alone cannot solve systemic problems.

"The challenge we have right now is that it has to be embedded in a governance structure and in a societal structure that are supportive of it being used in the most equitable and best possible way."

Without appropriate safeguards, digital technologies risk reinforcing existing inequalities. "It has very, very great potential to increase inequalities and not reduce inequalities."

Issues such as digital literacy, access to technology, algorithmic bias, misinformation and data governance all require careful attention. "If we don't put the systems in place, then they'll widen inequalities."

For EuroHealthNet, the answer is not to slow innovation, but to ensure innovation serves public wellbeing rather than undermining it. "Digital can be a tremendous force for good in so many ways, but it has to be harnessed in the right way. It has to be directed in the right way."

Practical action

Despite the scale of the challenges, Maassen remains focused on the need for practical action. Asked whether she is optimistic about Europe's future, she pauses. "I think I'm more of a pragmatist."

"I think people will realise that there's not really any other way, unless we want to go down the route of a truly dystopian future, where we are just experiencing even greater disparities and inequalities between the haves and the have-nots."

For her, the path forward involves investing seriously in prevention, confronting harmful commercial influences, rebuilding trust in institutions and empowering communities to participate in shaping healthier societies. It also requires organisations like EuroHealthNet to continue connecting people, sectors and ideas across Europe. "My dad had an expression that I loved," she says. "'Never underestimate the value of being competent.'"

It is a deceptively simple philosophy for tackling some of society's most complex challenges. Whether connecting policymakers with researchers, helping countries learn from one another, or ensuring that health is considered alongside education, housing and employment, EuroHealthNet's work is ultimately about making countless small connections that collectively create meaningful change.

The long-term vision, however, remains ambitious: "An economy and a society that works in the service of people, equitably in the service of people and in the service of our planet," says Maassen. "That we all have the best possible opportunity for a good quality of life and a life that we can live in dignity."

For EuroHealthNet, achieving that vision is not simply a matter of improving healthcare but of reshaping the conditions that allow health, wellbeing and opportunity to flourish in the first place. Because, as Maassen concludes, "there's not really any other way."

EP BrainHealth: Building a holistic European Partnership for Brain Health

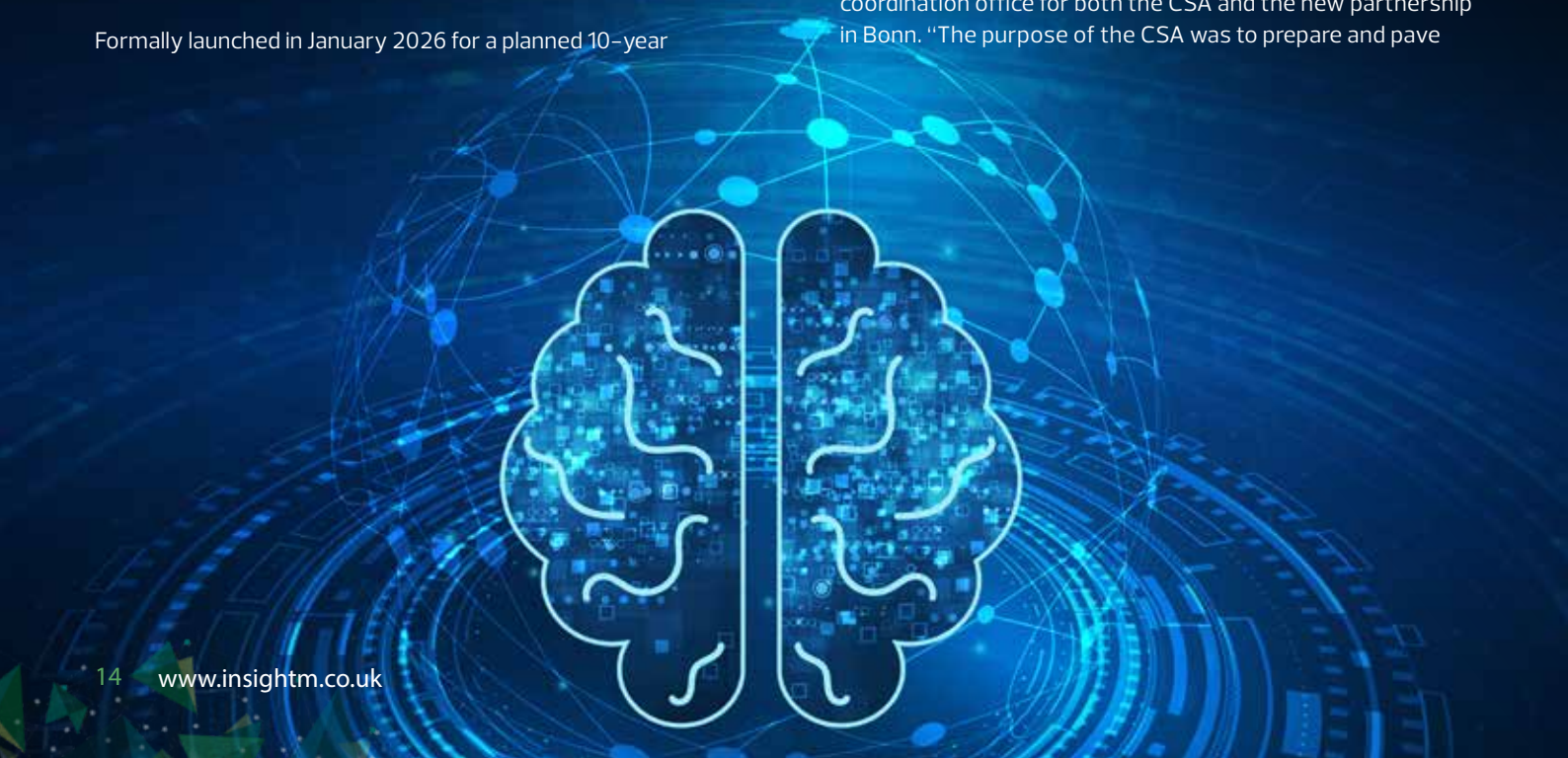
Leveraging decades of substantial investment across Europe's diverse brain research landscape, the **European Partnership for Brain Health** marks a transformative shift towards coordinated, long-term alignment and systemic impact. Emerging from the **CSA BrainHealth**, this 10-year initiative seeks to unite scientific, clinical, societal and policy communities under a single, holistic framework. With 60+ participating institutions from 36 countries across Europe and beyond, the initiative is one of the largest collaborative efforts in brain research worldwide. **Dr. Friederike Bathe**, head of the partnership's coordination office at the German Aerospace Center (DLR Projektträger) in Bonn, explains how this approach will redefine how research and innovation translate into meaningful solutions to prevent and treat neurological and mental disorders, improving people's lives.

For more than two decades, Europe has invested heavily in brain-related research, funding major initiatives that have advanced understanding of neurological, neurodegenerative and mental disorders. Yet despite this sustained effort, the European brain health landscape has largely remained fragmented, shaped by parallel programmes with distinct objectives and their own funding motivations.

The creation of the European Partnership for Brain Health (EP BrainHealth) represents a deliberate attempt to move beyond that fragmentation — not by replacing what came before, but by bringing it together and widening the scope under one long-term, collaborative framework.

Formally launched in January 2026 for a planned 10-year duration, EP BrainHealth has emerged from an extensive preparatory process conducted under the EU-funded CSA BrainHealth project (CSA stands for Coordination and Support Action). That process did more than design a new network structure. It redefined how research priorities in brain health should be set and how scientific and societal impact can realistically be achieved systemically over the long term.

A major driving force and contributor of the initiative has been the German Federal Ministry of Research, Technology and Space. It has appointed the DLR's project management agency to coordinate the huge project. Dr. Ulrike Bußhoff is the official coordinator, and Friederike Bathe heads the coordination office for both the CSA and the new partnership in Bonn. "The purpose of the CSA was to prepare and pave



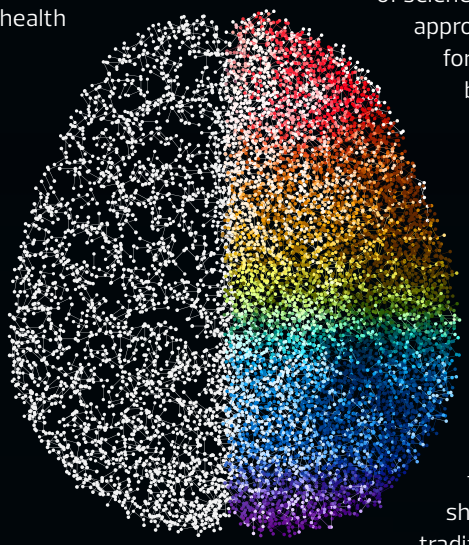
the way for the new European Partnership for Brain Health," Bathe explains. "With great ambition and bringing together 21 partners from 11 countries, we wanted to design the new partnership to grow beyond the sum of its predecessors."

The CSA ran from November 2023 to October 2025, bringing together EU Member States, Associated Countries and third countries and involving a broad range of stakeholders, including policymakers, national funders, scientific communities, health professionals, patients and industry across the brain health ecosystem.

Four objectives defined the CSA's work. The first, and arguably the most impactful, was the development of a Joint Strategic Research and Innovation Agenda (SRIA). Led by the French national research agency ANR and the health research agency INSERM, the SRIA was produced through an iterative process which, as well as involving funders and the European Commission, also involved researchers, patient organisations, health professionals, social sciences experts and industry representatives. The SRIA also received the input and support of the broader brain health ecosystem through an open consultation.

Published in October 2024, it set out four overarching research priorities for the partnership as well as a portfolio of transversal topics that now guide the partnership's activities.

"The SRIA is the basis document for everything we are doing now in the partnership," Bathe underlines. The process of developing it was a very important step towards alignment, enabling discussion of common definitions, joint priorities and key brain health challenges to tackle," she adds.



Another CSA objective focused on the structural design of the new partnership. Rather than starting from scratch, the CSA deliberately looked to capitalise on the work done by existing European initiatives, including the Network of European Funding for Neuroscience Research (ERA-Net NEURON), the JPND Neurodegenerative Disease Network, the former CSA EBRA, and the Human Brain Project, which led to today's EBRAINS RI, a research infrastructure focused on brain research. Many of the actors behind these initiatives were involved in CSA BrainHealth, enabling the partnership design to build on proven governance models and processes while addressing some of their limitations.

The third CSA objective was to gather partners and secure national commitments. Ministries, national funding agencies and foundations from across Europe and Associated Countries were brought into a single proposal for the co-funded European Partnership that was submitted in June 2025, leading to the formal start of the partnership on the 1st January 2026. The EP BrainHealth network brings together more than 60 participants from 36 countries across Europe and worldwide. The total planned budget sums up of approximately €500 million, making it one of the largest collaborative efforts in brain research worldwide.

The final, and possibly most crucial objective that runs through everything the partnership has now set out to achieve is meaningful stakeholder dialogue. "Patients, industry, global partners and society at large were engaged throughout the CSA, ensuring that the partnership was shaped not only by scientific priorities but by societal needs and expectations as well," says Bathe. It was this work that laid the foundation for what EP BrainHealth now refers to as its BrainHealth ecosystem.

Why a partnership?

Addressing one of the most pressing global challenges, brain health research is a complex and highly diverse field of science and translation. The European Partnership approach has emerged as the appropriate format for bringing together relevant stakeholders, bridging gaps and maximising synergies.

Bathe explains: "Europe has always supported a wide range of brain-related research, but funding has often been siloed by disease category or methodological approach. At the same time, scientific understanding of brain health has shifted, and biological, social and environmental factors have all now been recognised as influencing factors in health outcomes. That has led the research focus to move towards a more holistic view on brain health," she continues. The field is now overcoming traditional indication-related boundaries and beginning to understand the role of a broad range of influencing factors on the health of our brains.

The end, or impending end, of several major initiatives further reinforced the need for a more long-term, coordinating framework. EP BrainHealth is explicitly designed to provide continuity with these programmes, while also creating space for evolution. By acting as an umbrella over previous initiatives, and by actively building interfaces with other European Partnerships, research infrastructures and global programmes, it aims to strengthen Europe's global position in brain health research.

Improved brain health for all

At its core, EP BrainHealth is guided by a simple and well-articulated vision: improved brain health for all. This aligns closely with the World Health Organisation's definition of brain health as 'a lifelong, functional state encompassing cognitive,

sensory, emotional, behavioural and motor domains, irrespective of the presence or absence of disorder'.

The partnership's mission is explicitly research-driven. It will support brain health research and innovation by strengthening transnational collaboration and alignment. At its core, it also promotes the translation of results into tailored solutions for prevention, diagnosis, treatment and care that are accessible to all.

This dual focus of collaboration and translation is what differentiates EP BrainHealth from many previous efforts to coordinate brain health research. Rather than treating research, innovation and implementation as sequential or separate, the partnership is structured to support progress along the entire translational value chain. The work goes from fundamental research through clinical research and proof of concept to implementation science.

Crucially, the partnership recognises its limits in terms of the implementation of its outcomes. Implementing solutions within healthcare systems always depends on political decisions at national and regional levels. "But the partnership is designed to ensure that research outputs are relevant, accessible and visible to those who can take them forward – and that largely comes down to developing a community and to effective communication," Bathe points out.

Strategic priorities

The SRIA defines four research priority areas, which together reflect Europe's most pressing brain health challenges.

The first focuses on promoting brain health and preventing disease, grounded in a deeper understanding of brain development and functioning across life stages. The second addresses early detection, diagnosis, monitoring and treatment, recognising the need for improved insight into disease mechanisms and pathophysiology.The third priority shifts attention to care, support and quality of life – emphasising translation into clinical practice, patient involvement and equitable access to care. The fourth priority integrates social, ethical and legal dimensions, explicitly embedding social sciences and humanities into neuroscience research. "These aspects are critical to the success of the partnership in the long term," Bathe stresses. "They are essential if results are to be accepted by society and translated into real impact."

Across all four priorities, a set of cross-cutting themes, including data standardisation, access to high-quality data, participation, targeted treatment approaches and training the next generation of researchers, ensures coherence and continuity in all activities. Digital technologies and data-driven approaches play a central role in this strategy and interdisciplinary research teams working on EP BrainHealth projects will be encouraged to leverage AI-powered tools, advanced computational protocols and multilevel datasets to improve disease stratification and prediction, paving the way for tailored healthcare.

At the same time, the partnership places strong emphasis on responsible research and innovation. Ethical, legal and societal implications, particularly around data sharing, privacy and neurotechnologies, are embedded throughout the work programme. The participation of the relevant research infrastructures, such as EBRAINS AISBL, plays a key role in supporting data harmonisation, standards and access.

The first two calls

The partnership's ambitions are translated into practice through joint transnational funding calls under the leadership of the French National Research Agency (ANR). The calls use a variable geometry model that allows funders to participate according to national priorities. The first two calls, launched in January 2026, are deliberately designed as a bridge between past and future priorities.

Both calls share a single overarching topic focused on factors influencing brain health trajectories across the lifespan, including biological, social and environmental determinants. Call One addresses neurological, mental and sensory disorders, while Call Two focuses on neurodegenerative diseases. (https://www.brainhealth-partnership.eu/calls/)

This approach allows continuity with NEURON and JPND funding streams in the partnership's first year, while already bringing communities closer together. In future years, this separation will be further reduced as the partnership moves towards fully integrated brain health calls.

The expected outcomes from these first calls are multi-dimensional and transnational collaboration is one of them: "We have more than 40 funders from over 30 countries committing more than €50 million to the first calls," explains Dr. Christina Müller, scientific officer in the coordination office. "This is a significant achievement in the current political climate in which funding for international cooperation is often constrained."

Equally important is translation, with EP BrainHealth fostering interdisciplinary and innovative approaches in fundamental and clinical research. By funding research projects along the entire translational pathway up to proof-of-concept studies and implementation-oriented research, the EP BrainHealth is laying the groundwork for later-stage developments, for example in collaboration with industry.

With these core expectations in place, the partnership has been explicitly designed to attract multidisciplinary actors with these first two calls from the outset. Beyond neuroscientists and clinicians, they actively encourage

participation from social scientists, digital health experts, patient organisations and other adjacent sectors.

One notable innovation to this participatory approach has been the possibility to include patient organisations as independent consortium partners in the new research projects, who can be supported by a dedicated EU budget where national eligibility rules would otherwise exclude them. This is intended to enable meaningful patient involvement from the earliest stages of research.

But engagement is not limited to funding calls. The partnership's work plan also includes platforms for capacity building, training, global outreach, private sector engagement and citizen involvement, with dedicated boards being established to support this ecosystem approach.

The message to potential stakeholders is clear: The EP BrainHealth is not a closed partnership. New partners, new funders and new collaborations will be integrated throughout its entire lifetime.

Looking ahead

This is a long-term vision designed to shape brain health research and deliver meaningful improvements to brain health over the next ten years. The ambition is healthier populations, improved wellbeing, better prevention, diagnosis, treatment and care, and scientific breakthroughs that are not only published, but also implemented and applied.

Within the BrainHealth ecosystem, success will mean EP BrainHealth becoming established as a trusted, collaboration framework, recognised internationally and capable of sustaining momentum beyond individual projects or political cycles. Achieving that needs scientific breakthroughs, societal relevance and engagement, and a structure that allows all of this to come together.

"For Europe's brain health community, and for disciplines that have not traditionally seen themselves as part of it, we face a big challenge: we need stakeholders to engage early and to work across traditional boundaries. With EP BrainHealth, we now have a partnership structure in place to enable collaboration to deliver lasting impact over the next ten years."

PROJECT INFORMATION

Project Title
EP BrainHealth – European Partnership for Brain Health

Project Objective
EP BrainHealth aims to deepen understanding of the brain in all its dimensions and to foster translation of research results into tailored, accessible solutions for prevention, diagnosis, treatment, and care. The partnership involves relevant stakeholders and strengthens transnational collaboration to increase and align investment in brain health research and innovation.

Project Duration and Timing
10 years: 1 January 2026 – 31 December 2035

Project Funding
Overall amount: ~ €500 million
Source: ~€345 million national contributions from partner organisations, ~€146 million co-funding from the EU

Project Partners
54 partners and 10 additional participants from 36 countries; primarily funding organisations and ministries

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BrainHealth PARTNERSHIP

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COMPASS-NMD: Structuring uncertainty in neuromuscular disease

Across Europe, thousands live with neuromuscular diseases marked not only by physical decline but by prolonged uncertainty. Under the coordination of Rossella Tupler at the University of Modena, COMPASS-NMD is confronting that challenge by combining deep clinical phenotyping with genomics, imaging and digital infrastructure to deliver more precise classification, earlier diagnosis and meaningful prediction – laying the foundations for a more structured, data-driven space in neuromuscular care.

Across Europe, thousands of people live with neuromuscular diseases (NMDs) that do not necessarily shorten life dramatically, but profoundly reshape it. The burden is physical, social and economic, and for many patients the most difficult part is not only the management of the symptoms they suffer, but the uncertainty they live with.

It is against this backdrop that the COMPASS-NMD project was conceived. Funded under Horizon Europe, the project brings together clinicians, geneticists and computational scientists across Europe to rethink how neuromuscular diseases are diagnosed, classified and ultimately understood. Rather than focusing on genetics alone, COMPASS-NMD is building a new framework that integrates deep clinical phenotyping with genomic, imaging and histological data to transform uncertainty into structured, actionable knowledge.

"We started this project after many years working with patients with neuromuscular diseases," explains Rossella Tupler of the University of Modena and coordinator of COMPASS-NMD. "These diseases severely impair the quality of life and although most patients do not die from them, they live very difficult life: these diseases progress over time, and patients may lose their independence, eventually becoming unable to walk or care for themselves. In general, they encounter many difficulties in movement and they struggle to participate fully in work and social life.":

Yet for many, these burdens are compounded by something less visible but equally disruptive: the long and often inconclusive path to diagnosis. Despite decades of genetic discovery, clarity in diagnosis remains elusive. Since the first Duchenne muscular dystrophy gene was identified, DNA analysis has become central to clinical practice. "Diagnosis today is largely based on genetic testing," Tupler explains. "However, despite this, the majority of people remain undiagnosed because no clearly significant gene is identified.

"At the same time, neuromuscular diseases are strikingly heterogeneous," she continues. "Some people have a very slowly progressing disease; others have a very severe form that begins early and leads to wheelchair dependence by the age of 20. This is completely different from someone who develops symptoms in their 50s."

This variability does not simply describe different clinical trajectories; it shapes entire life paths. Life expectancy and quality of life can differ dramatically depending on when symptoms begin and how quickly they progress. For some, independence is lost early; for others, decline is slower but no less disruptive. In all cases, the consequences are felt

Diagnosis today is largely based on genetic testing. Despite this, the majority of people remain undiagnosed because no clearly significant gene is identified.

well beyond the diagnosis, carrying social and economic implications that are impossible to ignore. "We must be frank: a disabled person who cannot move easily may have difficulty working, and there is a cost associated with this. There is also a burden on caregivers, so the social costs are very high."

Against this backdrop of uncertainty about how the disease progresses in different individuals, the COMPASS-NMD team came to a clear conclusion: the core issue is not simply genetic complexity, but clinical classification. As Tupler explains: "From my experience, having seen thousands of patients, I realised that it is very important to classify what we call the phenotype, that is, the way the disease presents."

This, she argues, is "crucial first for classification and second for prediction." Because without understanding how a disease presents in detail, it is impossible to anticipate how it will unfold. The questions patients ask are immediate and deeply personal: "If a person is 30 and begins to have difficulty lifting their arms, what will happen next? Will they be able to run, walk, climb stairs? Parents ask me these questions when they want to have children: what will happen? These are very big questions."

Deep phenotyping

The project was, therefore, built around a deliberate shift in emphasis. Rather than relying primarily on genetic sequencing and attempting to interpret it in isolation, the core idea was to standardise deep phenotyping with whole-genome analysis, MRI and histology.

"Our approach is based on standardised deep phenotyping, combined with whole-genome analysis, MRI, and histology," Tupler explains further. "MRI is a key instrumental tool for defining the clinical aspects of these myopathies, while muscle biopsy histology remains essential for subdividing patients into clinically meaningful groups."

This integrated approach allows the consortium to do more than assign labels. "By taking all these aspects together, we believe that if we can stratify patients properly, we can better understand who may respond to therapy, how the disease develops and potentially how to stop it."

The project also builds on data generated in earlier Horizon-funded initiatives, reworking them within a new framework of structured clinical phenotyping. Working with computational scientists, the team has developed artificial intelligence-driven algorithms to analyse multimodal datasets — clinical assessments, genomic sequencing, MRI imaging and muscle biopsy histology — identifying patterns across them. The model analyses all four domains simultaneously, searching for clusters of shared characteristics that define clinically meaningful subgroups.

Now, a new cohort of 500 individuals with myopathy is being studied across these same four domains. Data from their deep phenotypic and harmonised description, integrated with genomic, imaging ang histological pictures, will serve to validate the model, testing whether the algorithm can reliably stratify patients and generate clinically useful classifications.

For Tupler, this shift in approach was cultural as much as technical. "What is important is making a paradigm shift. Clinicians must start considering the phenotype in depth. You cannot rely only on DNA. In the same family, people can carry the same mutation but show no disease. This is a major challenge."

Structured intelligence

One of the fundamental problems COMPASS-NMD addresses is fragmentation — not a lack of data, but a lack of integration. Over the past decade, previous projects have amassed large collections of MRI scans, genomic sequences or muscle biopsy data. Yet these datasets were often generated in

isolation and, crucially, without standardised, structured clinical descriptions. As a result, researchers could analyse images or genes but struggled to link them reliably to how a patient's disease actually presented and progressed. "If you do not have deep phenotyping, how can you correlate what you see in MRI or DNA with the patient's actual condition?" Tupler asks. "Deep phenotyping is missing in most studies and that is the critical point we took on."

To resolve it, the team developed a comprehensive clinical evaluation tool, the Structured Clinical Report Form, containing over 200 structured items. Clinicians select predefined options, with interpretation being standardised. As Tupler puts it, "There is no 'fantasy' interpretation. It is essentially binary: it is present or it is not." By transforming subjective clinical observation into harmonised, structured data, deep phenotyping becomes the anchor that allows imaging, genomics and histology to be meaningfully aligned. This structured input enables computational scientists to build robust algorithms on coherent datasets rather than disconnected fragments. The result is not only diagnostic refinement, but predictive modelling.

ATLAS: a European repository for neuromuscular intelligence

At the heart of this digital infrastructure lies ATLAS, a centralised repository designed not simply to store data, but to integrate and structure it in a way that makes meaningful clinical interpretation possible. "We developed ATLAS as a repository where all anonymised and pseudo-anonymised data are collected in a standardised way," Tupler explains. "Each patient is assigned a code linking clinical examination, MRI, DNA and histology. Data are then analysed at the Silesian University of Technology, in Gliwice, Poland, with results returned to ATLAS."

In effect, ATLAS becomes the operational core of the project's approach, the point at which deep phenotyping, imaging, genomics and histology converge. By ensuring that every dataset follows the same structured logic, it transforms what were once isolated streams of information into a coherent system capable of classification and, ultimately, prediction.

The long-term ambition for this approach extends beyond the life of the project. "ATLAS is designed to become a repository for the wider community. In the future, once validated, other clinicians could add patients and this would create a centralised European resource."

Tupler draws a comparison with the US cancer repository, The Cancer Genome Atlas or TCGA, which has grown over time into a cornerstone of oncology research. In Europe, she observes, sustained infrastructure funding remains more difficult. "There is no stable mechanism to support them long term." Yet without continuity, infrastructures like ATLAS, designed to turn structured data into structured intelligence, cannot fully realise their potential. And without that stability, data-driven transformation in health systems remains fragile.

Shortening the diagnostic odyssey

For patients, the implications of this work are immediate. Neuromuscular diseases are often characterised by prolonged diagnostic journeys, with many years of referrals and uncertainty. The project hopes that this can now change. A clinician could input a new patient's data into ATLAS and receive an informed classification. "The aim is that, by inputting a patient's data into ATLAS, a clinician can receive an accurate interpretation quickly, and this should improve diagnosis."

Over time, the predictive power of these interpretations will only strengthen. If patients with identical genetic profiles are identified at different ages, likely progression trajectories can be inferred. While not equivalent to a full longitudinal study, such modelling offers meaningful clinical insight.

The broader impact on therapy development is equally significant. "Stratification is essential for therapy development," says Tupler. "If you do not stratify patients, treatment effects may be diluted." By identifying homogeneous subgroups, the platform supports biomarker discovery, response prediction and more targeted clinical trials. Even though COMPASS-NMD itself is a foundational research initiative, it provides a structured entry point for companies developing therapies.

As Tupler points out, the value lies in order: "It creates an ordered system, like organising books in a library so you can find what you need."

Beyond the science

For Tupler, the implications of COMPASS-NMD extend beyond improved diagnosis and classification. They also touch on how neuromuscular diseases are understood within health systems and public policy. Reflecting on earlier registry work, she explains: "For years I ran the national registry for

facioscapulohumeral muscular dystrophy. We calculated how much the state spends on it, while we also understood how much money could be saved, how budgets could be reduced, with better physical therapy.''

She also highlights the links that exist between social conditions and clinical outcomes. ''We realised that the people with lower education, lower income, are more affected,'' she says. ''They often receive later diagnosis and reduced access to care, and this contributes to worse progression.''

Improved classification and earlier diagnosis have the potential not only to reduce uncertainty for patients, but to influence how care is delivered and resources are allocated, easing pressure on families, caregivers and health systems alike.

''These are things that the politicians and the policymakers should know about,'' adds Tupler. ''Structured data and better stratification are not abstract scientific exercises; they are tools that should inform decision-making and I would like to have a channel with the policymakers.''

Training and the next phase

Alongside these policy implications, COMPASS-NMD also reflects a deliberate model of interdisciplinary collaboration. Geneticists, clinicians, computational scientists, legal and ethics experts work side by side. Precision medicine, Tupler argues, demands new forms of dialogue. ''Clinicians must explain challenges to engineers; computational scientists must explain their algorithms.''

For her, this exchange is essential. Genetics has evolved dramatically over the course of her career, and clinicians must now understand genomic individuality as routine. At the same time, computational scientists must grasp clinical complexity and uncertainty. The consortium even convenes roundtables with philosophers, a recognition that prediction in medicine carries ethical as well as technical dimensions. As Tupler puts it, the aim is to contribute to ''the generation of the new generation of scientists.''

The project has now entered its validation phase. The cohort of 500 patients with neuromuscular disease who currently have no diagnosis is being recruited. For each, clinical, genomic, MRI and histological data are collected, harmonised and analysed within ATLAS. By the project's conclusion, the expectation is that clinicians will be able to input structured data and receive meaningful classification – the first operational proof of principle for the COMPASS-NMD model.

Ultimately, however, the project's ambition is human as much as scientific. ''The ultimate goal is to improve quality of life, to reduce confusion and fear, to shorten the diagnostic odyssey, and to enable better follow-up and participation in society,'' concludes Tupler.

If successful, COMPASS-NMD will have demonstrated that deep phenotyping, digital integration and structured analysis can turn fragmented datasets into clinically useful knowledge. But the remaining question is sustainability. As Tupler notes in relation to European infrastructures, ''There is no stable mechanism to support this work long term and for initiatives like ATLAS, only continuity will determine whether proof of principle becomes lasting transformation.''

PROJECT INFORMATION

Project Title
Computational Models for new Patients Stratification Strategies of Neuromuscular Disorders

Project Objective
CoMPaSS-NMD is developing a new multidimensional approach to better understand and, therefore, diagnose hereditary neuromuscular diseases. Leveraging artificial intelligence to analyse vast amounts of patient data—including genetic and clinical data, MRI scans, and muscle biopsies—clinicians can identify patterns and correlations that might otherwise be missed.

Project Duration and Timing
48 months (01/05/2023– 30/04/2027)

Project Funding
HORIZON-HLTH-2022-TOOL-12-two-stage, Grant Agreement n° 101080874; €4,956,701.25

Project Partners
Universita Degli Studi Di Modena E Reggio Emilia (Unimore), Italy,
Politechnika Slaska (Sut), Poland,
Fondazione Stella Maris (Fsm), Italy,
Fundacion Tecnalia Research & Innovation (Tec), Spain,
Ludwig-Maximilians-Universitaet Muenchen (Lmum), Germany,
Centre Europeen De Recherche En Biologie Et Medecine (Cerbm), France,
Samfundet Folkhalsan I Svenska Finland Rf (Sff), Finland,
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CoMPaSS-NMD

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LEAPS: Modelling the decisions behind pandemic response

The COVID-19 pandemic revealed not only the speed at which science can respond to a global crisis, but also the complexity of decision-making in uncertain and rapidly evolving situations. The **LEAPS** project brings together experts from multiple disciplines to model how pandemics unfold, how policy choices interact and how societies react to crisis interventions. Projects Magazine speaks with project coordinators **Nico Vandaele** and **Catherine Decouttere** about how these insights could help Europe respond more effectively to future pandemics.

When the COVID-19 pandemic swept across the world, governments were forced to make decisions at extraordinary speed, often with incomplete information and under intense public and media pressure. Scientific collaboration accelerated at unprecedented speed, vaccines were developed in record time, and global attention focused on public health as never before. Yet the crisis also exposed gaps in coordination, communication and decision-making that complicated the response across many countries.

The **LEAPS project** – Learning from Epidemics and Pandemics to Strengthen Preparedness and Response Systems – was created to address precisely that challenge. Rather than developing vaccines or diagnostics, the project takes a step back to examine how societies respond to health crises, how decisions are made under pressure, and how lessons from past outbreaks can be captured and used to improve preparedness for the future.

At its core is a simple: the experience of COVID-19 should not fade into institutional memory, but instead be transformed into practical tools that help policymakers respond more effectively to future pandemics .

"We want to capture the learnings," explains **Nico Vandaele**, of the **Access-To-Medicines Research Centre** at the **KU Leuven** and project co-coordinator. "And in those learnings, we have both the good and the bad. The good things we want to keep in policies for the future, but the bad things we find – things which went wrong or which could be improved – should be remembered and changed for next time."

Learning challenges

For many observers, one of the most surprising aspects of the pandemic was how quickly previous experience seemed to fade from institutional awareness. Earlier outbreaks – from H1N1 influenza to Ebola – had already revealed weaknesses in global preparedness, yet many

countries still struggled to coordinate their response when COVID-19 emerged. Part of the explanation for this delay lies in the distance between crises themselves.

"It was 100 years ago since we had the big pandemic," says **Catherine Decouttere**, research manager at the **Access-To-Medicines Research Centre** of the **KU Leuven** and project co-coordinator. "That is too long in a human life. We work in generations of about 30 years, so it was simply too far away from people's experience."

The perception that pandemics were unlikely to affect Europe also played a role. According to Decouttere, many societies had grown accustomed to a sense of stability that made such threats seem remote. "I have a feeling that the European population was almost reckless," she reflects. "There was a sense that nothing can really happen. It was only when the videos from Bergamo in Italy started circulating that people really woke up."

At the policy level, knowledge about past outbreaks often existed but remained concentrated among a small group of experts. As time passes, that knowledge risks being lost as individuals move on or retire. "You had people who understood the situation very well," Vandaele explains. "They knew what had happened and why certain decisions were taken. But the question is how you sustain that understanding for the future. You have to extract that knowledge from the experts' mental models and capture it so that it can be used by others – and LEAPS aims to do precisely that."

A systems perspective

What makes LEAPS different from many other pandemic-related research initiatives is its focus on systems rather than individual technologies or medical interventions. The project brings together experts in epidemiology, surveillance, public health, social sciences and systems engineering to examine how different elements of crisis response interact. Instead of looking only at how diseases spread biologically, the project explores how decisions, behaviour, communication and governance shape the trajectory of an outbreak.

"The whole idea is about connecting different scientific disciplines and making them available to policymakers," **Decouttere** says. "We want to create transparency and include the learnings of the past in the way decisions are made."

The central tool enabling this approach is **systems modelling**, a method that integrates multiple streams of information into a single analytical framework. These models combine epidemiological data with social and behavioural factors, allowing researchers to explore how decisions in one area can create ripple effects elsewhere. "If you push something in a system, it will bounce back," **Decouttere** explains. "You might implement a measure because it looks correct from a biomedical perspective, but you also have to understand what it leads to – how people react, what pressures arise, and what

unintended consequences appear. In that sense it may cause unexpected negative consequences, which are best known when interventions are designed."

This perspective emerged partly from **Decouttere**'s own research experience. Her earlier work on immunisation systems in Rwanda revealed that technical solutions alone rarely explain gaps in vaccination coverage. "We initially thought the problem was the availability of vaccines in remote areas," she says. "But it turned out that much of the issue was behavioural – people didn't necessarily know when they needed repeated (booster) vaccination or why it mattered."

That lesson proved equally relevant during COVID-19. Understanding how these dynamics played out in practice became a central part of the LEAPS research to understand how pandemic decisions unfold in practice. The LEAPS team has conducted extensive interviews and workshops with policymakers, health officials and scientists involved in the COVID-19 response. These discussions help reconstruct the sequence of decisions taken during the crisis, the information available at the time, and the pressures that shaped those decisions as they were taken.

"We talked to a lot of stakeholders in the countries involved," **Decouttere** explains. "We wanted to understand how decisions were made, what information was used, and how those conversations unfolded."

From this qualitative evidence, researchers construct **causal loop diagrams** that map the relationships between different factors in the system. These diagrams are then translated into quantitative simulation models capable of exploring how different decisions might affect the trajectory of a crisis. The project focuses on four countries – Belgium, France, Denmark and Greece – each of which experienced the pandemic in different ways. By comparing their responses, researchers can examine how national policies influenced outcomes.

"Neighbouring countries did not always respond in exactly the same way," **Decouttere** notes. "That allows us to see the effect of different policies and how they influenced the effectiveness of measures."

Once built, the models are validated by the same stakeholders who contributed to the research. "We bring the models back to them and ask: does this reflect what you experienced?" says **Vandaele**. "If the numbers come out and someone says, 'no way, this never happened', then we refine the model. We try to reach consensus about whether it captures reality."

This is important because LEAPS is modelling not only disease dynamics, but decision dynamics. Its aim is to reflect how choices are actually made in crisis conditions, how they are shaped by timing, uncertainty, pressure and imperfect information, rather than how decisions might appear on paper after the event. Grounding the models in the experience of those directly involved helps ensure that they capture the real explicit and implicit mechanics of policymaking, making them more useful as tools for future preparedness.

From COVID-19 to the next crisis

Capturing the past, however, is only the first step. So, while the initial modelling focuses on COVID-19, the project is designed to prepare for future outbreaks. The real purpose of the models is to allow policymakers to explore how similar decisions might unfold under different circumstances – including the next epidemic or pandemic, which may look very different from COVID-19.

To test the flexibility of their approach, the LEAPS team is extending the models to other disease scenarios, currently including influenza and West Nile virus. Each of these diseases introduces new complexities. Influenza represents a potential zoonotic threat, where viruses circulate between animals and humans, while West Nile virus highlights the role of environmental factors such as climate change through mosquito vector migration in shaping disease transmission.

"Disease X could be anything," **Decouttere** says. "So we start with COVID because it is in our collective memory, but then we look at other types of diseases that might emerge in the future."

The models can also incorporate new technologies that were not widely available during the early stages of the pandemic. For example, advances in genomic surveillance could allow scientists to detect new variants earlier, while targeted screening strategies could help contain outbreaks before they escalate.

"If we had detailed metagenomic surveillance across Europe, we might see variants emerging earlier," **Decouttere** explains. "We cannot predict everything, but we could have a much closer view of what is happening."

Understanding the human factor

One of the most distinctive features of the LEAPS approach is its emphasis on human behaviour. Pandemic responses are shaped not only by scientific evidence but also by political pressures, economic constraints and public trust. Ignoring these factors can lead to policies that look effective on paper but fail in practice. "Behavioural aspects can be part of the modelling," **Vandaele** says. "It is not only technological or medical elements. Citizens, healthcare workers, scientists and policymakers all have behaviour that influences what happens."

Vaccine hesitancy is a clear example of this dynamic. During COVID-19, public attitudes toward vaccination were influenced by communication strategies, social media narratives and perceptions of trust. "These mechanisms have many feedback loops," **Decouttere** explains. "Trust, information, social media – they all interact. And if you ignore them, you miss a very important part of the system."

By incorporating these behavioural dynamics into their models, LEAPS hopes to provide policymakers with a more realistic picture of how societies respond to interventions in any crisis. Measures such as vaccination campaigns, lockdowns or targeted screening do not operate in isolation. Their effectiveness depends on how people perceive risk, the trust they place in authorities and how they adjust their behaviour over time. Capturing these feedback loops allows the models to reflect not only the spread of a disease, but also how societal responses ultimately shape the course of an outbreak.

A tool for decision-makers

Ultimately, the goal of LEAPS is not to replace political decision-making but to support it. Scientists can provide evidence, models and scenarios, but final decisions remain the responsibility of governments. "What we do as scientists is propose possibilities," **Vandaele** says. "We put information on the table. Policymakers then combine that with their own judgement and political considerations."

The models offer a way to explore potential decisions before they are implemented in the real world. "Compared to real-life experiments, modelling is extremely cheap," **Vandaele** notes. "You can test scenarios on your computer without causing damage in the real world."

To make these tools accessible, the project is developing an online platform that will allow policymakers and practitioners

to interact with the models through a user-friendly interface. "We want an interactive learning environment," Decouttere says. "People can try different scenarios and see the consequences. That helps them understand the complexity of the system."

Although health policy remains largely the responsibility of individual countries, pandemics do not respect national borders. One of the ambitions of LEAPS is, therefore, to explore how better coordination across Europe could strengthen crisis response. Decisions taken in one country – whether related to travel restrictions, testing strategies or vaccination policies – inevitably influence what happens elsewhere, particularly in a highly interconnected region such as Europe. By modelling these interactions, the project allows researchers and policymakers to explore how different national strategies may affect one another.

In some cases, stronger coordination, such as aligning certain measures or sharing critical data and resources, could improve overall outcomes. In others, countries may need to respond differently depending on their circumstances, healthcare capacity or stage of the outbreak. "Coordination does not mean that everyone must take exactly the same decision," **Vandaele** explains. "But decisions should at least be aligned so that they do not work against each other."

Understanding those interdependencies is one of the key objectives of the modelling work. By simulating different policy combinations across multiple countries, LEAPS aims to highlight where cooperation can reduce barriers and ultimately strengthen Europe's collective resilience to future health crises.

This perspective reflects a broader shift in thinking about preparedness. Instead of focusing solely on individual threats, governments are increasingly considering how societies can respond to a wide range of emergencies, from pandemics to infrastructure disruptions. "The methodology can also be used for other crises," **Vandaele** says. "It could be applied to situations like nuclear contamination or disruptions to water systems. The same systems approach can help decision-makers understand complex risks."

Looking ahead

As the LEAPS project progresses, its immediate objective is to deliver a proof-of-concept platform that allows policymakers to explore pandemic scenarios and learn from past experiences. But its longer-term legacy may lie in changing how governments think about preparedness. By combining scientific evidence, behavioural insights and systems modelling, the project aims to make decision-making more transparent, more informed and more resilient to uncertainty.

"We want to bring science closer to decision-making," **Decouttere** says. "And to make sure that what we know – the lessons from the past – is visible and accessible to the people who have to act."

Whether the next global outbreak arrives in five years or twenty, the hope is that societies will be better equipped to respond. As **Vandaele** puts it, the goal is simple: "If we fill a portion of the gap that we observed during COVID, then we are adding value for the future."

PROJECT INFORMATION

Project Title
LEAPS - Learning and Adaptive European Pandemic Preparedness System

Project Objective
The goal of LEAPS is to demonstrate the value and feasibility of a proactive policy supporting the strategy for EU-based genomic health surveillance and emergency preparedness/response by delivering a system-wide stakeholder-validated proof of concept against pathogen X.

Project Duration and Timing
4 years, 01.10.2023-30.09.2027

Project Funding
3.000.000 €

Project Partners
Access-To-Medicines Research Centre (KU Leuven), Belgium
Statens Serum Institute, Denmark
Institut Pasteur, France
Hellenic Pasteur Institute, Greece
Rega Institute for Medical Research (KU Leuven), Belgium
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Vaccines, trust and the next steps for immunology

As researchers push vaccine science into new territory, from non-invasive delivery systems to immunotherapies for neurodegenerative disease, we delve into the latest edition of the Biochemical Society's publication The Biochemist. In a special edition, it examines the breakthroughs redefining immunology, alongside the social and behavioural challenges that will determine their real-world impact.

Vaccines have long been one of the defining achievements of biomedical science. They have eradicated smallpox and transformed the control of diseases such as measles, polio and influenza. They have also created a model of public health that is not only focused on protecting the individual from disease, but also on collective responsibility. The latest edition of The Biochemist, however, makes clear that the future of vaccination will depend on far more than continuing to develop new formulations in the laboratory.

Across a series of articles focused on vaccines and immunology, the publication, which is published by the Biochemical Society, explores a field being reshaped by the lessons of COVID-19, the demands of global access, the persistence of vaccine hesitancy and the emergence of precision immunology as a route to entirely new forms of treatment. Through this, we see a picture of vaccination as far more than a settled scientific approach of research and discovery. We see a picture of a dynamic and rapidly evolving area of research, engineering, communication and public engagement.

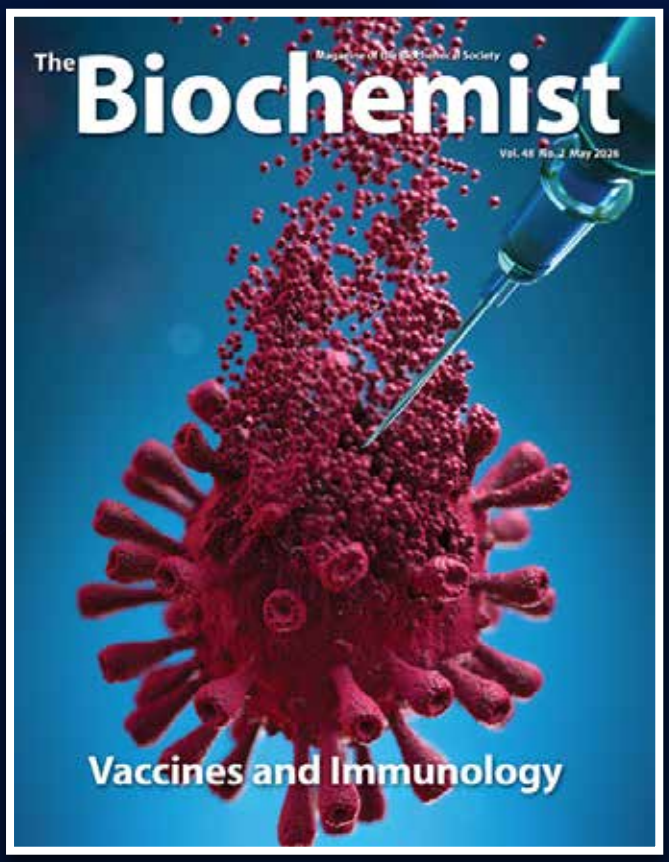
In her introductory editorial, Dr Kakoli Bose, Science Editor of The Biochemist, describes vaccines as "one of the most powerful and paradigm-shifting inventions of the modern scientific era." It is a statement that while setting the tone for the issue, is not one that frames it as a simple celebration. Together, the articles acknowledge that vaccines now sit at the intersection of scientific complexity and social challenge. Rapidly mutating pathogens, cold-chain requirements, manufacturing capacity, misinformation, fear and unequal access all shape whether immunisation succeeds or not in the real world.

One of the clearest examples is the development of needle-free vaccine systems. In "A gentle touch: engineering the future of needle-free vaccines", Ana Sara Cordeiro, a biomedical engineer and researcher specialising in advanced drug delivery systems at the University of Porto, examines how non-invasive delivery could make immunisation more accessible and practical, while also becoming more acceptable by the public. Most current vaccines still depend on needles, trained staff and careful disposal processes. By contrast, mucosal and transdermal systems offer the possibility of vaccines that are easier to administer, less intimidating for patients and more suitable for wider deployment.

This is not simply a matter of convenience. Needle-free technologies could help reduce barriers linked to fear, pain, workforce capacity and healthcare infrastructure. They also point to a more patient-centred model of immunisation, where vaccine design takes account of the practical and emotional realities that influence uptake. In this sense, the engineering of delivery systems becomes part of the public health solution.

That theme connects strongly with the Biochemist's article on vaccine misinformation. In "Why vaccine misinformation sticks: the emotional roots of vaccine hesitancy", Dr Daniel Jolley, Associate Professor in Social Psychology at the University of Nottingham, Dr Lee Shepherd, Associate Professor of Psychology at Northumbria University, and Anna Maughan, a researcher focused on misinformation and public attitudes towards vaccination at University of Cumbria, explore why misinformation is so difficult to dislodge once it takes hold. The key message here is that vaccine hesitancy is not driven by a lack of information alone. It is also shaped by emotion, identity, fear, distrust and the social environments in which people encounter health claims.

This matters because conventional science communication often assumes that better facts will automatically correct the ideas and beliefs people may hold, false or otherwise. The article suggests a more complex reality. If misinformation speaks to anxiety or mistrust, then communication must also engage with those emotions. Public confidence cannot be built only through correction;



it needs to be both credible as well as empathetic, while also demonstrating clear understanding of why people find certain narratives so persuasive in the first place.

Together, the needle-free vaccine and misinformation articles show that the future of immunisation depends on reducing barriers of many kinds. Some are technical: stability, delivery, scalability and manufacturability. Others are human: fear of needles, mistrust of institutions, emotional responses to risk and the influence of misinformation. Effective vaccination strategies will need to address both.

The Biochemist also pushes the idea of vaccination into a more unexpected space: the brain. In "Can we vaccinate the brain? The promise of precision immunology", Dr Damian Alvarez Paggi, a biochemist and structural biology researcher at the National University of La Plata, and Professor Salvador Ventura, Professor of Biochemistry and Molecular Biology at the Autonomous University of Barcelona, explore how precision vaccinology could contribute to next-generation immunotherapies for neurodegenerative diseases. Here, vaccines are not framed primarily as tools for preventing infectious disease, but as programmable interventions capable of directing the immune system towards specific pathological targets.

The article points to approaches such as rational antigen design, pathway-targeted adjuvants and modular delivery platforms. The aim is to generate durable, conformation-specific antibodies that can recognise toxic protein assemblies associated with neurodegenerative conditions, while avoiding harmful inflammation. This is a striking example of how vaccine thinking is expanding beyond its traditional boundaries.

The broader significance is that immunology is becoming increasingly precise. Rather than simply stimulating immunity, researchers are learning how to shape immune responses: where they act, what they recognise, how long they last and how safely they can be controlled. That shift has implications not only for infectious diseases, but also for chronic, age-related and previously intractable conditions.

This points to another a common theme that emerges in this edition of The Biochemist: vaccines are no longer only about the antigen. They are about systems. Delivery systems. Immune systems. Health systems. Trust systems. In other words, the scientific breakthroughs that make the vaccines possible are inseparable from the conditions needed to make them work in practice.

COVID-19 demonstrated the extraordinary speed at which vaccine science can respond to a global emergency. It also exposed weaknesses: unequal access, fragile trust, misinformation, logistical barriers and the difficulty of sustaining public confidence once the immediate crisis fades. The work highlighted in The Biochemist responds to these lessons by looking at both the molecular design of vaccines and at the social contexts in which they are received.

For the Biochemical Society, bringing these perspectives together is important. By giving space to researchers working on delivery technologies, behavioural science and precision immunology, The Biochemist helps highlight the breadth of modern vaccine research and the many disciplines now involved in shaping its future. Like this edition of Projects Magazine, it also gives critical exposure to individual scientific advances, as well as the wider ecosystem of ideas needed to turn discovery into public health impact.

The Biochemist is an essential read for anyone with an interest in the fundamental processes of molecular biology, health and disease. Each issue is themed around a key topic, exploring diverse themes and includes features reviewing the area, written by experts in the field. Acting as the voice of the Biochemical Society, the magazine also provides regular items on careers, policy and outreach. The magazine is published bi-monthly by Portland Press on behalf of the Biochemical Society.

To read the Vaccines and Immunology edition of this publication, visit ***https://portlandpress.com/biochemist/issue/48/2***

OPADE: Ending the trial-and-error era in depression treatment

Using clinical data, molecular biology and artificial intelligence, the OPADE project is working to predict how patients with major depressive disorder will respond to treatment – helping clinicians move beyond trial-and-error prescribing towards faster, more effective and more personalised care. Key project partners Giulio Corrivetti, Riccardo Panella and Alessandra Marenna explain this groundbreaking approach and the impact it could have.

For all the advances in modern medicine, the treatment of depression remains, in many ways, lacking the precision seen in other fields. Diagnosis is largely based on conversation, while treatment is often a process of trial and error, particularly when drugs are prescribed. For millions of patients, the path to recovery can be long, uncertain and deeply challenging, with treatment programmes that are often difficult to endure.

"Depression is a really big problem of our time," says Dr. Giulio Corrivetti, Psychiatrist and Principal Investigator of the OPADE project, and Vice President of the European Biomedical Research Institute of Salerno (EBRIS), as well as Director of the Department of Mental Health at ASL Salerno. "It is already one of the most common disorders in the world, and it may become the leading one in the years ahead. But for psychiatrists, it is still very difficult to characterise."

A systematic updated analysis on the prevalence and global burden of mental disorders from 1990 to 2023, within the Global Burden of Disease (GBD) 2023 study, published in The Lancet this year, demonstrated that in 2023, approximately 1.17 billion people worldwide are living with a mental disorder, nearly twice as many as in 1990. The increase in burden has mainly been seen in anxiety disorders and major depressive disorder.

At the heart of this mental disorder challenge is a fundamental gap: unlike many other areas of medicine, psychiatry still lacks objective biological markers to guide diagnosis and treatment. Where other specialities can draw on measurable data to inform clinical decisions, depression is still largely assessed through behavioural observation, patient narratives and clinician interpretation.

This reliance on subjective assessment inevitably introduces uncertainty into both diagnosis and treatment, shaping not only how the condition is understood, but also how it is treated and managed. "We have some bias from the subjective style of observation," Corrivetti explains. "We organise information from observation and conversation with the patient, rather than from biological data that can guide us. This makes it much more difficult to define the condition and to choose the most effective treatment."

The consequences are profound. Across Europe, only a small proportion of patients receive what could be considered optimal treatment. Many never reach specialist care at all. And even for those who do, the process of finding an effective pharmacological antidepressant treatment can take weeks or months. "If they don't see a response within a month, it's very hard to keep a patient on a drug," adds Professor Riccardo Panella, Head of Research at EBRIS. "So, if we can predict in advance which option will be most effective, we can improve both outcomes and adherence."

Biological insight

It is this ambition to move from reactive, trial-and-error prescribing to informed, predictive decision-making that sits at the core of OPADE. The project represents a shift in

how depression is understood and treated, moving from a predominantly behavioural model toward one that integrates behavioural parameters with biological markers, paving the way for a more detailed characterisation of the disease, integrating data and measurable indicators. It brings together clinical centres across Europe and beyond to build one of the most comprehensive datasets yet assembled in this field. Patients diagnosed with major depressive disorder are followed over time, with repeated assessments capturing both clinical progression and underlying biological changes.

"We recruited 350 patients, which is already a very strong cohort for this kind of study," says Dr. Alessandra Marenna, who leads the Microbiome Core at EBRIS and is part of OPADE coordinating team. "From every patient, we take behavioural data, biological samples like blood, stools, saliva, as well as other indicators."

The project is designed to uncover relationships that cannot be captured through any one type of observation alone. By combining biological, behavioural and clinical data, OPADE is building a more complete picture of the disease that reflects its underlying complexity rather than reducing it to a single set of symptoms. Genetics, microbiome composition, immune response and metabolic activity are analysed alongside behavioural assessments and patient-reported experience, creating a multi-dimensional view of the condition.

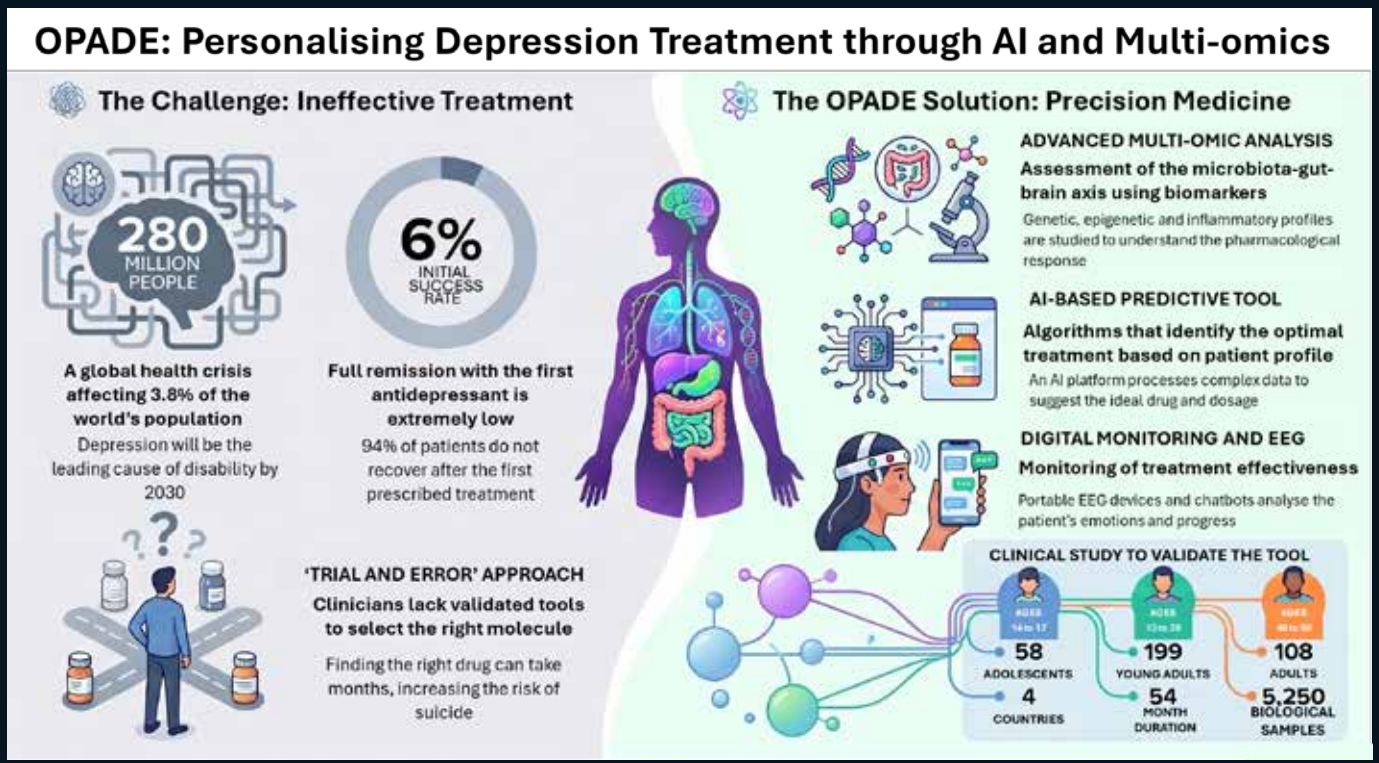
"There is a very large variability in depression," Corrivetti explains. "Genetic variability, behavioural variability and it is very difficult to connect these. We are looking to address this variability by bringing together the different layers of data to better understand how the biological and behavioural aspects of the disorder interact."

Crucially, this approach reflects a recognition that depression is not just a disorder of the mind, but one that is deeply rooted in the body. "The depression is in the mind, but also in the brain and in the body," Corrivetti adds. "So, from this type of analysis, we can gain the knowledge we need to change how we approach treatment."

The real breakthrough, however, lies not just in collecting this data, but in making sense of it. The biological, behavioural and clinical information gathered forms a complex multi-omics dataset, which captures the genetic, microbiome, immune and metabolic signals alongside patient experience. This is then integrated through artificial intelligence and machine learning, identifying patterns and correlations that would be impossible to detect manually.

"All these data together are fed to our AI partner," explains Riccardo Panella. "They find patterns and help us understand which biomarkers are more predictive than others — particularly in terms of how patients are likely to respond to different treatments."

Rather than searching for a single defining marker, the AI is identifying combinations — clusters of biological signals that, together, can predict how a patient will respond to treatment. "It might be one metabolite, three microbiome markers, two microRNAs," Panella further explains. "But all together, they become very predictive for response to therapy."



This iterative process allows the model to refine itself over time, narrowing down from a broad, exploratory dataset to a focused set of clinically useful indicators. "We started with an unbiased approach," adds Marenna. "Now we are filtering down to the biomarkers that can actually be used in practice."

Clinical decision-making

The ultimate goal for OPADE is to translate this analytical capability into a tool that can support real-world clinical decision-making. Today, antidepressant prescribing often begins without a clear indication of how a patient will respond, requiring weeks of observation before effectiveness can be assessed. In the OPADE vision, that uncertainty is replaced with early, data-informed guidance.

"Patients will take behavioural tests and provide biological samples, and then in a matter of days you can know which treatment will be most effective," says Panella. "This will allow clinicians to move more quickly towards the most appropriate therapeutic approach, rather than working through a sequence of options over time."

Crucially, this is not about reducing depression to a set of rigid categories. Instead, it reflects a deeper understanding of the condition's variability, not just between patients, but in how individuals respond to treatment. "We don't have just responders and non-responders," notes Corrivetti. "We have different levels of efficacy. Treatment response exists along a spectrum, shaped by the complex interaction of biological and behavioural factors."

"By identifying patterns within this variability, the system can begin to group patients into more meaningful subtypes," he continues. "Each one of these can then be associated with a different likelihood of responding to specific therapies."

The result is not personalised medicine in the sense of developing entirely new treatments for each individual, but a new knowledge that will allow for more precise patient stratification: matching patients to the therapies most likely to work for them based on their underlying profile. It is a shift away from one-size-fits-all prescribing towards a model that reflects the complexity of depression itself.

Faster response

For patients, this shift could be transformative. One of the most persistent challenges in depression treatment is the delay before antidepressants take effect — typically four to six weeks. During this time, many patients experience little improvement and may abandon treatment altogether.

"A lot of patients drop out after the first month," says Corrivetti. "But when they feel an effect in a few days, with energy and well-being, adherence to treatment plans improves dramatically."

By predicting effective treatments from the outset, OPADE aims to shorten the timeline between prescription and a patient beginning to feel the benefits of therapy. In turn, this has the potential to reduce both the duration and severity of depressive episodes, limiting the prolonged uncertainty that often characterises treatment.

"If we can show an effect earlier in the right group of patients," adds Marenna, "it becomes much easier to keep them engaged with the treatment. That improves adherence and ultimately leads to better clinical outcomes."

The implications extend beyond clinical practice. The absence of objective biological markers has not only shaped how depression is diagnosed and treated, but also how it

is perceived, contributing to a persistent stigma distinguishing it from many other medical conditions. Without measurable indicators, the disorder is often framed in subjective or personal terms, rather than as a clearly defined clinical condition.

By grounding depression in measurable biological processes, OPADE has the potential to shift that perception. "With a clear set of tests, we can approach the disease in a more objective way," says Panella. "This can give the disease the dignity of being defined with measurable parameters."

For Corrivetti, this reflects a broader need to reconnect the psychological and biological dimensions of the disorder. "Depression is in the mind, but also in the brain and in the body," he explains. "From this kind of analysis, we can gain the knowledge we need to change how we approach treatment. In a field still shaped by stigma, this shift could be significant and will help us reframe depression not as a personal failing, but as a complex, biologically grounded condition requiring targeted and informed intervention, just like other diseases."

Future discovery

While the immediate focus is on treatment response, the project's long-term value may lie in the data itself. The extensive multi-omics dataset being built will form a resource for future research, enabling new hypotheses to be tested and new therapeutic targets to be identified.

"We are collecting all the information we can," says Panella. "Even things we are not analysing today could become important in the future. This allows us to build a bank of samples, information and data that will be an added value for the entire scientific community and have the potential to support future analysis and research. This includes factors such as diet and the gut–brain axis, areas of growing interest in mental health research."

Ultimately, OPADE is about more than improving individual prescriptions. It is about aligning psychiatry with the broader shift toward precision medicine seen across healthcare. "The future is more personalised and closer to the patient," says Corrivetti. "We want to bring psychiatry in line with other medical disciplines, but this will take time. We have to consider regulatory frameworks, clinical guidelines and healthcare systems, and all will need to be adapted.

"But the direction of travel is clear," he continues. "Paving the way for new clinical practices based on biomarkers and multiomic approach."

OPADE is not just attempting to simplify the biological, psychological and social dimensions of depression, but to provide a framework for understanding them more clearly.

And, by combining clinical data, behavioural test, response to treatment biological data and AI, it offers a path beyond trial and error towards a future where treatment is faster, more effective and grounded in the individual realities of each patient. "This may mark the beginning of a new era in mental health care," Corrivetti concludes, "one where psychiatry finally joins the precision medicine revolution already transforming the rest of healthcare."

PROJECT INFORMATION

Project Title
Opade: Optimise And Predict Antidepressant Efficacy For Patient With Major Depressive Disorders Using Multi-Omics Analysis And Ai-Predictive Tool

Project Objective
Opades Objective Is To Identify Key Biomarkers That Support The Decision-Making Process Of The Healthcare Providers. The Project Focuses On The Microbiota – Brain -Axis Which Plays A Major Role In Mental Health And In Particular Mdd.

Project Duration And Timing
Start Date: 01/12/2022;
End Date: 31/05/2027

Project Funding
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Project Partners
European Biomedical Research Institute Of Salerno, Fondazione Ebris; Universita Degli Studi Di Siena; Fundacio Institut D'investigacio Biomedica De Girona Doctor Josep Trueta; Artificial Intelligence Expert Srl; Stichting Universitaire En Algemene Kinder; En Jeugdpsychiatrie Noord-Nederland; Eurecat; Ceinge Biotecnologie Avanzate Franco Salvatore Scarl; Istanbul Medipol Universitesi; Fundacion Universitaria Sanitas; Mama Health Technologies Gmbh; Perseus Biomics; Cephalgo; Protobios Ou; Biokeralty Research Institute Aie

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OPADE

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SmartCHANGE: Forecasting risk, changing behaviour, preventing Disease

Cardiovascular and metabolic diseases remain the leading causes of death, yet their roots often lie in childhood behaviour. **SmartCHANGE** is developing an explainable AI system that links a child's diet, physical activity and sleep patterns to long-term disease risk, giving health professionals a new tool for early intervention. We speak to project coordinator **Mitja Luštrek** of the **Jožef Stefan Institute** about how the project is reshaping prevention.

SmartCHANGE is building something that does not yet exist in paediatric medicine: a robust, explainable AI risk prediction system that helps health professionals identify which children, based on their current behaviours such as diet and exercise, are most likely to develop chronic disease so they can intervene before it becomes inevitable.

"The problem is that children often behave in unhealthy ways and, of course, down the line, this leads to all sorts of chronic diseases," says Mitja Luštrek, Head of the Department of Intelligent Systems at the Jožef Stefan Institute and project coordinator. "What we are trying to do is build a tool that allows doctors to evaluate better than they currently do whether a given child or adolescent is at risk and whether something should be done."

He is not dramatising the issue here, but the implications are stark. The chronic diseases he is referring to are not rare or marginal conditions, but cardiovascular and metabolic diseases – "these are the conditions that kill about a third of people, probably even more," he explains. Crucially, they are also largely preventable.

The logic behind SmartCHANGE is therefore deceptively simple: if cardiovascular and metabolic diseases are both widespread and preventable, then prevention must begin early, long before cholesterol levels, blood pressure and insulin resistance are firmly entrenched. Yet prevention in childhood has remained underdeveloped, particularly when it comes to systematic risk assessment.

For adults, predictive tools are abundant. "There are probably dozens of cardiovascular risk calculators, several for diabetes and many for other diseases," Luštrek says. "But there is nothing comparable for children."

This gap between what we can measure in adulthood and what we understand in childhood became the foundation for SmartCHANGE. The project's central ambition is to create a clinically usable system that enables health professionals to evaluate risk in children and adolescents more accurately and more consistently than they currently can.

He is quick to point out that this is not simply about raising awareness. Many clinicians and parents already know that physical activity, diet and sleep matter when it comes to children's health. The challenge lies in the fact that recognising these behaviours as important is not the same as knowing whether a child's lifestyle actually meets recommended standards.

"Research has shown that many health professionals are unfamiliar with guidelines," Luštrek explains. "Most of them do not know the guidelines for physical activity, for example.

Parents may also misjudge their child's health and many think their own children are healthy and leading healthy lifestyles when, in reality, they are not.

"They cannot judge whether a child's behaviour is appropriate or whether it requires change. Deciding what that change should be comes later."

For SmartCHANGE, this gap in perception is exactly where prediction becomes critical. The project is not simply encouraging healthier lifestyles in general terms; it is building a structured way to connect specific childhood behaviours with measurable future health risks.

The model is grounded in behavioural data because these everyday habits – physical activity, diet and sleep – are what ultimately shape long-term cardiovascular and metabolic outcomes.

By embedding that connection between daily behaviour and future disease directly into clinical practice, and combining systematically collected behavioural data with explainable analytics, SmartCHANGE aims to forecast risk in a way that is both scientifically rigorous and practically usable.

At the behavioural level, the focus is deliberately conventional. "Physical activity, diet and sleep are the three main behaviours we have included," Luštrek says. "We also touch on screen use, and we include some mindfulness in our application, but these are not the core elements.

"Physical activity, diet and sleep are not novel risk factors either; they are the foundational determinants of long-term cardiovascular and metabolic health. Our aim is to identify risk through current behaviour and to change that risk by recommending changes in behaviour that we know lead to healthier outcomes in the future."

To deliver this in practice, the project has developed two interconnected applications: one for children and families, and one for health professionals. The two are designed to work as a single system. The children's app gathers behavioural data through short nutrition questionnaires, sleep tracking via wearable devices, physical activity measurement and self-reported fitness information.

"These data are combined into a continuous behavioural profile," Luštrek explains. "When the child visits a health professional, further data are added: clinical measurements, health history, medications and lifestyle information. In some contexts, the system aims to connect directly to existing national fitness monitoring databases, streamlining data flow."

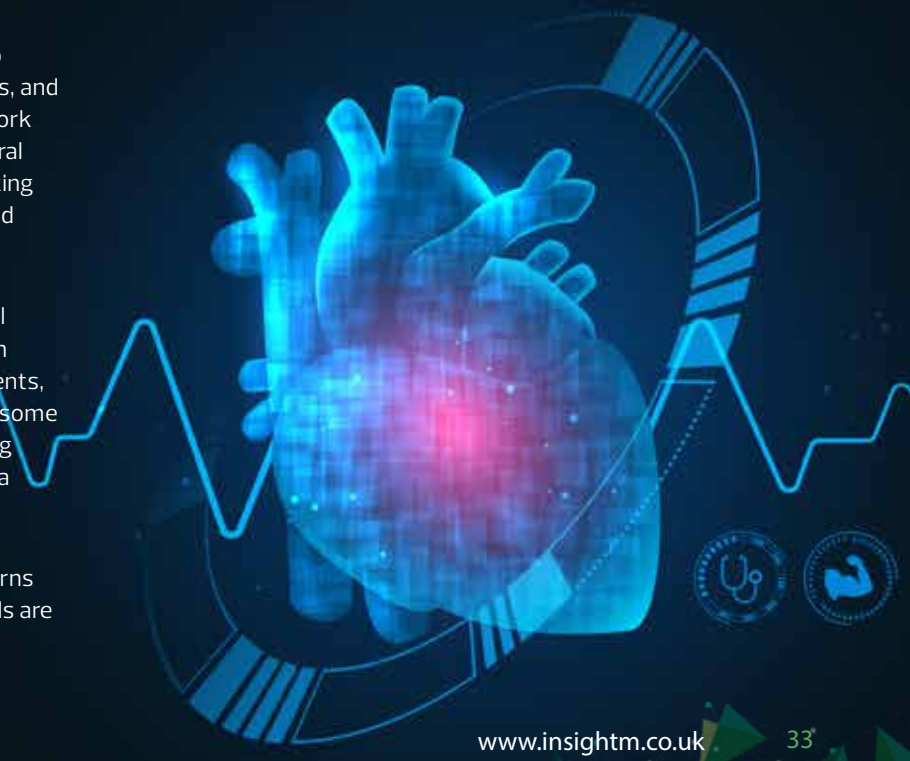
In practical terms, a child's daily activity and sleep patterns are tracked, nutrition habits are logged, and fitness levels are recorded. When they attend a consultation, whether with a paediatrician or a school nurse, the clinician accesses a dashboard that combines behavioural and clinical data into a single profile. From there, the system generates a structured risk assessment, highlights the behaviours driving that risk and allows concrete goals to be set, which are then transferred back to the child's app for ongoing monitoring.

The methodological challenge at this point is clear: there are currently no long-term datasets tracking children from early life through to the eventual development of cardiovascular disease. "Because there are no proper risk models for children and no long-term datasets that track children all the way until they develop disease, we have to forecast risk factors."

Rather than predicting disease directly, SmartCHANGE forecasts adult risk profiles. Using current child data, the system estimates what blood pressure, cholesterol, weight and related risk markers may look like at the age of 55. These forecasted values are then entered into established adult models, including SCORE2 and the Healthy Heart Score, along with a diabetes model.

The result is a quantified risk assessment, but one that does not operate as a black box, that is, a system that produces a score without revealing how it reached that conclusion. In many AI-driven systems, complex mathematical processes generate outputs that are difficult for clinicians to interpret or challenge.

A defining feature of SmartCHANGE, therefore, is its commitment to explainable AI. "We use explainable AI techniques to attribute risk to behavioural factors," Luštrek



says. "So we can say, for example, most of the risk is due to low physical activity and some due to diet, while sleep risks are fine.

"Instead of simply presenting a number, the system shows which behaviours are contributing most strongly to predicted future disease, making the output both interpretable and actionable for health professionals."

The system also generates "counterfactuals" – alternative versions of the same child's profile with lower predicted risk but otherwise similar characteristics. "This helps the health professional understand what is driving the risk and suggests interventions to move the child into a lower-risk state."

This emphasis on transparency emerged partly from empirical findings within the project. In one study, the team deliberately inserted errors into AI outputs to test clinical responses. "Doctors tended to trust AI too much. We intentionally inserted mistakes into outputs, and they did not flag them." The experience reinforced that explainability is not only about interpretability, but about encouraging appropriate scepticism.

SmartCHANGE has also demonstrated that its modelling approach performs "significantly better" than simple risk-factor flagging, such as high BMI alone, though, as Luštrek acknowledges, "it is still not perfect."

While the health professional interface represents the core innovation, behaviour change ultimately depends on engagement, and engagement, particularly among children, requires a different strategy. "Everyone agrees prevention is important – except perhaps the kids!"

Participatory design workshops across four countries ensured children's perspectives shaped development. When discussing risk communication, the consortium confronted a psychological reality: "Teenagers often believe they are immortal and discount negative outcomes, meaning fear-based messaging would be ineffective. Gamification then became central as kids don't care about health, they care about fun."

The result is the Happy Plant app. Children complete healthy challenges and receive "water" to grow a virtual plant; when fully grown, it joins a garden, and parents may link completion to real-world rewards. "Even adults who saw it said they would like to use it."

Beneath the playful game lies a serious behavioural insight. Habits formed in childhood persist, and identity shapes action. "If someone identifies as a healthy person, they behave accordingly. We don't only want to modify behaviours, but to reinforce healthy self-concepts during formative years."

From both a technical and ethical perspective, SmartCHANGE has proceeded carefully. Accessing existing datasets required extensive data-sharing agreements, while all new project data needed formal ethical approval. Before any wider

rollout, identifying information will be removed, and certain variables will be adjusted to reduce the risk of re-identification.

To further protect privacy, the project uses federated learning. Rather than pooling all data into a single central database, each country keeps its data locally and contributes to a shared model through privacy-preserving techniques such as differential privacy.

The system is also designed to evolve. Models can be retrained regularly and monitored for "concept drift", ensuring predictions remain accurate as behaviours and population patterns change over time.

As the project moves through its feasibility study phase, now being tested in Taiwan as well as in the original four European countries, attention has turned to sustainability. Integration with national fitness monitoring systems and e-health infrastructures appears the most promising pathway. The risk prediction engine itself is "likely the main exploitable outcome."

Yet perhaps the most grounded insight from SmartCHANGE is its realism about scale and pace. "Behaviour change is difficult and rarely dramatic," says Luštrek. "Risk prediction alone will not transform public health overnight. But embedding it consistently within healthcare systems, small improvements may accumulate.

"Children today probably lead less healthy lifestyles, partly due to digital devices and reduced outdoor play. If habits persist into adulthood, and if identity solidifies early, then prevention must begin long before disease manifests," he concludes.

SmartCHANGE does not promise immediate transformation. What it offers instead is a structured, clinically grounded system that connects childhood behaviour to lifelong health, making prevention actionable at the stage when it can still reshape a person's future rather than manage its consequences.

PROJECT INFORMATION

Project Title
SmartCHANGE: AI-based long-term health risk evaluation for driving behaviour change strategies in children and youth

Project Objective
Non-communicable diseases (NCDs) are the leading cause of death and healthcare expense. Rooted in childhood habits, SmartCHANGE develops AI-driven long-term risk-prediction models for cardiovascular and metabolic diseases in youth aged 5–19.

Project Duration and Timing
May 2023 – April 2027 (4 years)

Project Funding
€ 5 967 395,00 (European Commission—Horizon Europe)

Project Partners
Jozef Stefan Institute (coordinator)
ConnectedCare Services BV
Engineering SpA
Jyvaskylan Ammattikorkeakoulu Oy
Sitchting Amsterdam UMC
Technische Universiteit Eindhoven
Trust-IT Services Srl
-COMMpla Srl (affiliate entity)
Universidade do Porto
University of Piraeus University Center
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Smart CHANGE
Empowering Youth with AI for healthier lives

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FLUNIVERSAL: Rethinking influenza vaccination for a more predictable future

Influenza remains one of the world's most persistent infectious diseases, with existing vaccines often struggling to keep pace with an ever-changing virus. The FLUNIVERSAL project is using novel vaccine design, controlled testing models and scalable manufacturing technologies to deliver broader and more durable protection. We talk to key project partners about rethinking influenza vaccination and strengthening Europe's preparedness for future outbreaks and pandemics.

Influenza is one of the most persistent global health challenges and, despite decades of vaccination programmes, it continues to evolve unpredictably, remains difficult to contain and places a significant burden on both public health services and the global economy every year.

"Influenza is an enormous problem worldwide," explains Geert Groeneveld of Leiden University Medical Centre. "It causes significant sickness and mortality every year, with around 700,000 people dying annually. Even in countries with strong vaccination uptake, protection remains far from optimal at around 50%, meaning that even with vaccination, you still have a reasonable risk of infection."

At the heart of the FLUNIVERSAL project is this fundamental question: if vaccination programmes are widespread yet protection remains limited, is the problem simply vaccine uptake, or is the way influenza vaccines themselves have been designed really the main cause? So, rather than simply refining an approach that continues to deliver these inconsistent results, the project is exploring whether a different vaccination strategy could offer a more effective way forward.

Pipetting of immunological assays at Vivaldi´s lab

A moving target

The core difficulty lies in the nature of the virus itself and how it constantly mutates, shifting its structure in ways that allow it to evade immune protection. This forces vaccine developers into a reactive cycle. "Each year, vaccine strains are selected based on what is currently circulating," explains Amy Aspelund of Vivaldi Biosciences. "But if the virus mutates after that selection is made and people are then vaccinated, the vaccine used is far less effective than it should have been."

Having a system based on prediction rather than knowing exactly what virus is in play at any particular time means vaccine strains need to be chosen months in advance, manufactured at scale, and then deployed, only to sometimes miss the mark. In bad seasons, this means that protection drops sharply.

Compounding this is the fact that the underlying production process has changed little over time. As Ed Schmidt of Leiden University Medical Centre (LUMC) notes: "The vaccine being used today is essentially based on the same process developed over 80 years ago. It's a primitive vaccine, but it's cheap and safe and does provide some protection to many people."

Paradoxically, we have a system that works just well enough to be worth persisting with, but not well enough to address the underlying challenge of delivering broad and reliable protection across constantly evolving virus strains.

Beyond prediction

To break out of this reactive cycle, FLUNIVERSAL is taking a different approach. Rather than designing vaccines around the specific influenza strains expected to circulate in a given season, the project is investigating whether broader and more durable protection can be achieved by targeting elements of the virus that remain relatively unchanged over time.

The ambition is often described as a "universal" flu vaccine, although the consortium itself is careful not to overstate the claim. "Let's be honest," says Schmidt. "It's broad protection, not universal. We should not overplay our cards." Even so, achieving reliable protection across multiple strains, including those not yet circulating, would represent a major advance over the current seasonal model.

At the centre of this effort is a novel vaccine platform developed by project partner Vivaldi Biosciences. Unlike conventional influenza vaccines, which typically rely on selected viral proteins or fragments, FLUNIVERSAL uses a live attenuated virus, a weakened form of the virus engineered so that it cannot cause disease, but can still train the immune system to recognise and respond to infection. "We create a virus that is unable to replicate in humans," explains Aspelund, "but still expresses all the antigenic parts needed to induce a broadly protective immune response."

This approach allows the vaccine to mimic important aspects of a natural influenza infection without allowing the virus to multiply in the body and cause illness. But the innovation extends beyond simply weakening the virus. Researchers have also removed a gene that would normally help influenza suppress the body's first line of immune defence, effectively turning the immune response itself into an advantage. "The virus goes into the upper respiratory tract and immediately activates the immune response," Aspelund explains. "This creates a strong mucosal immunity exactly where infection would normally occur."

This differs from traditional injected vaccines, which primarily generate a systemic immune response. By stimulating protection at the point where influenza first enters the body, researchers believe they may be able to trigger broader and potentially more effective protection.

Targeting what doesn't change

A second innovation lies in how the vaccine directs the immune system's attention. Conventional vaccines tend to focus on the most visible part of the virus, the "head" of its surface proteins, which also happens to be the most variable.

FLUNIVERSAL takes a different approach. "The head changes constantly," explains Ingrid de Visser-Kamerling, of the Centre for Human Drug Research (CHDR). "But the stem is much more conserved. If you can target that part, the vaccine could work not just this year, but also in future years and across different strains.

"To achieve this, we use a prime–boost strategy, exposing the immune system to different viral variants in sequence. The effect is to steer immunity towards these conserved regions, potentially unlocking broader protection." Early data from this aspect of the project's work is encouraging. "We've


Testing in LUMC laboratory

seen broad cross-reactive antibody responses in humans," adds Aspelund, though she is quick to emphasise that larger efficacy studies are still to come.

If successful, the implications would be profound. As Manfred Reiter of Vivaldi Biosciences, puts it, "anything above 70–80 per cent protection would be a huge improvement over current vaccines."

Controlled testing

At the same time, FLUNIVERSAL is aiming to contribute more than a single vaccine candidate. The consortium is also developing a broader scientific toolkit intended to support how future influenza vaccines are tested, evaluated and improved.

One important element of this work is the development of controlled human infection models, where volunteers are exposed to influenza under carefully regulated clinical conditions. While the approach may sound unusual, the project believes it can provide critical early insight into whether a vaccine is genuinely protective before moving into much larger and more expensive trials. "If you vaccinate people and then challenge them with the virus, you can very quickly see whether the vaccine has real potential," explains Groeneveld. "If only one person becomes ill instead of seven or eight, then you know the vaccine is doing something important."

Alongside this, the project is also developing new animal models and working to identify stronger "correlates of protection". These are the measurable biological markers that indicate whether a vaccine is likely to work effectively. "We think these tools could help accelerate influenza research by making it easier to evaluate future vaccine candidates with greater confidence and consistency," says Groeneveld. "These outputs will contribute not only to this vaccine, but to influenza vaccine research worldwide."

Scaling up

For any vaccine to have real impact, however, it must also be manufacturable at scale, and this is another important element of FLUNIVERSAL's work. Most influenza vaccines are still produced using fertilised chicken eggs, a method that has changed little in decades and requires enormous specialised egg supplies to support global production. While effective, the approach is time-consuming and potentially vulnerable to supply disruption, particularly during a large-scale outbreak affecting animal populations.

FLUNIVERSAL is instead using a cell-based manufacturing approach, which researchers believe could provide a faster, more flexible and more scalable alternative. Once the genetic sequence of a newly emerging influenza strain has been identified, the system allows researchers to rapidly engineer vaccine candidates without relying on the lengthy egg-based production cycle used in conventional influenza vaccines.

"Within weeks, we can engineer new virus strains from sequence data," says Reiter. "And using established cell lines, we can scale production to millions of doses."

The implications for pandemic preparedness are significant. In a crisis scenario, speed and flexibility are critical. "If a new virus appears, we could produce a vaccine in weeks and begin large-scale manufacturing within months," he adds.

The model also lends itself to decentralised production. Instead of relying on a small number of large manufacturing sites or vulnerable international supply chains, vaccine production could potentially be distributed across multiple facilities in different countries. In the event of a future pandemic or supply disruption, this could help Europe maintain vaccine production capacity and respond more quickly to emerging outbreaks.

Rethinking delivery

Beyond efficacy and production, FLUNIVERSAL could also change how vaccines are delivered and improve how people experience the process of being vaccinated, moving away from injected doses to intranasal administration. "You could simply go to a pharmacy and receive a nasal spray," says Reiter. "It's a completely different vaccination strategy."

By reducing the need for injection-based administration in clinical settings, the approach could make vaccination easier to distribute across wider populations, including areas where access to healthcare infrastructure may be more limited.

"We also believe that this intranasal approach may offer another important advantage," says Schmidt. "Because

the vaccine is designed to generate immunity directly in the upper respiratory tract, where influenza infections typically begin and spread from, it may help reduce transmission as well as disease severity."

There are already early indications of this in animal studies. Vaccinated animals exposed to infected peers remained protected, even under close-contact conditions. "Even when co-housed with infected animals, the vaccinated ones did not get sick," adds Aspelund.

"If replicated in humans, this could represent an important shift: not simply reducing how ill people become after infection, but helping interrupt the spread of the virus itself."

Towards preparedness

Taken together, these different elements of FLUNIVERSAL all point towards something larger than a next-generation influenza vaccine. The project is also exploring how Europe could respond more quickly and more effectively to future influenza outbreaks and potential pandemics.

Faster vaccine design, scalable cell-based manufacturing, distributed production models and simplified nasal delivery all contribute to a system intended to move more rapidly than traditional influenza vaccine approaches have allowed in the past. Combined with the project's controlled testing models and broader scientific toolkit, the consortium believes this could help strengthen Europe's long-term preparedness capacity. "It's a good example of how experienced experts across Europe can work together with a common goal," says Reiter.

For Schmidt, this collaborative approach has become increasingly important in the years following COVID-19. "The EU realises that you cannot depend on big pharma and preparedness is a responsibility we need to take ourselves," he says. "It is not simply about the EU funding individual products, but about building the scientific, manufacturing and regulatory capabilities needed to respond rapidly when new threats emerge."

The project is now entering a critical phase. With vaccine candidates successfully manufactured, the focus is shifting towards first-in-human trials and controlled infection studies that will determine whether the early promise seen in preclinical work can be replicated in clinical settings. The underlying platform already shows potential for adaptation to other infectious diseases and future vaccine applications. "We've already explored expressing antigens from other pathogens," says Aspelund. "There's potential for a much broader product profile."

For now, however, the immediate ambition remains to develop broader and more reliable protection against a virus that has consistently outpaced conventional vaccination strategies. FLUNIVERSAL does not claim to have eliminated the challenge of influenza. But by rethinking how vaccines are designed, tested, manufactured and delivered, the project is attempting to address some of the structural limitations that have shaped influenza control for decades.

And if that approach succeeds, the impact may extend far beyond a single vaccine and help to reshape how future influenza outbreaks, and potentially future pandemics, are approached altogether.

PROJECT INFORMATION

Project Title
FLUNIVERSAL
Intranasal, rapid-acting vaccine for all seasonal and pandemic influenza viruses

Project Objective
Create the foundation of novel universal influenza vaccination by combining an innovative vaccine (DeltaFLU) based on our understanding of the viral interferon antagonist function of NS1 and a unique prime-boost immunisation strategy, enabling protection against all influenza viruses.

Project Duration and Timing
Start date 01 Jun 2023 for a 48 month project, to be extended in a submitted amendment with 12 months to 60 months

Project Funding
EU Horizon Health 2022 €7,567,787.50

Project Partners
Vivaldi Biosciences [Austria], Leiden Academic Medical Center & Center for Human Drug Research [The Netherlands], Statens Serum Institut [Denmark], VisMederi [Italy], Meditox [Czech Republic], Medicines and Healthcare products Regulatory Agency [UK], Zafiro [Hungary]

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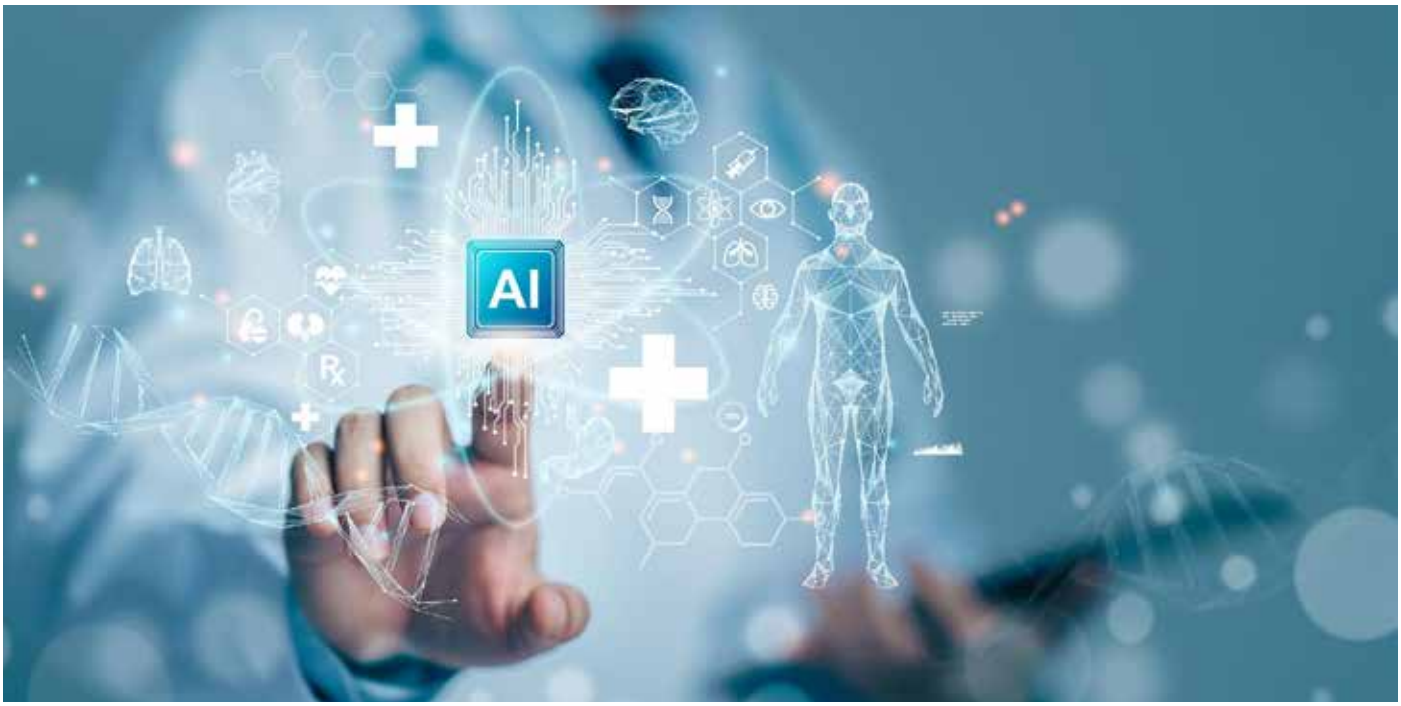


Designing trust into medical AI: from principle to clinical practice

Artificial intelligence has the potential to transform healthcare, but technical performance alone is not enough to secure clinical adoption. In A design framework for operationalizing trustworthy artificial intelligence in healthcare, researchers from Tampere University, Tampere Heart Hospital in Finland and TECNALIA in Spain, outline a practical framework for embedding trust, transparency and accountability into medical AI systems, helping bridge the gap between ethical principles and real-world clinical practice.

Artificial intelligence is increasingly capable of matching – and in some cases approaching – expert-level performance in medical diagnosis, prognosis and decision support. Yet despite this technical progress, the real-world clinical adoption of AI remains limited. The reasons are not primarily computational, but ethical, regulatory and social: concerns about transparency, accountability, bias, data governance and the erosion of human agency continue to undermine trust among clinicians, patients and healthcare providers.

In A design framework for operationalizing trustworthy artificial intelligence in healthcare, Moreno-Sánchez and colleagues address this gap directly by proposing a structured, design-phase framework that translates high-level Trustworthy AI (TAI) principles into concrete, actionable requirements for medical AI systems . Rather than treating trust as an abstract aspiration or post hoc compliance exercise, the authors argue that trustworthiness must be embedded from the earliest stages of system design if AI is to be safely and meaningfully integrated into clinical workflows.

From abstract principles to operational requirements

The paper is grounded in the widely recognised principles of Trustworthy AI, including human agency and oversight, technical robustness and safety, privacy and data governance, transparency, fairness, societal well-being and accountability. While these principles are well established in ethical guidelines and policy frameworks, the authors identify a persistent problem: they are rarely operationalised in ways that reflect the complexity of real healthcare processes or the diversity of stakeholders involved .

To address this, the authors propose a disease-agnostic design framework that maps TAI principles onto specific requirements across the main stages of care delivery — screening, diagnosis, prognosis, treatment and follow-up — and across the full ecosystem of healthcare actors. These include patients, clinicians, healthcare providers, AI developers, policymakers and regulators, each of whom engages with AI systems in distinct ways and with different expectations of trustworthiness .

A central contribution of the work is its explicit recognition that trust is not monolithic. Clinicians tend to prioritise human oversight, explainability and clinical accountability; patients emphasise privacy, transparency and robustness; while providers and regulators focus on fairness, safety, governance and compliance. The framework accommodates these differing perspectives by specifying tailored requirements for each stakeholder group, rather than assuming a single, universal notion of trust .

Stakeholder interaction as the core of trust

Rather than focusing narrowly on algorithms, the framework places stakeholder interaction at its centre. The authors show how AI systems mediate relationships between patients and clinicians, clinicians and healthcare organisations, and providers and regulators, with trust shaped through these interactions rather than by technical performance alone.

This emphasis is reflected in detailed mappings of how AI is used across clinical processes. In diagnosis and prognosis, for example, AI may support clinician decision-making by analysing complex data streams such as imaging, electronic health records or biosignals. In treatment and follow-up, AI systems may be iteratively updated as patient conditions change, introducing new challenges around oversight, accountability and model adaptation over time.

By grounding trustworthiness in these concrete use contexts, the framework moves beyond abstract ethical checklists and instead frames TAI as a dynamic, socio-technical property that must be negotiated continuously across the AI lifecycle.

Cardiovascular disease as a practical use case

To demonstrate how the framework can be applied in practice, the authors use cardiovascular disease (CVD) as an illustrative case. CVD remains one of the leading causes of mortality globally and is a domain in which AI has shown

particular promise for diagnosis and prognosis. At the same time, the authors note that many AI-based CVD solutions fail to address trustworthiness in a systematic way across their lifecycle, limiting their clinical uptake.

Within this use case, the paper illustrates how different TAI requirements manifest at different stages of care and for different stakeholders. For example, explainability becomes critical when clinicians must justify AI-supported diagnoses, while data governance and privacy are paramount when sensitive longitudinal patient data are used for model training or updating. The CVD case highlights both the feasibility of the proposed framework and the practical challenges involved in balancing competing requirements in real clinical settings.

Managing trade-offs in trustworthy AI

A key insight of the paper is that TAI principles often come into tension with one another. The authors explicitly reject the idea of a "one-size-fits-all" solution, instead identifying common trade-offs that arise in medical AI development. These include accuracy versus fairness, privacy versus transparency, and robustness versus explainability.

Rather than treating these tensions as failures, the framework encourages developers and stakeholders to make such trade-offs explicit and to manage them through informed design choices and stakeholder dialogue. For each identified trade-off, the authors outline potential mitigation strategies, while acknowledging that these decisions are inherently context-dependent and must be revisited as systems evolve.

Evaluation, regulation and the AI Act

The paper also highlights a critical gap between design intent and real-world performance: the lack of robust, principle-specific methods for evaluating whether TAI requirements are actually met. This challenge is not only technical but regulatory, particularly in light of emerging frameworks such as the EU AI Act, which classifies many medical AI systems as high-risk and subjects them to stringent conformity assessments.

The authors argue that meaningful operationalisation of TAI will require qualitative and quantitative evaluation frameworks that allow trustworthiness claims to be verified and audited. These may include stakeholder interviews, risk assessments, performance metrics and traceability mechanisms, providing the foundation for future certification schemes or trust labels in healthcare AI.

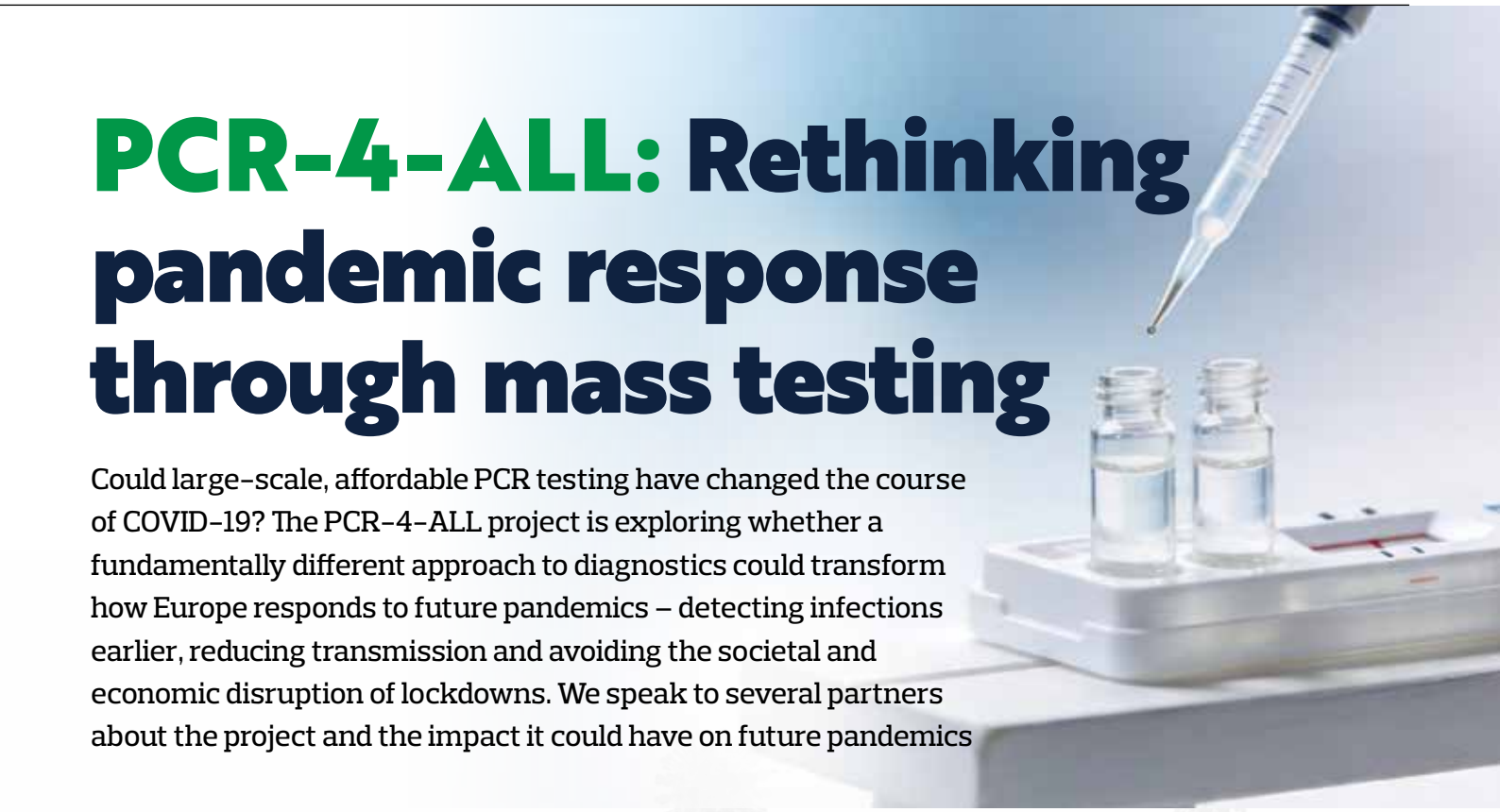
Broader relevance beyond healthcare

While the framework is developed explicitly for medical AI, the authors note that its underlying methodology is transferable to other high-stakes domains such as education, law, finance and social services. Each of these areas shares similar challenges: complex stakeholder ecosystems, sensitive data, regulatory oversight and significant societal impact. With appropriate domain-specific adaptation, the proposed TAI-by-design approach could support trust-aware AI development well beyond healthcare.

A foundation for responsible clinical AI

In conclusion, the paper positions its framework as both a practical guide for AI developers and a reference point for healthcare stakeholders seeking to demand more trustworthy AI systems. By translating ethical principles into operational requirements grounded in real clinical processes, it offers a structured pathway toward responsible, transparent and accountable medical AI.

As AI systems continue to expand into areas such as clinical decision support, patient communication and generative medical content, the authors argue that frameworks of this kind will be essential to ensuring that innovation aligns with patient safety, professional integrity and societal values. The challenge now, they conclude, lies in validating and extending these approaches through interdisciplinary collaboration and real-world deployment.



PCR-4-ALL: Rethinking pandemic response through mass testing

Could large-scale, affordable PCR testing have changed the course of COVID-19? The PCR-4-ALL project is exploring whether a fundamentally different approach to diagnostics could transform how Europe responds to future pandemics – detecting infections earlier, reducing transmission and avoiding the societal and economic disruption of lockdowns. We speak to several partners about the project and the impact it could have on future pandemics

At the start of the COVID-19 pandemic, the science moved fast. Within weeks of the virus being sequenced, PCR tests were developed that could detect infection with remarkable accuracy. And yet, despite this scientific success, the virus spread rapidly across the globe, overwhelming health systems and forcing governments into blunt, disruptive measures like full lockdowns and school closures.

For the researchers behind PCR-4-ALL, this disconnect pointed to a critical gap, not in scientific capability, but in how that capability was translated into real-world response. Xevi Casadevall i Solvas, project coordinator and PI at KU Leuven , the issue was not whether testing worked, but whether it could be deployed at the scale and speed required to make a meaningful difference.

"Everything started with the sequencing of the virus in early January," he says. "Then a couple of weeks later, there was already a PCR protocol to detect that virus and a few weeks after that, the pandemic was declared. Just a few weeks later, we had half the world in lockdown. And then after practically a full year, rapid tests started to become widely available."

By that point, the damage had already been done. "Vaccination began and somebody like me got the first shot after 3.8 million people had died."

The question that sits at the heart of PCR-4-ALL is, therefore, a simple one: what if large-scale, systematic testing had been available much earlier?

Proactive testing

During COVID-19, testing strategies were largely reactive. Individuals were tested once they developed symptoms, followed up by contact tracing and isolation. While effective to a degree, this approach struggled to keep pace with a rapidly spreading virus, particularly one capable of asymptomatic transmission.

"People who had symptoms were tested. If they turned out to be positive, then contact tracing followed and people stayed at home," says Casadevall i Solvas. "At some point, everybody was at home. This was not an effective way to manage transmission."

PCR-4-ALL proposes a fundamentally different model: population-wide, routine testing carried out early and systematically, rather than selectively and reactively. "Our idea is to implement population-wide testing early on," says Casadevall i Solvas. "That would allow us to isolate those who are actually infectious and maintain normal activity across society."

The implications of this shift are significant. Rather than relying on broad restrictions such as lockdowns, public health responses could become more targeted, isolating only those who are infectious while allowing society and the economy to continue functioning.

The limitations of PCR

At first glance, PCR may seem an obvious candidate for such a strategy. It is widely regarded as the gold standard for

diagnostic testing, offering high sensitivity and specificity. But as the pandemic revealed, its strengths at the individual level do not easily translate to population scale. "It's very simple," says Javier Martinez-Picado of IrsiCaixa and principle investigator. "PCR is not a test that has been designed to test a lot of people. It's more of a clinical test that helps diagnose individuals."

This limitation becomes stark when viewed in operational terms. As Martinez-Picado explains, even well-equipped hospital laboratories struggled to process sufficient volumes during the pandemic. "Most of the machines we have in hospitals to do PCR diagnostics cannot run more than 96 samples at once," he says. "Even if you run multiple cycles per day, it's not going to be more than 300 samples overall and that is nowhere near the scale of testing we need."

Faced with this constraint, the response during COVID-19 was to scale up existing infrastructure – buying more machines, expanding laboratory capacity – but without fundamentally changing the underlying model. "It was the best we had," he concludes. "But it was still not good enough for mass testing."

A new testing paradigm

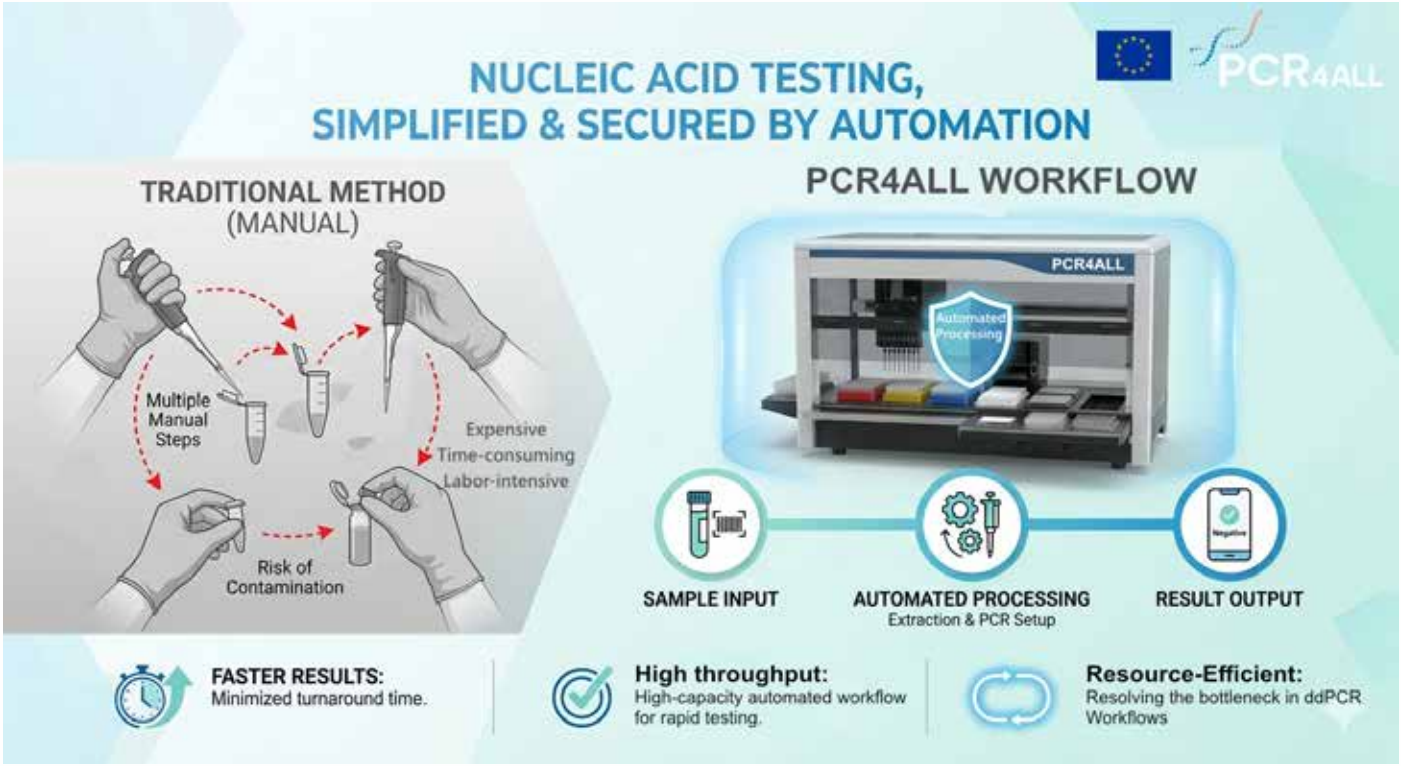
PCR-4-ALL seeks to overcome these limitations by rethinking the entire testing pipeline – from the collection of samples to processing and analysis. The project is built around three interconnected technological innovations, designed to work as a coherent system, with each addressing a different bottleneck in scaling PCR.

The first focuses on sample collection. Rather than relying on clinical settings and trained personnel, PCR-4-ALL focuses on developing saliva-based self-sampling strategies, enabling individuals to collect samples at home. "If we are talking about mass testing, people should be able to collect samples by themselves," Dragana Spasic of KU Leuven explains. "We opted for saliva because it is non-invasive, and it contains the targets we need to detect respiratory infections."

But the innovation goes beyond this convenience. The collection device is designed not only to stabilise the sample, but to prepare it for immediate integration into an automated processing system—removing the need for manual handling in laboratories and enabling the kind of scale PCR has traditionally struggled to achieve.

It is this seamless transition from collection to processing that underpins the second core component of PCR-4-ALL: a highly automated pipeline capable of analysing vast numbers of samples in parallel. Central to this is the concept of pooling, combining multiple samples into a single test within standard laboratory plates made up of multiple small compartments. "Each well would not contain one single sample," says Casadevall i Solvas. "It would contain, we estimate, around 30 samples. And by doing this repeatedly, we can process up to 100,000 samples in a short period of time, dramatically increasing throughput while reducing both time and cost."

The third innovative element of PCR-4-ALL addresses one of the key challenges created by pooling: how to retain individual



PCR-4-ALL aims to demonstrate basic technologies for fast, high throughput ddPCR supported by automated workflows and minimizing the need for manual processing

PCR4ALL Partners

Dragana Spasic
KU Leuven

Javier Martinez-Picado
IrsiCaixa and principle investigator

Mari Carmen Puertas
Immunobiologist at IrsiCaixa

Xevi Casadevall i Solvas
Project coordinator and PI at KU Leuven

results when multiple samples are analysed together. To solve this, the project has developed a novel reagent system that effectively labels each sample before processing and compartmentalizes them in small picolitre-sized droplets, allowing them to be combined without losing traceability.

"You have to imagine combinations of fluorochromes like a barcode that identifies each individual sample," explains Javier Martinez-Picado. "Once we run the PCR, we can determine the result for each person based on that barcode."

In practice, this means that even when dozens of samples are tested simultaneously within a single reaction, positive cases can still be traced back to the individual with precision. The approach preserves the sensitivity and reliability of PCR while enabling the scale and efficiency required for population-level testing – turning what is traditionally a one-sample, one-test system into a high-throughput, multiplexed process.

Together, these innovations create a system designed not only for scale but for rapid, actionable insight, enabling large populations to be screened in a matter of hours rather than days. The ambition is to process samples overnight, with results delivered the following morning, allowing potential cases to be identified before further transmission occurs.

"The goal would be that when you wake up, you get a message saying you have tested positive," says Casadevall i Solvas. "At that point, you would go for a confirmatory test."

This two-step approach is central to the PCR-4-ALL strategy. The initial test is designed as a high-throughput screening tool – fast, cost-effective and sensitive enough to identify likely infectious individuals at scale. Any positive result can then be verified using a conventional, highly sensitive PCR test, ensuring accuracy while avoiding the cost and complexity of applying gold-standard diagnostics to entire populations.

Balancing act

One of the more nuanced aspects of the PCR-4-ALL approach lies in how it redefines the role of diagnostic accuracy. While traditional PCR testing is designed for maximum sensitivity, detecting even very low levels of viral material, this level of precision is not always aligned with the needs of large-scale public health response.

"PCR is extremely sensitive," Casadevall i Solvas explains. "It can detect the virus at levels where you are not infectious and not sick, so you do not present a problem."

In a mass testing context, the priority shifts from detecting every trace of the virus to identifying those individuals most likely to transmit it. Rather than maximising sensitivity, PCR-4-ALL focuses on achieving the level of detection needed to act quickly and effectively at population scale. Crucially, this approach is not defined by a single test result, but by repetition. As Spasic notes, frequency can compensate for lower sensitivity. "If you have the capacity to do mass testing with a certain frequency, then you can compromise to some extent on sensitivity," she says. "You will still catch enough people who are infectious."

This balance between sensitivity, speed and frequency is central to making large-scale PCR testing both practical and sustainable.

Cost and resilience

Beyond technology, PCR-4-ALL also addresses one of the most pressing challenges exposed during the pandemic: dependence on global supply chains. "In the worst months of the pandemic, it was very difficult to get enough reagents," says Mari Carmen Puertas, an immunobiologist at IrsiCaixa. "We were dependent on big companies, and the reagents were very expensive. To address this, we have developed our own reagent formulations using patent-free components, significantly reducing costs. The idea is to reduce cost and to be independent of these big companies."

Early estimates suggest that these reagents could be up to 13 times cheaper than commercial alternatives. "And this is at a very early stage," adds Martinez-Picado. "We haven't even optimised production yet."

This combination of cost reduction and supply chain

independence is central to the project's broader ambition: making mass PCR testing economically viable at national and European scale. It is also what begins to shift PCR-4-ALL from a technological concept to a realistic public health strategy, one that can be implemented and scaled up.

With these technological foundations in place, attention turns to how such a system could be implemented in practice. PCR-4-ALL recognises that real-world impact will ultimately depend on policy decisions and system-level adoption. To address this, epidemiological modelling has been integrated by project partners at the Helmholtz Centre for Infection Research in Germany (Berit Lange and Carolina Klett-Tammen) and economic modelling by the University of Verona in Italy (Stefano Landi) and IDIAP JordiGol in Spain (Catia Nicodemo). This activity assesses not only whether mass testing is technically feasible, but whether it delivers measurable benefits and can be sustained over time.

A key output will be a comprehensive white paper, bringing together these findings. "We want to show that with this implementation, and with certain policies, this should work," says Casadevall i Solvas. "And that the cost is compatible with the economic model."

The project is also drawing on real-world experience from the COVID-19 pandemic to inform these models. One example is Luxembourg, which implemented large-scale testing with notable success. "Luxembourg had one of the lowest excess mortalities and avoided prolonged lockdowns," adds Puertas. "The idea is that what Luxembourg did, we could make every country look like that."

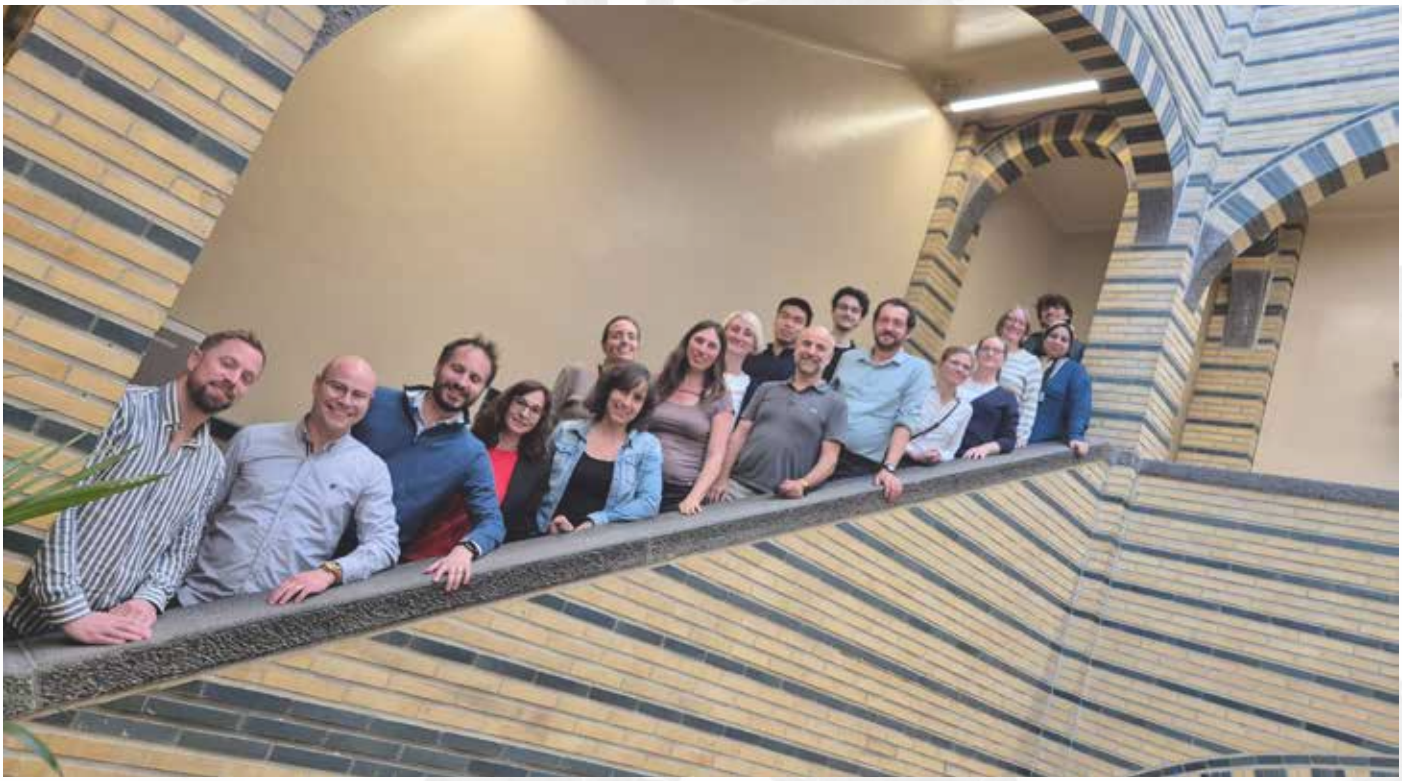
Luxembourg was able to sustain its strategy in part because of its size and resources, conditions not easy to replicate across larger or less well-resourced countries. PCR-4-ALL is designed to bridge that gap. "By dramatically increasing testing throughput while reducing cost and reliance on constrained supply chains, we aim to make this kind of proactive, large-scale testing strategy feasible across Europe," continues Puertas. "This will help transform what was, in Luxembourg, an exceptional case into a scalable model for pandemic response."

Beyond pandemics

Although PCR-4-ALL is rooted in pandemic preparedness, its potential applications extend far beyond crisis response. One area of interest is surveillance, not only in human populations, but also in animal reservoirs where new pathogens may emerge. "This could be useful not just for pandemics, but for surveillance of zoonotic viruses," says Casadevall i Solvas "Testing birds, pigs and other wild animals will help us detect threats before they jump to humans."

By enabling high-volume, cost-effective testing, the platform could support continuous monitoring at a scale that is currently impractical, providing early warning signals and enabling health authorities to act before outbreaks take hold.

There is also growing interest within the consortium in how the same technological principles could be applied to broader health screening. As Spasic explains: "The combination of speed and affordability opens up new possibilities for earlier intervention. Imagine using the same platform for mass screening of other diseases, catching biomarkers early, before symptoms appear." This points to a longer-term vision in



which testing is no longer triggered solely by illness, but becomes part of a more preventative, system-wide approach to health. Population-level screening could help identify changes in health status earlier, shifting the emphasis from treatment to timely intervention. "We have been discussing how this could be used more broadly," Casadevall i Solvas adds, "not just for infectious diseases, but as a way of monitoring health more generally."

While these applications remain at an exploratory stage, they highlight the versatility of the platform. The same characteristics that underpin PCR-4-ALL — scale, speed and affordability — could support a transition toward more proactive, data-driven models of healthcare, moving from reactive response to continuous population-level monitoring.

A uniquely interdisciplinary effort

Underlying the PCR4ALL project is an unusually diverse consortium, bringing together expertise from biology, engineering, epidemiology and economics. "This is a very comprehensive study," says Casadevall i Solvas. "We are trying to do something that is logistically and economically viable. And to achieve that, we need people from very different areas. "It's not easy to coordinate such a spread-out consortium," he admits. "But hopefully we will make something that can help us continue and further validate that this can work."

And if this diverse consortium does succeed, its impact could be transformative. By enabling early, large-scale detection of infectious individuals, it offers a pathway to managing pandemics without resorting to the disruptive measures that defined COVID-19. This could reduce transmission, ease pressure on health systems and ultimately save lives. In addition to this, it could also deliver the possibility of countries being able to maintain economic and social activity even in the face of a new outbreak. As Casadevall i Solvas reflects, "The idea is to implement large-scale testing much earlier, so that next time, we are ready."

PROJECT INFORMATION

Project Title
PCR-4-ALL - Impact and viability of a novel mass PCR testing method as a pandemic-fighting strategy

Project Objective
The aftermath of the SARS-CoV-2 pandemic has highlighted the need for improved preparedness against future pathogen outbreaks. PCR-4-ALL aims to analyze the benefits (health and economic) of early mass testing based on PCR, while at the same time developing key technologies to demonstrate its technical feasibility.

Project Duration and Timing
4 years. From 1 December 2022 to 30 November 2026

Project Funding
Funded under HE Pillar 2, Cluster 1 (Health). Total amount € 3 397 611.25

Project Partners
KU LEUVEN (Belgium)
HELMHOLTZ-ZENTRUM FUR INFEKTIONSFORSCHUNG (Germany)
UNIVERSITA DEGLI STUDI DI VERONA (Italy)
FUNDACIO PRIVADA INSTITUT DE RECERCA SOBRE IMMUNOPATOLOGIES-CAIXA, IRSICAIXA (Spain)
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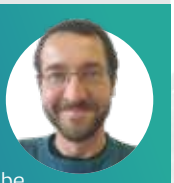

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PCR4ALL

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FORTIFIEDx: Bringing true sample-to-result diagnostics to the point of care

As healthcare systems look for faster and more accessible ways to diagnose infectious diseases, the **FORTIFIEDx** project is developing a new generation of point-of-care diagnostics. We speak with a few project partners about the novel technologies behind and how it could help bring reliable testing closer to the patient.

Healthcare systems around the world increasingly depend on rapid diagnostics. Whether identifying infectious diseases early, preventing the spread of outbreaks, or reaching populations far from clinical laboratories, the ability to test quickly and reliably at the point of care has become one of modern medicine's most pressing needs.

Yet despite decades of research and development, most point-of-care diagnostic technologies still fall short of delivering a fully integrated solution. Samples often need to be transferred, processed externally, or handled by trained personnel before a result can be obtained. In practice, the journey from sample to result frequently remains fragmented, costly and difficult to deploy outside laboratory environments.

The FORTIFIEDx project aims to change that. By combining novel sampling technologies, advanced microfluidics and integrated bioassays within a single disposable patch, the project is working towards what researchers describe as a true sample-to-result diagnostic system – one capable of performing the entire testing process autonomously at the point of care.

This innovation is driven by a clear objective: to overcome many of the practical barriers that still limit point-of-care testing today. "The idea is that we would like to develop a fully integrated disposable diagnostic patch based on microfluidics, to deliver a true sample-to-result test at the point of care," explains Dragana Spasic, Research Manager in the Biosensors Group at KU Leuven. "Because this sample-to-result concept is still mostly missing when we talk about true point-of-care solutions."

The FORTIFIEDx patch is designed to combine several processes that are usually carried out separately. Sampling, fluid handling, biochemical analysis and result generation are integrated into a single device intended to operate autonomously once activated.

"The idea behind this is to eliminate as much as possible the manual sample handling, external instrumentation and dependency on laboratories," Spasic says. "All of these aspects are very important if we're talking about point-of-care devices."

Decentralised diagnostics

The motivation behind FORTIFIEDx reflects broader shifts in global healthcare. Increasingly, clinicians and public health systems are looking for ways to move diagnostics closer to patients. Part of that shift stems from the continued

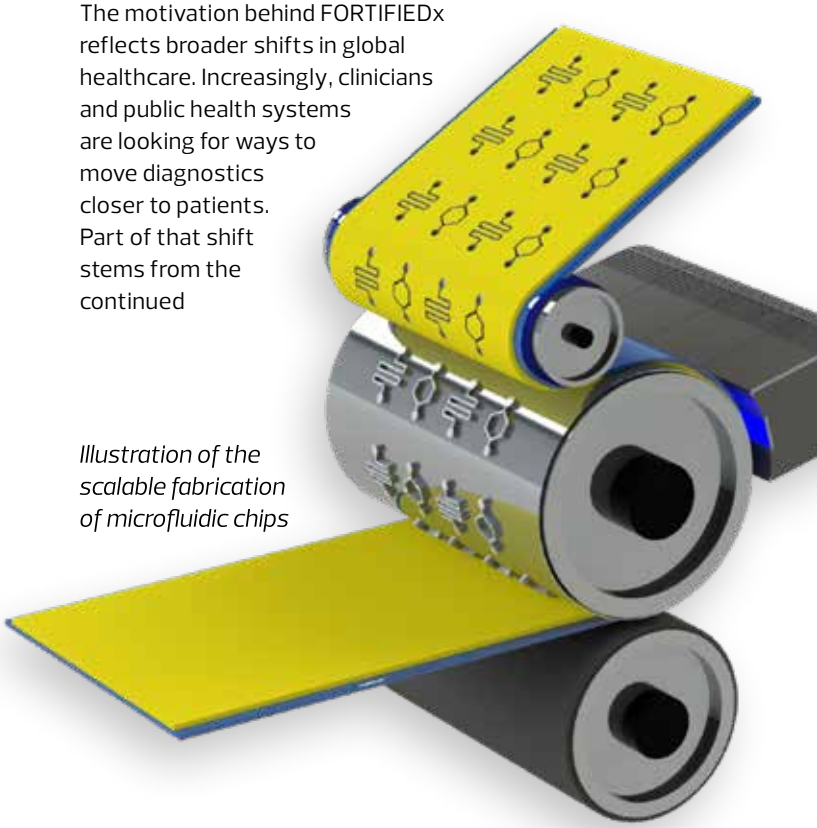


Illustration of the scalable fabrication of microfluidic chips

global burden of infectious diseases, including both established conditions and emerging pathogens. Another factor is the growing strain on laboratory infrastructure, highlighted starkly during the COVID-19 pandemic.

"While the demand for more decentralised care and better point-of-care solutions is clearly increasing, the technologies capable of delivering fast, reliable diagnostics directly at the point of care are still not fully there," Spasic explains. "At the same time, the need for them is becoming more urgent."

The urgency of that challenge is reinforced by a rapidly changing global landscape of infectious disease. Increased travel, environmental change and globalisation all contribute to the spread of pathogens across regions, placing greater pressure on healthcare systems to diagnose infections quickly and close to the patient.

For Dorien Van den Bossche, a microbiologist at the Institute of Tropical Medicine in Antwerp, these broader pressures are reflected in the ongoing challenges of diagnosing and controlling infectious diseases such as sexually transmitted infections like syphilis and HIV – diseases where timely and accessible testing remains critical.

"For syphilis, the latest numbers are certainly increasing," she says. "So there is a need for reaching underserved populations, for example, to really bring testing towards the people that need the test."

HIV presents similar challenges. While global trends show improvements in diagnosis and treatment, access to testing remains uneven. "UNAIDS has set a target to diagnose 95 per cent of people living with HIV by 2030," Van den Bossche notes. "But we already struggle with reaching those numbers, so we really see that there is a need to expand testing services."

Beyond these diseases, the diagnostic platform being developed in the project is also designed to address needs linked to emerging outbreaks, including viral haemorrhagic fevers such as Ebola and Lassa. "With the latest Ebola outbreaks, for example, we also noticed that there is a need to do safer testing at the point of care," she adds. "And there the FORTIFIEDx patch would really help, because you don't need a blood transfer anymore."

Safer testing is only part of the challenge. In many infectious diseases, the ability to diagnose cases quickly and close to the patient is equally critical. Early diagnosis not only improves patient outcomes but also helps limit transmission. As Van den Bossche points out, this is a common challenge across many infectious diseases. "The earlier you can get a diagnosis, the more you reduce transmission and prevent further spread."

DECIPHER consortium

Sample collection

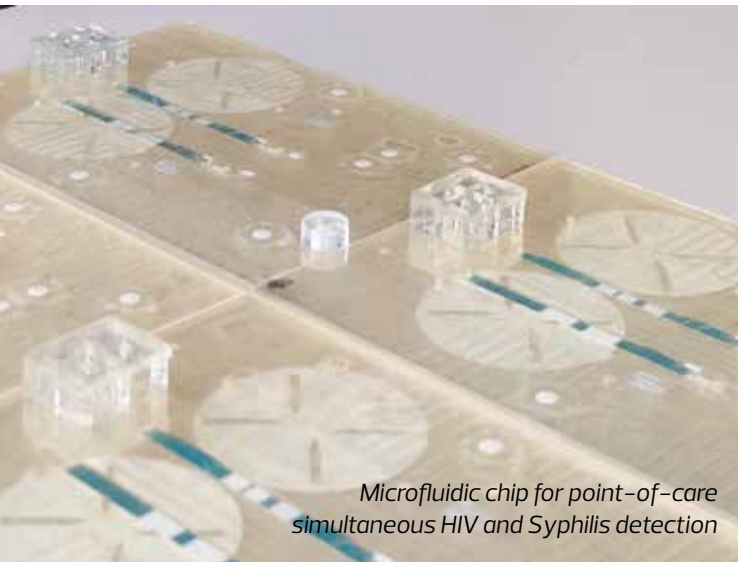
Meeting these challenges requires more than incremental improvements to existing diagnostic tools. FORTIFIEDx approaches the problem by rethinking how point-of-care testing can be carried out, from the moment a sample is taken through to the delivery of a result. One of the project's a few innovations in this sense lies in the way biological samples are collected. Instead of relying on traditional blood draws or finger-prick tests, the project integrates microneedle technology capable of extracting tiny quantities of interstitial fluid from the upper layers of the skin.

Developed by researchers at the Tyndall National Institute in Ireland, the microneedles offer a minimally invasive alternative to conventional sampling methods. "We're looking at microneedle technologies to remove tiny amounts of fluid from the upper skin layers," explains Conor O'Mahony, Principal Scientist at Tyndall. "This is in contrast to most diagnostic systems today, which rely on blood drawn from the finger."

For many patients, blood sampling is uncomfortable and sometimes a barrier to testing altogether. "No one likes taking blood," O'Mahony says. "It's painful, it's inconvenient, it's messy."

Microneedles operate on a different principle. Typically, around half a millimetre long, they penetrate only the uppermost skin layers without reaching nerve endings or blood vessels. "Because of that length, they don't strike the blood capillaries and they don't strike the nerve endings," he explains. "So the use is both painless and bloodless to the user."

The microneedles draw interstitial fluid, the liquid that surrounds cells within tissues. While less commonly sampled than blood, this fluid contains many of the same biological markers used for diagnostic testing. "That fluid is full of



Microfluidic chip for point-of-care simultaneous HIV and Syphilis detection

biomarkers," O'Mahony says. "Almost everything that you find in blood is also present in interstitial fluid."

The approach also addresses practical and social challenges associated with conventional needles. Around ten per cent of the population experiences severe needle phobia, a condition that can deter individuals from seeking medical care. "We call it trypanophobia," he explains. "And that prevents quite a number of people from taking medication, from undergoing diagnostic procedures and even from going to the doctor in the first place."

In addition, microneedles reduce the risk of needle reuse, an important safety issue in some parts of the world. "There's an enormous trade in used needles in many developing countries," O'Mahony says. "This technology eliminates that risk."

The microfluidic engine

Once the sample has been collected, the challenge becomes processing it automatically within the device. This is where FORTIFIEDx's novel microfluidic architecture comes into play. The system builds on iSiMPLE (infusion Self-powered Imbibing Microfluidic Pump by Liquid Encapsulation), a microfluidic platform developed by the KU Leuven Biosensors Group. The technology enables passive, finger-activated liquid handling without the need for external pumps or power sources, using pressure differences to move and control tiny volumes of fluid within the device. In the case of FORTIFIEDx, this enables complex biochemical reactions to be carried out on a compact chip in the patch.

"The big innovation is that we integrate everything into a standalone, self-powered device," explains Jeroen Lammertyn, who leads the Biosensors Group coordinating the project.

"Inside the patch, fluids move through networks of channels roughly the width 8 to 10 times larger than that of a human hair," Lammertyn explains. "These channels allow the system to measure, mix and process tiny volumes of liquid with remarkable precision."

Because each patient sample can vary, the system must also control exactly how much fluid enters the reaction. "You have to take a metered sample," he says, "and that sample may need to be diluted or combined with reagents."

In traditional laboratory systems, these steps require pumps, instrumentation and trained operators. FORTIFIEDx replaces that complexity with a self-powered mechanism driven by capillary forces. "We use capillary paper as a kind of engine," he says. "It creates pressure differences that allow us to move liquids through the chip and perform all the necessary fluid manipulations."

This approach avoids one of the limitations of many existing rapid tests, which rely on lateral flow strips where samples are drawn through porous materials. "In lateral flow systems, molecules you are interested in can stick to the paper," Lammertyn explains. "In our case, the sample itself moves through channels, while the paper only provides the driving force."

The result is a level of control over fluid handling that is rarely achieved in portable diagnostic devices. "We can do very complex liquid manipulations on just two layers of plastic bound with double-sided tape," he says.

Turning samples into results

Once the fluid is processed inside the microfluidic network, the system performs the biological analysis required to detect specific diseases. For sexually transmitted infections, the project integrates lateral flow assays capable of detecting both HIV and syphilis. Importantly, the syphilis component includes functionality not typically available in standard rapid tests.

"What is new compared to current self-tests is that we include a component that allows us to determine the activity of the disease," Van den Bossche explains. "Current tests usually only detect whether someone has been exposed to syphilis in the past, but they cannot distinguish between active disease and a previously treated infection, which can be critical for determining whether treatment is required."

In parallel, the system is also being developed to detect viral haemorrhagic fevers using molecular amplification techniques. Rather than relying on conventional PCR testing, which requires repeated temperature cycling to replicate genetic material, the project uses isothermal amplification, allowing the reaction to take place at a constant temperature.

For point-of-care diagnostics, that distinction is important.

Fortifiedx Partners

Jeroen Lammertyn
Biosensors Group Lead

Dragana Spasic
Research Manager in the Biosensors Group

Conor O'Mahony
Principal Scientist at Tyndall

Dorien Van den Bossche
Microbiologist at the Institute of Tropical Medicine in Antwerp

PCR systems typically require precise thermal cycling equipment, which adds complexity and limits where tests can be performed.

"We perform the assay at a single temperature using isothermal amplification," Spasic explains. "Because the reaction runs under constant conditions, it removes the need for the complex temperature cycling used in PCR systems, which makes the technology much easier to integrate into a portable diagnostic device."

Once the reaction has taken place, the result can be translated into a simple visual signal within the device itself. The system is designed to display the outcome in a familiar format, similar to a pregnancy test. "It's a qualitative result," Lammertyn adds. "So the answer is yes or no, simple to understand."

Making diagnostics accessible

While the technology behind FORTIFIEDx is complex, the user experience is designed to be straightforward. The device is applied to the skin like a patch. After sampling, the internal processes run automatically without further intervention and the result becomes visible after a short period. The aim is to reduce the level of training required to perform diagnostic tests as even relatively simple rapid tests can prove challenging for untrained users, as Van den Bossche notes.

"If you think about COVID tests, you had to add drops of buffer," she says. "Did I put one drop too many? Did I do it correctly? It creates questions."

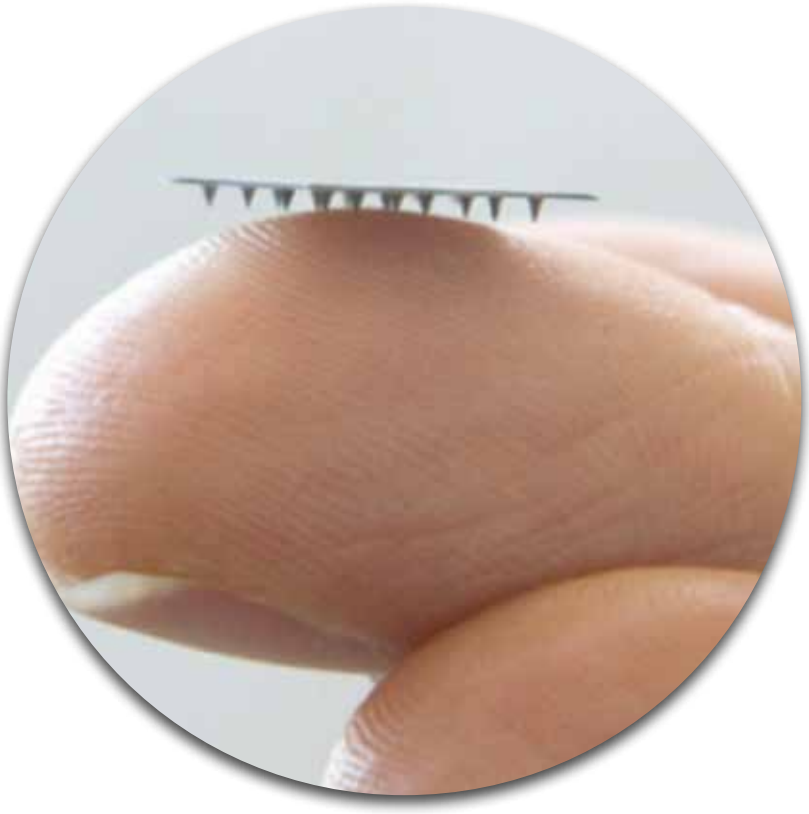
Handling blood samples adds another layer of difficulty. "It seems easy, but when you have to do it with lay users, it becomes much more complex," she explains.

By automating the entire process, including sample metering and reagent mixing, the FORTIFIEDx system could make testing more robust and reliable. "It would create more accurate test results compared to current rapid diagnostic tests when they are used by non-experts," she says.

Real-world deployment

Taken together, these design choices are intended to make the device simple to use outside traditional laboratory settings. By integrating sampling, fluid handling and analysis into a single patch, the system is designed to minimise the need for specialised training or complex equipment – an important consideration for point-of-care testing, particularly in underserved or remote regions.

The project is currently just over halfway through its development phase. According to Lammertyn, the individual components of the system are already taking shape. "We have developed many of the different modules," he says.



Microneedles for painless interstitial fluid sample collection

"Now the challenge is to bring them together and test them in real-life situations."

Those tests will take place not only in European laboratories but also in settings where access to diagnostics is limited. "The validation will also be done in developing countries, which will be supported by our ITM partner (Belgium) and CNFRSR partner from Guinea" he says.

Even with a successful prototype, however, significant work will remain before the technology reaches patients. Medical devices must undergo extensive regulatory approval processes, particularly when they incorporate invasive components such as microneedles. "We have to prove safety, reliability, sensitivity and specificity," Lammertyn explains. "Because we integrate microneedles, the regulatory pathway becomes more complex."

Navigating these regulatory requirements is a complex process that extends beyond the laboratory and this project scope. Universities typically work with specialist regulatory consultants and industrial partners who can help manage the approval pathway and prepare emerging technologies such as FORTIFIEDx for eventual market deployment. Despite these challenges, however, the project team is optimistic about its long-term potential. "Our aim is to deliver a strong proof of concept," Spasic says. "A prototype that clearly demonstrates the potential of this approach."

If successful, FORTIFIEDx could represent an important step towards a new generation of decentralised diagnostics. By bringing sampling, analysis and result delivery together in a single device, the technology is designed to make reliable testing possible in settings where laboratory infrastructure, specialist equipment or trained personnel may not be readily available.

That could have significant implications for how infectious diseases are detected and managed, particularly in communities where access to healthcare services remains limited and where diagnosis needs to happen closer to the patient rather than in distant laboratories. "In many settings, people have to travel long distances to reach a healthcare facility," Lammertyn says. "If they do that and they don't receive the result immediately, they may never come back."

Providing immediate results at the point of care could change that dynamic entirely, enabling earlier diagnosis, faster treatment decisions and reducing the risk of transmission. "And that," he adds, "is where this technology can bring real value."

PROJECT INFORMATION

Project Title
FORTIFIEDx: MULTIFUNCTIONAL MICROFLUIDIC PATCH FOR INFECTIOUS DISEASES DIAGNOSIS

Project Objective
By making use of novel biocompatible polymers and mass fabrication technology, the aim of the project is to develop a FORTIFIEDx microfluidic-based patch capable of biofluids (self-)sampling via hollow microneedles and immediate analysis of this sample on the very same patch in a completely self-powered manner, with the application in viral detection [in particular HIV and Syphilis and Ebola and Lassa viruses].

Project Duration and Timing
01/08/2023 – 31/07/2027 (48 months)

Project Funding
Horizon Europe HORIZON-CL4-2022-RESILIENCE-01-13
Project number: 101092049
Project budget: 4 986 072,05 Eur

Project Partners
KU Leuven (Belgium).
Joanneum Research (Austria).
Montanuniversität Leoben (Austria).
Polymer Competence Center Leoben (Austria).
Institute of Tropical Medicine Antwerp (Belgium).
Tyndall National Institute (Ireland).
Temicon (Germany).
Zdalny Serwis sp (Poland).
Centre National de Formation et de Recherche en Santé Rurale de Maferinyah (Guinea).

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FORTIFIEDx

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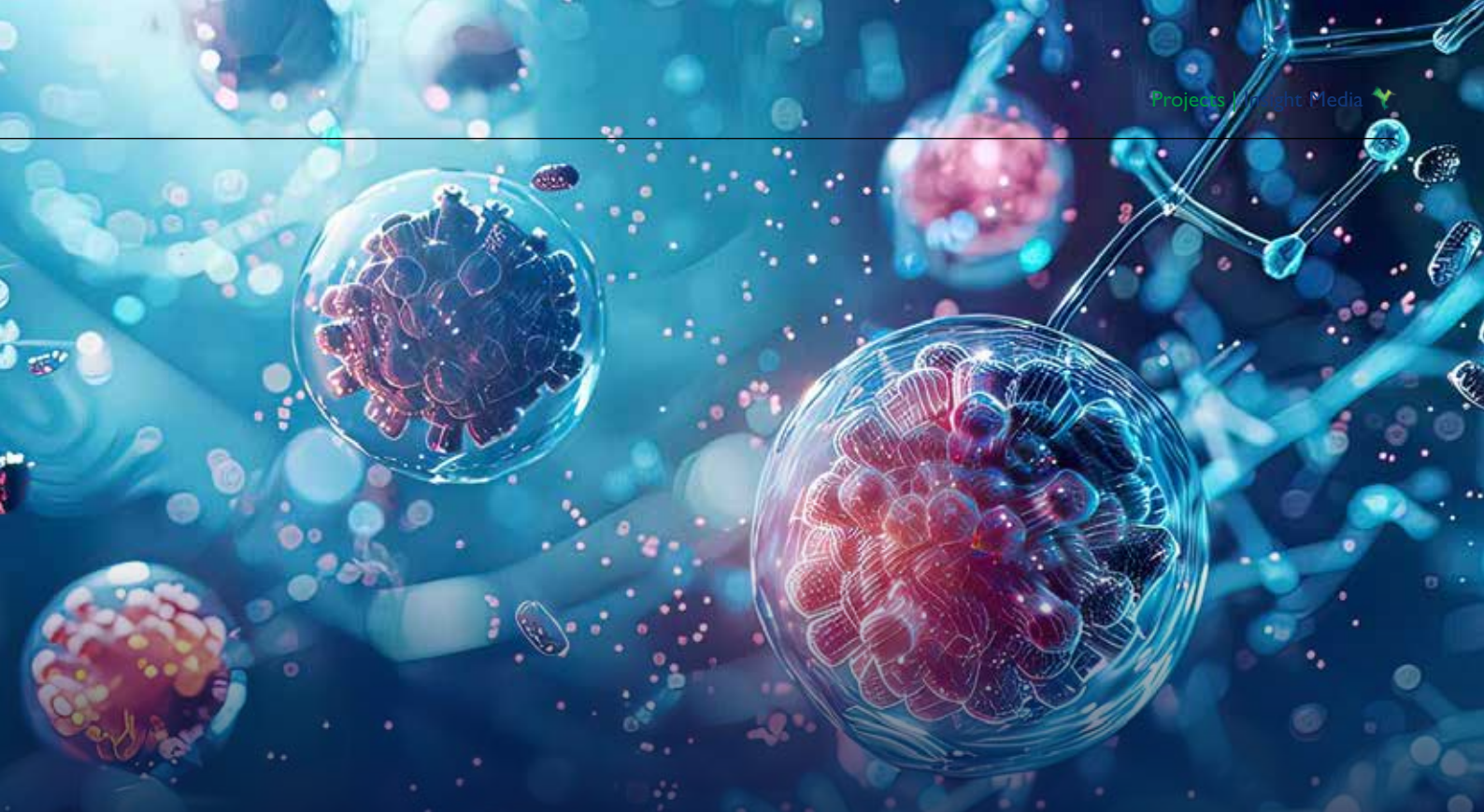


Cells found to fight infection from within

Scientists at the **Medical Research Council Laboratory of Molecular Biology** (MRC LMB) have described a previously unknown mechanism that allows cells to destroy bacteria and viruses after they have entered the cell, providing new insight into how the body protects itself against infection.

Published in Molecular Cell, the research identifies a process known as **antibody-directed xenophagy** (ADX), which enables cells to recognise and digest pathogens such as Salmonella bacteria and adenoviruses from within. The discovery challenges the traditional view that antibodies primarily function outside cells by marking pathogens for destruction by immune cells. Instead, the study shows that antibodies can continue to play a protective role after pathogens have crossed the cell membrane.

The process begins when antibodies attached to an invading pathogen are detected by a specialised protein called TRIM21. Researchers found that **TRIM21** labels the pathogen with ubiquitin, a molecular marker that alerts the cell to the presence of an invader and triggers its destruction through a cellular recycling process known as autophagy.

According to the research team, the mechanism appears to have broad activity. Experiments demonstrated that it could target both viruses and bacteria and was observed across a range of human cell types. Studies in mouse models also indicated that ADX-mediated immunity may operate widely throughout the body. The findings build on earlier work by MRC LMB researchers that first identified TRIM21 as a protein capable of enabling antibodies to combat viruses inside infected cells. The latest study provides what the researchers describe as the first detailed demonstration of how this intracellular defence pathway operates, from molecular mechanism through to physiological importance in living organisms.

Researchers believe the discovery could have important implications for the future development of therapies against infectious diseases. The study suggests that antibodies or small-molecule treatments could potentially be designed to mark pathogens for recognition by TRIM21, allowing the ADX pathway to be activated once infection occurs within cells. However, the team stresses that further research is needed before such approaches could be translated into clinical treatments.

Beyond its therapeutic potential, the work advances scientific understanding of immunity itself. The researchers suggest that ADX may represent not simply a backup mechanism that acts when pathogens evade other defences, but an important component of protective immunity in its own right. Future research will investigate whether additional proteins are involved in stimulating ADX and how broadly the mechanism can be applied across different pathogens.

IMMUTOL: Reprogramming immunity to move beyond management towards a cure for autoimmune disease

Autoimmune diseases have long been treated as conditions to be managed rather than cured. The IMMUTOL project is challenging that paradigm, developing a new form of cell-based immunotherapy designed to restore the body's natural balance. Project coordinator **Dr. Silvia Gregori** explains how this approach could redefine treatment for multiple sclerosis (MS) and beyond, and why patients are ready for this change.

For decades, the treatment of autoimmune disease has focused on managing symptoms rather than treating the cause. Therapies have been developed to suppress immune activity, control symptoms, and slow disease progression, often with meaningful benefits for patients, but rarely offering a lasting solution. The IMMUTOL project takes a different approach. Rather than dampening the immune response, it aims to retrain it.

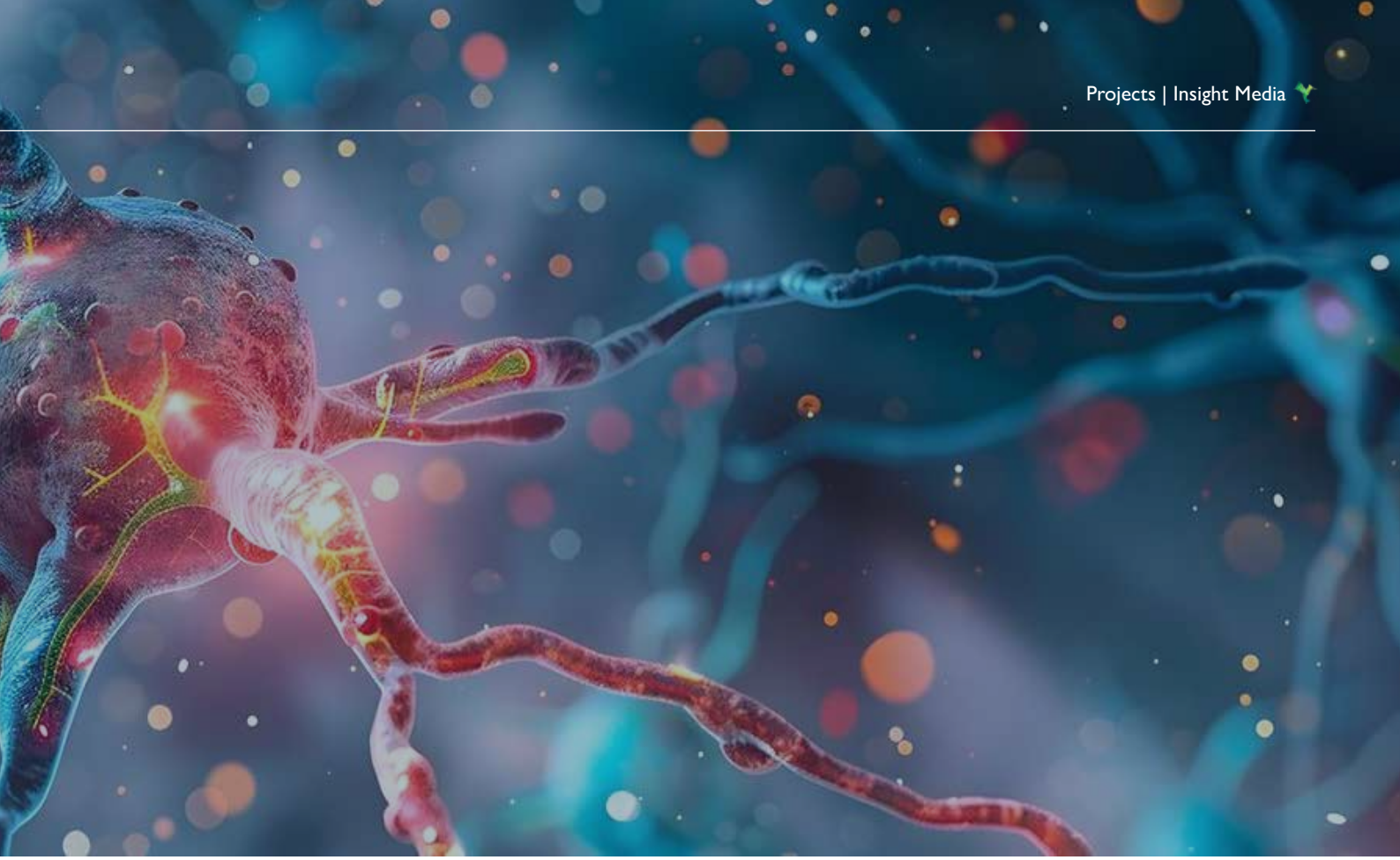
"At the moment, all the treatments that are applied to patients with an autoimmune disease like multiple sclerosis are focused on controlling the symptoms, but not the real cause of the disease," explains Dr. Silvia Gregori, Head of the Mechanisms of Peripheral Tolerance Unit at the San Raffaele Telethon Institute for Gene Therapy (SR-TIGET), and coordinator of the project. "So, despite the treatment patients receive, the disease still progresses. It may be delayed, but it is not stopped."

This distinction between control and cure is not just a clinical one. It shapes how the disease is experienced day to day. While treatments may slow progression, they do not remove the underlying risk, leaving patients living with the uncertainty of complex, long-term conditions. Over time, treatments evolve, often losing effectiveness, requiring patients to switch approaches while managing side effects that can be as disruptive as the disease itself.

"Patients take the medication, but they are not satisfied," Gregori explains. "Treatments control the disease, but patients have other symptoms, and what many tell me is that they know they are not cured."

"This is difficult for them, particularly for younger patients," she continues. "There is a persistent sense that the disease may worsen, even under treatment, and so they live with something on their shoulders, never knowing when the disease may progress."

"This reality of partial control combined with long-term uncertainty has created a space for new approaches like the one under development in IMMUTOL, which is looking not simply for better drugs, but for fundamentally different strategies."



A broken balance

At its core, IMMUTOL builds on a simple principle of how the immune system is meant to function. In healthy individuals, the immune system balances the need to respond to threats with the ability to stop that response at the right time. It can react aggressively to threats, but just as importantly, our immune system knows when to stop and switch off. In autoimmune disease, that balance breaks down.

"The immune system is educated not to attack our own tissues," Gregori explains. "In patients with autoimmunity, the mechanisms that control the immune homeostasis are broken, and the result is a sustained immune attack against the body's own cells – myelin in MS, insulin-producing cells in type 1 diabetes, joints in rheumatoid arthritis."

"What we propose in IMMUTOL is not to suppress this attack, but to restore the balance that prevents it," she continues. "If we can reinstall the balance, then the natural mechanisms will be reactivated, and the patient can be cured in the longer term."

Re-educating the immune system

To restore that balance, IMMUTOL turns to one of the immune system's most influential cell types: dendritic cells. These are the cells that decide how the immune system responds – whether to trigger an attack or to hold back. "They are critical for both the activation and the regulation of the immune response," Gregori explains. "If you have an infection, dendritic cells activate the immune system. But they are also responsible for switching it off." In autoimmune disease, the ability to restrain the response no longer works as it should. IMMUTOL's approach is to rebuild it. "The idea is to generate these cells in vitro, educate them to be regulatory, and then reinfuse them into the patient," she says.

That "education" process is central. Cells are taken directly from the patient's blood and guided, outside the body, into a state where they promote tolerance rather than attack. This is achieved using a combination of biological signals, most notably vitamin D3 and interleukin-10. "Vitamin D3 has already been used to generate tolerogenic dendritic cells," Gregori notes, referring to earlier clinical trials. "In IMMUTOL, we combine this with interleukin-10 to make these cells even more strongly regulatory."

The result is a cell designed not to suppress the immune system broadly, but to recalibrate it – to reintroduce the signals that control it. Crucially, these are not donor cells or synthetic constructs. They come from the patient themselves. "We use the same cells of the patient," Gregori explains. "We generate them from circulating monocytes, educate them, and then reinfuse them in an autologous setting."

This autologous approach avoids the risk of rejection and allows the therapy to work with the patient's own immune system, rather than against it. It is personalised in the most practical sense: each treatment is created individually from the patient's own cells. "What we are attempting, then, is not to override the immune system, but to remind it how to function as it was originally intended – restoring a balance that has been lost."

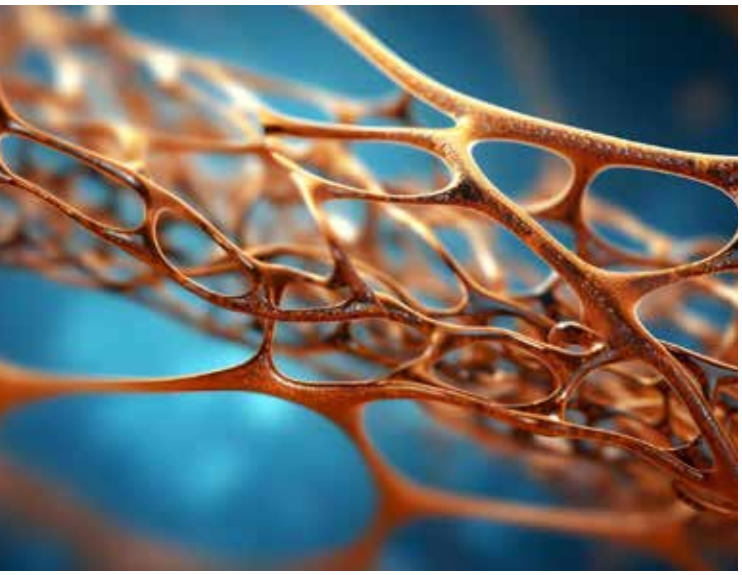
From concept to clinic

Translating this approach from lab success into a treatment that patients can use is another demanding challenge the project faces. Developing a cell-based therapy involves not only demonstrating biological efficacy but also navigating a rigorous pathway of validation, manufacturing, and regulation. The project is now well advanced along that road. "We have generated the new product, validated it in vitro, and performed in vivo studies in preclinical models," Gregori explains.

The next phase focuses on scaling up production under Good Manufacturing Practice (GMP) conditions, a critical step in preparing the therapy for clinical trials. Yet even here, the challenges are substantial. Unlike conventional pharmaceuticals, these are living therapies produced individually for each patient. "Production is patient to patient," she says. "The procedure is the same, but we need to produce the cells for each individual, and this introduces both logistical and economic challenges. It is this complexity that will ultimately shape how widely therapies like these can be deployed."

If successful, the implications of this approach could be profound. The immediate goal is to stabilise disease progression and reduce reliance on existing medications. Over time, however, the ambition is to eliminate the need for treatment altogether. "The best outcome would be that patients can gradually reduce their medication and eventually no longer need it at all," Gregori says. "At that point, you are no longer managing the disease – you are effectively curing it."

"There are limits to what can be reversed, particularly in diseases like MS, where tissue damage accumulates over time," she continues. "But even halting progression would represent a major advance."



Looking further ahead, Gregori believes the greatest potential in this work may lie in intervening much earlier in the disease process. "The best outcome would be to treat the patient before the onset of the disease," she says. "If we can restore tolerance at that stage, we could stop the disease before any damage occurs. That would mean moving away from treating symptoms and progression, towards preventing the disease altogether."

Patient response

One of the most striking aspects of IMMUTOL is not only the science itself, but the response it has generated among patients. Despite the complexity of the process and the fact that the therapy involves genetically modified cells, there is a clear willingness to engage. "I was completely surprised," Gregori admits. "Patients said to me, if there is this kind of approach tomorrow, I will take it."

For her, this response reflects the limitations of current treatments. "Patients are not simply looking for better ways to manage their condition; they are looking for something more," Gregori explains. "They are looking for something that offers the possibility of resolution rather than control, and they are open to new therapies that may finally give them that hope to be cured."

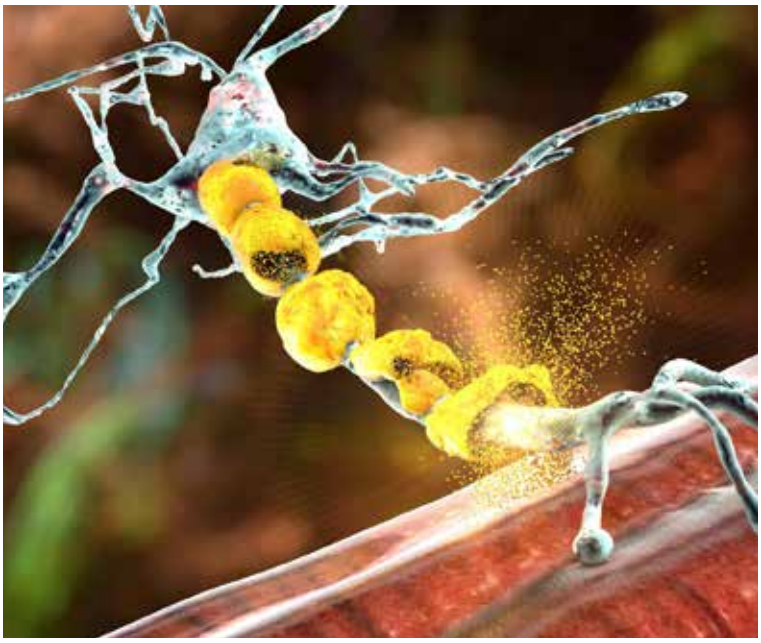
What emerges even more strongly, however, is a broader perspective on what this kind of research represents. Many patients recognise that therapies like IMMUTOL will take time to reach the clinic, and that they themselves may not ultimately benefit.

Yet that does not diminish their support. "They are not really focusing on themselves, but on the whole community," Gregori observes, suggesting a willingness by sufferers to support progress that may ultimately only help others and not necessarily themselves.

The cost of innovation

For all its promise, the path to real-world impact for IMMUTOL will not be defined by science alone. One of the most significant barriers facing IMMUTOL, and cell therapies more broadly, is the expense of production. Overcoming this barrier will require more than scientific progress alone. It will demand changes in how these therapies are funded, regulated, and brought to market, areas where European institutions have a critical role to play.

For Gregori, the challenge lies in the cost and complexity of bringing this type of therapy into real-world use. "The manufacturing cost is very, very high," she says, pointing to the realities of producing personalised, cell-based therapies under strict regulatory conditions. That cost creates a disconnect between scientific progress and investment. "When you start to discuss with venture capital, as soon as they hear about ex vivo cell therapy, they say the cost is too high," she explains.



Bridging that gap will require sustained engagement between researchers, regulators, and policymakers. Gregori points to ongoing discussions at the European level – particularly in fields such as gene therapy – where there is growing recognition that development pathways and cost structures may need to evolve if these treatments are to reach patients. "We need to continue the discussion with regulatory authorities and the European community," she says, "to find the right way to allow people to access these kinds of therapies."

A platform for the future

While IMMUTOL focuses on MS, its implications extend far beyond it. "The approach can be easily transferred to other autoimmune diseases," Gregori says, pointing to a wider field of conditions driven by the same underlying immune response imbalance. In that sense, MS serves as a valuable proving ground for the therapy and a way to demonstrate that immune tolerance can be restored in practice. "If that can be shown, the same principle could then be applied across a range of diseases," Gregori says. "We can treat many diseases, from type 1 diabetes to rheumatoid arthritis, where current treatments still revolve around long-term management rather than resolution."

For Gregori, however, this is not a standalone advance limited to autoimmune disease, but part of a broader shift already underway within the field. Researchers across Europe are working collectively to refine and extend these approaches, building a foundation for therapies that do more than suppress disease. "We are all working together in this direction," she says. "There is a growing community focused on making cell-based immunotherapies viable across multiple indications."

There are still significant barriers to overcome, particularly in cost and manufacturing, but the trajectory is becoming clearer. IMMUTOL is part of a broader effort to change what treatment means in autoimmune disease. "If we are successful in this, the long-term impact will not simply be better ways to manage these conditions, but the possibility of restoring the balance that prevents them from developing in the first place."

PROJECT INFORMATION

Project Title
Advanced Antigen-Specific Dendritic Cell-Based Therapy To Re-Establish Tolerance In Immune-Mediated Diseases

Project Objective
IMMUTOL aims to pave the way for new tolerogenic cell-based therapies to cure/reverse several autoimmune conditions. To fast-track the development and validation of an advanced therapeutic medicinal product (cell-based therapy) based on optimized Vitamin D3 (VitD3)-modified tolerogenic dendritic cells to treat patients with immune-mediated diseases.

Project Duration and Timing
48 months, 1 May 2023 - 30 April 2027

Project Funding
Granting authority: European Health and Digital Executive Agency

Project Partners
Fondazione Telethon Ets
1ospedale San Raffaele Srl
Institut De Investigacio En Ciencies De La Salut Germans Trias I Pujol
Stichting Sanquin Bloedvoorziening
Klinikum Der Universitaet Regensburg
Universidad De Navarra
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ESCAPE: Preparing for the next pandemic before it arrives

As Europe reflects on the lessons of COVID-19, the ESCAPE project is working to ensure that future pandemic responses are faster, smarter and better informed. By combining modelling, behavioural insight, data analysis and new preparedness tools, the project aims to give policymakers a stronger foundation for action when the next threat emerges. We speak to project coordinator **Prof. Dr. Niel Hens**, Director, Data Science Institute at UHASSELT and affiliated to the University of Antwerp, about the importance of this work.

When COVID-19 began to spread across the world, governments, health authorities and scientists were forced to respond at extraordinary speed. Decisions had to be taken quickly, often with incomplete information, against a backdrop of uncertainty, public anxiety and mounting pressure on health systems. For all the scientific advances made during the pandemic, the crisis also exposed how fragile the relationship can be between data, analysis and decision-making when a new infectious threat emerges.

That is the space in which the ESCAPE project is working. Rather than focusing on a single pathogen, ESCAPE is aiming to strengthen pandemic preparedness at a more structural level, asking how Europe can be better equipped to understand an emerging threat early, assess its likely impact and support policymakers with tools and evidence that are both scientifically robust and practically useful.

For Professor Niel Hens, the roots of the project lie directly in the experience of COVID-19 and the work that many of the partners had already undertaken during the crisis. "We were heavily involved in the COVID-19 pandemic in another European project called EpiPose," he explains. "Six out of the eight partners that are in this project as well were already involved in that one."

That earlier work was focused on informing policymakers as effectively as possible through modelling. "We looked at many, many different things, all with the aim of informing policymakers as much as possible with modelling outcomes," Hens says. "So that means forecasting, that means scenario analysis and so on – what-if scenarios. What if you do this? What will then happen in terms of hospital load and so on?"

That support was vital during the acute phase of the

pandemic. But as the immediate emergency began to ease, it became clear that there was more to do in terms of ensuring Europe was prepared for any future pandemic. The experience had revealed not only the importance of rapid scientific input, but also the limitations of existing preparedness systems. "The whole idea after the EpiPose project, or at the end of the acute phase of the pandemic at least, was that we couldn't stop there, that we had to look into how we can actually improve things for the future," Hens adds.

Pandemic intelligence

This shift in thinking underpins ESCAPE's central concept: pandemic intelligence, the underlying logic of which is clear. In Hens' words, "preparedness is not simply about having plans on paper. It is about knowing what kind of threat is emerging, understanding its defining features quickly enough to make a difference, and making sure that the right evidence reaches the right people in time to shape action."

"If we want to be better prepared, we need to know what's coming at us and we need to provide tools to people, the data to people and so on, to be exploited in time to react when the pandemic hits," Hens says.

At the start of any pandemic, that means one thing above all: understanding the pathogen. Hens points to the importance of core disease characteristics such as the incubation period, the generation interval and the extent of asymptomatic spread. These are not obscure technical details. They determine how quickly a disease can propagate, how visible it is likely to be and whether it can be contained through conventional public health measures or requires broader behavioural interventions.

Taken together, these characteristics help scientists build an early picture of the threat. They show how long it takes for symptoms to appear, how quickly infection passes from one person to another and how much transmission may be happening unnoticed. Asymptomatic spread is especially important. "If there is a lot of it you will fail to detect and isolate infected individuals in time," Hens says. "You can't stop it because you don't know it's there, basically. People then won't change their behaviour and the disease propagates quite quickly."

Combined with the basic reproduction number, which indicates transmission potential, these parameters begin to define both the scale of the problem and the kind of response required. In other words, good preparedness starts not with a political decision, but with a scientific picture of what is unfolding.

Yet COVID-19 showed that having data in principle is not the same as being able to use it in practice. According to Hens, one of the major difficulties lay not only in data availability, but in accessibility – how quickly it could be shared, interpreted and translated into action. In many cases, the

problem was not the absence of data, but the absence of systems and relationships needed to connect it to decision-making. Some countries had well-established links between academic experts and national public health systems, allowing evidence to flow more easily into policy discussions. Others had to build these connections in real time, often under intense pressure.

"Some countries are well-organised," he says, citing the UK as an example. "But for a lot of countries, including Belgium and other countries, this was not set up and needed to be set up quickly. This was not always the best way."

Addressing that gap is a central part of ESCAPE's work. Rather than focusing only on generating new data, the project is working to ensure that evidence can move more effectively from research into decision-making. This includes developing tools and building closer, ongoing relationships between modelling teams and public health institutions. By engaging policymakers throughout the project, ESCAPE aims to ensure that the systems, tools and data pipelines needed in a crisis are already in place, rather than having to be built under pressure when the next pandemic arrives.

Planning with archetypes

Understanding a pathogen is only part of the challenge. Preparing for the unknown requires a different way of thinking, and one of ESCAPE's other distinctive ideas is that preparedness should not revolve solely around anticipating one named pathogen after another. Public discussion often defaults to familiar threats – influenza, another coronavirus, or the as-yet undefined "next COVID". ESCAPE is trying to move beyond that logic and instead is working to identify archetypes of pathogens with pandemic potential. This means clustering diseases according to defining characteristics that shape how they spread and how they might best be controlled.

"We've taken a different route," Hens says. "We've tried to investigate these key characteristics for pathogens with pandemic potential. And what we're trying to define is archetypes of pathogens rather than pathogens themselves one by one."

This approach could prove highly valuable for preparedness planning. Rather than producing isolated plans for individual diseases, it allows researchers and policymakers to think in more transferable categories. "Using different archetypes allows you to cluster some of these pathogens and then to develop preparedness plans specifically for the archetypes rather than for each pathogen on its own," Hens explains.

The concept is still developing and, as he notes, still needs to be more fully picked up by the scientific community. But its practical value is already evident. A pathogen characterised by high levels of pre-symptomatic transmission, for example, poses a very different challenge from a vector-borne disease. Grouping such threats by shared behaviour opens the door to more flexible, anticipatory planning.

That principle also helps explain why ESCAPE is not simply a retrospective exercise in pandemic lessons learned. It is trying to create a system that can be activated early, even when the precise identity of a pathogen is not yet fully understood.

Tools for foresight

If archetypes provide the conceptual framework, ESCAPE's tools are designed to make that framework usable in practice. The project is developing tools that public health experts and policymakers can use to explore the likely consequences of different response options. Here, Hens is careful with language, choosing not to use the word prediction. For him, the strength of modelling lies elsewhere. "It's scenario analysis," he says. "I always compare it to being on a boat and it's very foggy and you need to find your way. At least that spotlight on the boat will give you a direction. It will not say you're going to land exactly there, but at least it will give you some kind of foresight."

It's an important distinction. The value of modelling is not that it tells governments exactly what will happen. It allows them to test the implications of choices before making them: what happens if certain contacts are reduced, if schools close, if working patterns change, if contact tracing is scaled up early, or if the pathogen has a particular transmission profile?

ESCAPE is now moving towards making some of these tools available. Hens describes an app in development that will allow users to vary parameters and simulate likely trajectories. Initially, this is aimed more at public health professionals than direct public communication, and he remains cautious about over-simplification. Some modelling outputs are not easily translated into a public-facing interface without risking misunderstanding. Still, the ambition is clear: to create tools that help decision-makers explore what-if scenarios in a more structured and accessible way.

Just as importantly, ESCAPE is not assuming that such tools can simply be handed over from scientists to policymakers in a one-way transaction. Hens emphasises repeatedly that this must be a conversation. "It needs to be some kind of co-creation," he says. "They have the boots on the ground."

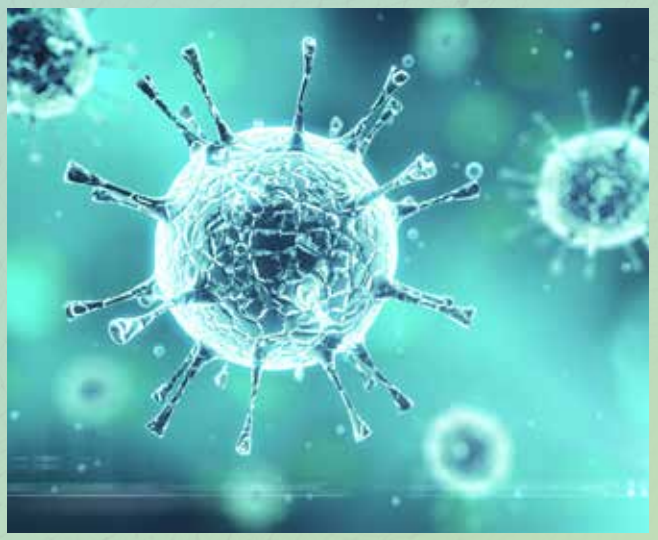
That means the project is actively engaging policymakers to understand what they need, how they would use the tools and what level of complexity would be useful in practice. This translation from the technical to policy usability is, he admits, proving harder and slower than first anticipated, but is essential if the science is to provide value on the ground.

The human factor

If COVID-19 revealed anything, it was that pandemic control is not just an epidemiological challenge, it is also a behavioural one. People's actions shape transmission, their trust shapes compliance and their interpretation of official messages shapes whether policies work as intended.

Hens is clear on this: "COVID-19 has been very much about how people behave," he says. "That is why ESCAPE includes work on behavioural data, including contact patterns collected across 20 European countries. These data proved more useful than expected, helping researchers understand how social mixing changed and what that meant for transmission under different restrictions."

The project is also exploring whether mobility data, such as that held by telecom operators or major digital platforms, might offer a more readily available proxy for contact behaviour in future outbreaks. The goal is not to eliminate the need for dedicated studies, but to reduce delay and cost at the start of a crisis.



Beyond contact data, however, lies a deeper question: what counts as success in a pandemic response? One of ESCAPE's approaches is examining this directly. COVID-19 often reduced public debate about the success of various policies to a narrow epidemiological frame: cases, hospitalisations, deaths. But societies were also grappling with isolation, disruption, education loss, economic harm and long-term effects on quality of life.

Hens notes that this broader perspective emerged as a key challenge. "What do policymakers believe is a success if you want to fight the pandemic?" he asks. "Is that keeping the burden in hospitals at bay? Or is it something more than that?"

ESCAPE is working with a large database of such determinants, using quality of life as a key indicator. This reflects a broader and more realistic understanding of preparedness – one that does not isolate health outcomes from the social conditions in which they unfold.

Trust, too, remains central and ESCAPE has explored how communication can be improved, including discussions with science journalists about what they would need in a future crisis. One strong message was the importance of rapid, reliable fact sheets on emerging pathogens. In response, the project is also looking at AI-supported tools that can rapidly gather and synthesise evidence from multiple sources to support early reviews of key disease parameters.

For Hens, the challenge is not just generating evidence, but embedding habits of communication and cooperation before the next emergency begins. "If we can do it in peacetime, then it will be easier to rely on that in crisis times as well," he says.

What next?

ESCAPE will not solve every weakness exposed by COVID-19. Hens is realistic about the complexity of political systems, the unevenness of European coordination and the fact that science can advise but not decide. But the project's contribution could nevertheless be significant.

At its core, ESCAPE is trying to reduce the time lost at the beginning of a pandemic: the time it takes to understand a threat, to interpret early signals, to organise evidence, to build confidence around emerging findings and to turn science into action. That matters because delay, as COVID-19 demonstrated, can be profoundly costly.

Looking ahead, Hens hopes the project will leave behind more than a set of isolated outputs. He wants it to help change the way preparedness itself is understood. "We hope that we can show people that you can actually work with archetypes, that that's the way to go, not looking only at specific pathogens," he says.

He is also clear that the work will not end with the formal close of the project. The collaborations behind ESCAPE are longstanding, and the ambition will continue beyond the current funding period. "We're a bit stubborn," he says. "We will continue to develop the systems to be ready before the next pandemic arrives."

PROJECT INFORMATION

Project Title
ESCAPE: Efficient and rapidly SCAlable EU-wide evidence-driven Pandemic response plans through dynamic Epidemic data assimilation

Project Objective
The main objective of ESCAPE is to improve the efficiency and scalability of early pandemic response plans. We will aim to provide evidence-based guidelines, standardised protocols, retroactive insights and digital solutions.

Project Duration and Timing
4 years (01.01.2023-31.12.2026)

Project Funding
Horizon Europe project
European contribution: € 2 420 930,00
Full budget: € 3.207.206,87

Project Partners
Coordinator: Universiteit Hasselt (Belgium)
Universiteit Antwerpen (Belgium)
Rijksinstituut voor volksgezondheid en milieu (The Netherlands)
Institut national de la sante et de la recherche medicale (France)
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DECIPHER: Redefining point-of-care diagnostics

When disease outbreaks strike, delays in diagnosis can cost lives. The DECIPHER project is developing a radically simplified diagnostic platform that brings rapid, quantitative testing directly to the point of care, while combining real-time data with predictive modelling. We speak to several of the project's partners about how this approach will revolutionise the detection, understanding and containment of infectious diseases.

When a suspected case of Ebola or Lassa fever appears in a remote health clinic, the clock starts ticking. The symptoms – fever, fatigue, headache – resemble many other common illnesses, yet if the patient is carrying one of these highly dangerous viruses, early detection can make the difference between containment and a rapidly escalating outbreak.

Today, confirming such infections usually requires centralised laboratory PCR testing. Samples must be transported, processed by trained personnel and analysed using specialised equipment. Even under ideal conditions, results may take a day or more and in remote regions, delays can stretch far longer.

For healthcare systems already under pressure, those lost hours can have serious consequences. In practice, diagnosis often begins with non-specific symptoms alone, before samples are taken and sent to a laboratory for confirmation. During that time, exposure may already be happening.

The challenge highlights a persistent weakness in global outbreak response: the ability to obtain reliable diagnostic information directly where care is delivered. **The DECIPHER** project is attempting to close that gap.

Bringing together expertise from materials science, microfluidics, bioassay development, clinical medicine and artificial intelligence, the European research initiative is

developing a radically simplified diagnostic platform designed to compress the entire laboratory workflow into a single device. If successful, it could fundamentally change how infectious diseases are detected and managed in decentralised healthcare settings.

Moving diagnostics

At the centre of the project is a deceptively simple idea: what if the entire process of sample collection, preparation, analysis and result generation could happen inside a single disposable patch?

"The idea behind DECIPHER is to address a gap that still exists in outbreak response and point-of-care diagnostics," says project coordinator **Karen Leirs**, group lead in microfluidics and bioassays at KU Leuven leading the project's technology development. "We want truly quantitative and rapid detection from sample to result at the point of care – without needing a laboratory or complex equipment."

In principle, this type of technology could detect many different pathogens, but the DECIPHER consortium has chosen to focus on the **Ebola virus disease and Lassa fever** as model systems. Both are high-consequence viral infections that continue to cause outbreaks in parts of West and Central Africa and present major diagnostic challenges.

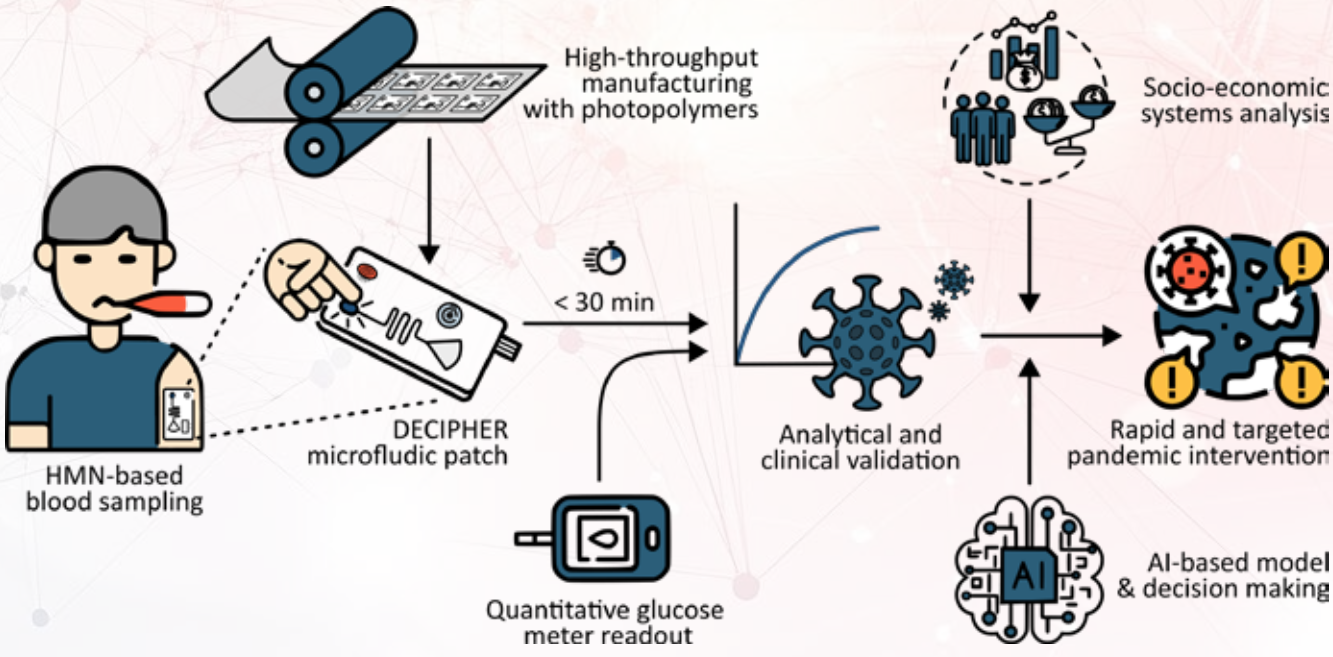
"Early symptoms are easily confused with other viral, bacterial or parasitic illnesses such as malaria or typhoid," explains **Karifa Kourouma**, PhD researcher and clinical research Lead at the Centre National de Formation et de Recherche en Santé Rurale de Maferinyah, and coordinator of DECIPHER activities in Guinea. "As a result, cases are often missed or detected too late, so having a device available directly in decentralised health posts and centres would allow healthcare workers to obtain results immediately. For us in Guinea and other parts of West Africa, this would be a real game-changer."

Bringing testing closer to the point of care is therefore critical, shifting detection out of the laboratory and into frontline settings, enabling faster decisions and earlier intervention. DECIPHER, however, wants to go further and deliver more than a rapid yes-or-no result. The project aims to embed deeper clinical insight within the test itself.

"Our goal is not merely to produce a rapid test, but something more powerful," says Leirs. "We are embedding a quantitative diagnostic tool into the patch, which will be capable of estimating viral load directly at the point of care."

This distinction is important. While field-ready rapid tests are hugely important, a simple positive or negative result, offers limited insight into how advanced an infection is or how urgently intervention is required. Being able to estimate viral load provides a far more nuanced picture. Higher viral loads are often associated with increased infectiousness and more severe disease, allowing clinicians to make faster, more informed decisions about isolation, treatment and patient management. In outbreak settings, this can directly influence how transmission is controlled. "If you can identify cases earlier and understand their level of infection, you can respond much more effectively," explains Kourouma. "That changes how you manage patients, but also how you protect others."

At a population level, quantitative data also strengthen surveillance. Rather than simply tracking case numbers, health systems can begin to understand how an outbreak is



evolving – where it is intensifying, where it is being contained and how interventions are shaping its trajectory.

Diagnostic workflow

Achieving this level of quantitative insight outside a laboratory environment, however, has proven extremely difficult. Traditional molecular diagnostics rely on tightly controlled laboratory conditions. Samples must be carefully measured, processed and purified before amplification and detection steps can occur.

"Determining viral load accurately requires precise control of the starting sample," Leirs explains. "You need to meter the sample very carefully, extract the RNA and work with calibrated standards under controlled conditions. In a laboratory that is straightforward, but outside the lab, it becomes much more difficult to maintain that level of precision."

DECIPHER's answer is to redesign the diagnostic workflow from the ground up. The device takes the form of a small patch equipped with hollow microneedles. When placed on the skin, the microneedles collect a tiny capillary blood sample painlessly from the upper layers of the skin.

"We are responsible for developing the microneedle arrays for minimally invasive blood sampling and integrating them with the iSIMPLE chip for testing," explains **Dr. Burak Ozdoganlar**, DECIPHER partner and Ver Planck Endowed Chair Professor of Engineering at Carnegie Mellon University in Pittsburgh, US. "The aim is to make sampling as simple and as safe as possible – removing the need for traditional blood draws, reducing handling steps, ensuring sample robustness, and minimising the risk of exposure. That is particularly important for high-consequence infections."

Once collected, the sample is transferred directly into the iSIMPLE chip – the core of the system, where the entire diagnostic process takes place. "Self-powered microfluidic channels draw the sample through a sequence of miniature processing steps," Leirs explains: "Plasma is separated from red blood cells, reagents are mixed automatically and the viral genetic material is amplified using an isothermal reaction that avoids the temperature cycling required in PCR systems.

"The moment the sample enters the chip, the entire process runs automatically," she continues. "There is no manual sample handling and no laboratory equipment."

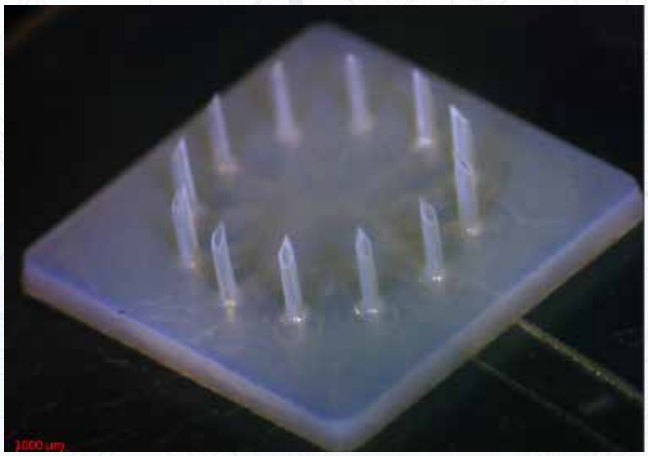
The system ultimately converts the viral signal into something familiar: a glucose measurement. By coupling the biochemical reaction to a repurposed glucose meter – a device already widely used around the world – the platform can produce a numerical readout representing the amount of viral RNA present in the sample.

In effect, the technology transforms a ubiquitous medical device into a miniature molecular laboratory.

Beyond testing

While the patch forms the technological core of DECIPHER, the project's ambition extends far beyond the diagnostic device alone. The consortium is also developing a **data-driven epidemic intelligence platform** designed to interpret test results within a broader public health context. "Testing as close as possible to patients is extremely important for contagious diseases," says **Caroline Van Cauwelaert**, **CEO of Epcon**, leading the development of AI-based disease prediction models to support deployment of the patches. "But the real value lies in what we can do with that data, not only understanding outbreaks, but predicting how Ebola and Lassa fever will evolve geographically over time."

Using environmental data, demographic indicators, mobility patterns and healthcare access information, the project's models aim to identify where transmission is emerging, and forecast how it is likely to spread across regions over time. "By combining real-time diagnostic data with predictive modelling, the DECIPHER platform can support more informed decision-making," adds **Van Cauwelaert**. "It enables health authorities to move from reactive outbreak response to proactive management, forecasting where diseases will spread next and acting before transmission accelerates.



Decipher Partners

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Jeroen Lammertyn

Karen Leirs

Karifa Kourouma
PhD researcher and clinical research Lead & coordinator of DECIPHER

Rather than producing opaque predictions, the platform emphasises transparency. Risk maps and data layers can be visualised through a geo-portal, allowing public health experts to understand the factors driving potential outbreak hotspots. "We want decision-makers to understand the reasoning behind the models," **Van Cauwelaert** explains. "The goal is to support their expertise, not replace it."

Combined with rapid point-of-care testing, this creates a more responsive system — enabling health authorities to deploy diagnostics strategically, directing tests and medical teams to the areas where outbreaks are predicted to emerge or intensify.

Outbreak response

The need for such approaches has become increasingly evident in recent years.Globalisation, climate change and population mobility are expanding the geographic range of many infectious diseases. At the same time, healthcare systems are moving towards more decentralised models of care, with greater emphasis on community-level diagnostics.

The COVID-19 pandemic exposed the fragility of laboratory-centred testing infrastructures during large outbreaks. "Laboratories can become overwhelmed with samples," says **Jeroen Lammertyn**, Professor at KU Leuven and coordinator of the DECIPHER project. "Point-of-care screening tools can help identify high-risk patients quickly before confirmatory testing is performed."

For diseases such as Ebola, the implications could be profound. "Early diagnosis allows infected individuals to be isolated more quickly, reduces transmission risk and enables supportive treatment to begin sooner," adds **Lammertyn**. "It also improves biosafety by reducing the need for manual blood handling."

Leirs explains why this matters: "In many outbreak situations, hours matter," she says. "If we can move reliable diagnostics directly to the frontline, that changes how quickly health systems can respond."

The patch could also ease the burden on laboratories. In many hospitals, patients suspected of viral haemorrhagic fevers must be retested multiple times during treatment. "A decentralised diagnostic tool could reduce laboratory workload and testing costs," notes Kourouma.

Real-world deployment

DECIPHER is currently progressing through the integration phase of the project, where the various components of the platform are being combined into a single functional system. "Many of the individual processes have already been demonstrated in the laboratory," says **Lammertyn**. "The next step is integrating them onto the chip and ensuring the system is robust."

Future stages will include larger-scale validation and eventual clinical testing. The consortium is also working closely with industrial partners to ensure that the device can be manufactured at scale.

Unlike many academic microfluidic systems, which remain confined to laboratory prototypes, the project's materials and fabrication methods have been selected specifically for compatibility with industrial roll-to-roll manufacturing processes. "From the beginning, we have been thinking about how this can be produced at scale," says Leirs. "The materials and processes we are using are chosen to be compatible with existing manufacturing technologies, so this is not something that remains in the lab."

The goal is to move beyond proof-of-concept devices toward something that could realistically be produced and distributed worldwide. "That translation to real-world use is essential," adds **Lammertyn**. "We are not just developing a technology — we are working towards a system that can be deployed where it is needed, at the scale required during an outbreak."

Europe's preparedness

The project also reflects a broader strategic ambition within Europe to strengthen technological sovereignty in health diagnostics. During the COVID-19 pandemic, global supply chain disruptions exposed Europe's dependence on external manufacturing for key diagnostic components. By developing

new materials platforms and scalable microfabrication technologies within European research and industrial ecosystems, DECIPHER contributes to rebuilding domestic capabilities in advanced in-vitro diagnostics.

At the same time, the project's international collaborations highlight the importance of global partnerships in outbreak preparedness. "We learn a great deal from our partners in Africa," says Van Cauwelaert. "They have extensive experience managing outbreaks and provide essential insights into real-world implementation."

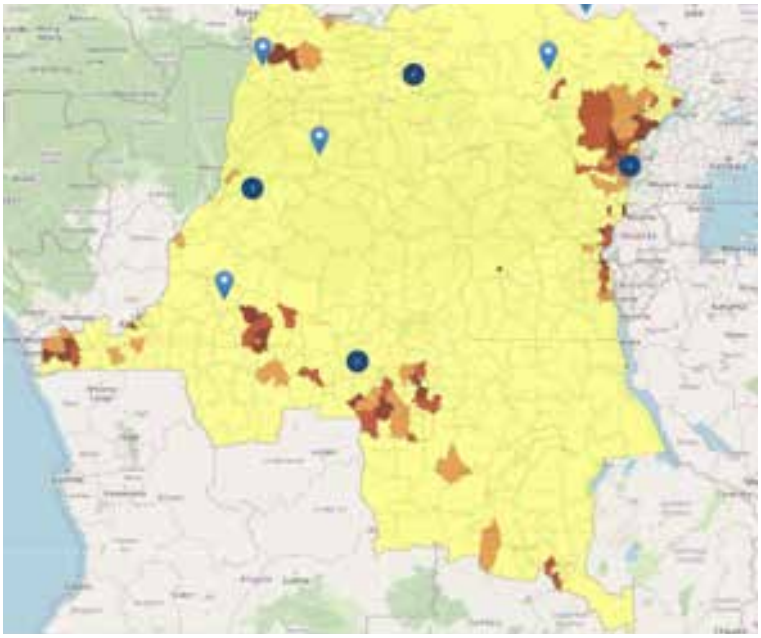
Such collaborations help ensure that the technology is designed for the environments where it will ultimately be used and not only in terms of performance, but also scalability, usability and real-world deployment. This forward-looking approach also underpins the project's longer-term vision as a platform for the future.

A platform for the future

Although the project currently focuses on Ebola and Lassa fever, the underlying technology is designed to be adaptable. "This is fundamentally a platform," explains Ozdoganlar. "Once the system is validated, it could be adapted for measuring a range of biomarkers, including pathogens for other infectious diseases."

That flexibility could prove crucial in a world where emerging pathogens continue to pose unpredictable threats. For the researchers involved, the ultimate measure of success will be whether the technology reaches the communities that need it most. "If this device can help prevent deaths during future outbreaks," says Lammertyn, "that would be the greatest impact we could hope for."

More broadly, the project aims to develop something larger than a single diagnostic product: a blueprint for how advanced materials science, microfluidic engineering, digital modelling and clinical expertise can be combined to build the next generation of decentralised healthcare technologies. In an era when the next pandemic could emerge at any time, that capability may prove essential.



PROJECT INFORMATION

Project Title
DECIPHER – Enabling quantitative point-of-care diagnosis as a sustainable and powerful solution for pandemic threats

Project Objective
The DECIPHER consortium aims to revolutionize the in vitro diagnostic (IVD) point-of-care (POC) field by developing for the first time a true quantitative sample-to-result POC test based on a re-purposed glucose meter, supported by socio-economic system analysis and artificial intelligence (AI)-based models for efficient and effective implementation in the field.

Project Duration and Timing
48 months (1/01/2024 – 31/12/2027)

Project Funding
Horizon Europe, HORIZON-HLTH-2023-TOOL-05, grant number 101137242, 7,053,633.03 Euro

Project Partners
KU Leuven, BE. Joanneum Research, AT. Montanuniversitaet Leoben, AT. Polymer Competence Center Leoben, AT. Institute of Tropical Medicine Antwerp, BE. Carnegie Mellon University, US. Temicon, DE EPCON, BE. Centre National de Formation et de Recherche en Sante Rurale de Maferinyah, GN. Institut National de Recherche Biomedicale Du Zaire, CD Médecins sans Frontières Belgium, BE

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DECIPHER

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TELEREHAB: Bringing rehabilitation into the real world

Balance disorders are one of the most persistent and complex challenges in modern healthcare, affecting mobility, independence and quality of life for millions of patients. The TELEREHAB project is combining artificial intelligence, augmented reality and connected health technologies to transform how rehabilitation is delivered. Project coordinator **Professor George Matsopoulos** and technical coordinator **Dr. Vassilis Tsakanikas** explain how this approach is moving rehab beyond the clinic and into people's everyday lives.

For many patients, rehabilitation does not begin and end in the hospital or clinic. It continues quietly and often inconsistently at home, in daily routines designed to rebuild confidence and mobility gradually and sustainably. This is particularly true in areas where rehabilitation depends on consistency and gradual improvement over time. Nowhere is this more apparent than in balance rehabilitation.

Whether linked to ageing, neurological conditions or musculoskeletal recovery, impaired balance is one of the leading causes of falls, hospitalisation and long-term loss of independence. Yet despite its importance, rehabilitation remains difficult to monitor and personalise and for patients to sustain over time.

"What makes balance disorders particularly challenging is that fall risk rarely has a single cause," explains Prof. George Matsopoulos, Director Biomedical Engineering Laboratory, Institute of Communication and Computer Systems in Greece and project coordinator.

"It can be related to movement, symptoms, cognition, comorbidities or the way someone responds to therapy. That is why fall prevention needs a more rounded and more personalised rehabilitation approach."

This complexity has consequences far beyond the individual. Falls place a significant burden on healthcare systems, driving hospital admissions, extending recovery times and

Telerehab Partners

Dr. Vasilis Tsakanikas

Technical co-ordinator, Unit of Medical Technology and Intelligent Information Systems, University of Ioannina

Prof. George Matsopoulos

Director Biomedical Engineering Laboratory, Institute of Communication and Computer Systems

increasing long-term care needs. Yet despite this, the way rehabilitation is delivered has changed relatively little.

Beyond the clinic

Traditional rehabilitation pathways, however, are not well equipped to provide the level of continuity or personalisation needed to address this problem. "Traditional rehabilitation still depends a lot on face-to-face sessions and on what the clinician can observe during those appointments," says Matsopoulos. "Between visits, it is often difficult to know whether the patient is following the programme, whether symptoms are changing or whether the exercises are being done correctly and consistently."

The result is a fragmented view of recovery, where clinicians see isolated snapshots rather than how a patient is progressing over time. In a field where consistency and sustained engagement with rehabilitation programmes are critical, this makes it harder to identify problems early and adjust treatment effectively.

At the same time, there are increasing pressures on healthcare delivery. Ageing populations, rising demand for rehabilitation services and limited access to specialist treatments are making it increasingly difficult to rely solely on clinic-based care. "In recent years it has become very clear that rehabilitation cannot depend only on what happens inside the clinic," Matsopoulos says. "Patients need support that extends beyond occasional appointments."

A connected model of care

The TELEREHAB DSS project is designed to address this challenge by rethinking rehabilitation as a continuous, connected process, rather than a series of isolated interventions. At its core is a digital platform that brings together assessment, treatment planning, exercise delivery and monitoring into a single, integrated system.

"The core idea behind TELEREHAB DSS is to bring the whole rehabilitation pathway together instead of treating it as a series of separate steps," says Matsopoulos. "In many cases, these elements are still handled in a fairly disconnected way. What we are trying to do is create a more coherent model of care that supports both clinicians and patients throughout the rehabilitation process."

This is achieved through a combination of technologies: a cloud-based decision support system, a clinician dashboard, a patient-facing mobile environment, a virtual coach and a network of connected sensors. Together, these components allow rehabilitation to move beyond periodic assessment towards continuous monitoring and adaptive support, where treatment can be adjusted in response to how patients are progressing in their daily lives.

What sets TELEREHAB DSS apart is not any single technology, but the way they are combined. "A lot of digital rehabilitation tools concentrate on a single layer," Matsopoulos explains. "TELEREHAB DSS is trying to support the whole pathway, from initial assessment and intervention planning to exercise execution, adherence support and outcome tracking."

Making rehabilitation visible

A key enabler of this connected approach is the ability to capture detailed, continuous data on patient activity and performance. Wearable devices and connected sensors track movement, exercise execution and broader indicators such as activity levels, heart rate and sleep patterns. This information is transmitted to the platform, where it can be analysed and used to support clinical decisions.

"Wearable devices and IoT sensors are basically how the platform sees what is happening outside the clinic," explains Dr. Vasilis Tsakanikas, Technical co-ordinator, Unit of Medical Technology and Intelligent Information Systems, University of Ioannina. "They capture movement and performance data while patients carry out their exercises at home."

This transforms rehabilitation from a largely subjective process into one that can be measured, monitored and understood over time. "Clinicians get a much richer view of the patient than they would from a standard follow-up appointment alone," Tsakanikas adds.

Artificial intelligence plays a central role in making sense of the data this technology collects. Rather than simply gathering information, the platform uses AI models to assess fall risk, evaluate treatment effectiveness and support decisions around therapy planning and progression.

These models draw on both baseline clinical data and continuous inputs from sensors and patient interaction, building a more dynamic picture of each individual's rehabilitation journey. "AI is really at the centre of TELEREHAB DSS," says Tsakanikas. "It is what turns the platform from a monitoring tool into a decision support system."

At the heart of this approach is the platform's decision support system (DSS), which combines data analysis with predictive modelling to guide rehabilitation strategies.

By integrating information on patient performance, symptoms and behavioural patterns, the DSS can support clinicians in selecting appropriate interventions, adjusting exercise intensity and identifying when progress is slowing or risks are increasing. In this way, rehabilitation becomes a more adaptive process, shaped by ongoing feedback rather than fixed treatment plans.

Importantly, the aim is not to replace clinical judgement, but to support it. "The point is to support clinical judgement in a more structured way," Tsakanikas continues. "AI can help bring together different factors that clinicians already think about, and do so in a way that is more consistent, more scalable and more personalised."

Rehabilitation in the real world

Alongside monitoring and analysis, TELEREHAB also rethinks how rehabilitation exercises are delivered. Through the use of Augmented Reality (AR), patients can perform exercises in interactive, guided environments designed to improve both understanding and engagement. "AR is used to make rehabilitation more guided, more engaging and easier to follow at home," says Tsakanikas. "Instead of just handing the patient written instructions, the platform creates a more interactive training experience."

As part of this experience, a virtual physiotherapist provides real-time guidance, helping patients perform exercises correctly and maintain consistency, two factors that are critical for successful rehabilitation. For patients, this represents a shift from the more traditional periodic care to continuous support at home. "The biggest advantage is continuity," Tsakanikas explains. "Rehabilitation does not stop when patients leave the clinic, and support does not depend only on the next appointment."

Personalisation

Also central to TELEREHAB's approach is the idea that rehabilitation should be tailored to the individual, rather than delivered as a standardised programme. By combining clinical data, sensor inputs and contextual factors, the platform supports more nuanced decisions about treatment type, intensity and progression.

These decisions are informed not only by clinical indicators, but also by how patients engage with their rehabilitation in practice – how consistently they follow the programme, how they respond to different exercises and how they progress over time. This allows treatment plans to be adapted in a more responsive and realistic way, reflecting the conditions in which rehabilitation actually takes place.

"The main idea is that rehabilitation should not be prescribed in exactly the same way for everyone," says Matsopoulos. "The system helps clinicians adjust rehabilitation in a more structured way, based on what is actually happening over time."

But personalisation in itself is not enough. Its effectiveness depends on how patients engage with rehabilitation in their daily lives. Even the most advanced system will fail without patient engagement. TELEREHAB therefore places strong emphasis on adherence, usability and digital literacy as core components of effective rehabilitation. "Adherence is critical because even the best rehabilitation plan does very little if it is not followed consistently," Matsopoulos notes.

The platform actively monitors engagement, tracking exercise completion, activity patterns and user interaction, while also incorporating tools to assess usability and patient experience.

"Engagement is not just about asking a patient whether they liked the system," says Tsakanikas. "It is about whether they actually used it and whether the platform supported the rehabilitation process instead of getting in its way."

Recognising the diversity of patient needs, the system also takes into account levels of digital confidence and familiarity with technology. "Digital literacy plays a bigger role than people sometimes think," Matsopoulos adds. "The system recognises that successful tele-rehabilitation depends not only on medical need, but also on whether the technology actually fits the person using it."

A new model of care

As the project moves through its validation phase, the focus now is on demonstrating not only its technical feasibility, but also its real-world clinical value. "The aim is to show that the platform can improve both subjective and objective rehabilitation outcomes and strengthen patient compliance," says Matsopoulos.

If successful, TELEREHAB could contribute to a broader shift in how rehabilitation is delivered. "It could help move rehabilitation away from a mainly episodic model and towards something more continuous and patient-centred," Tsakanikas explains.

This shift also has implications at the system level, offering a more scalable approach to delivering specialist care, one that will help healthcare systems address some of the many challenges they face. "By combining remote assessment, AI-assisted decision support and monitoring in one environment, the platform can help extend specialist expertise beyond the physical clinic," adds Tsakanikas.

Looking ahead

Despite its promise, the path to widespread adoption for TELEREHAB is not without its challenges. Clinical validation, integration into healthcare systems and user acceptance will all play critical roles. "One of the biggest challenges is not just building the technology, but getting it adopted in real healthcare settings," Matsopoulos acknowledges.

Nevertheless, the direction of travel is clear. As digital tools become more sophisticated and more embedded in healthcare delivery, they offer the potential to reshape not only how rehabilitation is delivered, but how it is experienced by patients.

"AI and AR can make rehabilitation more adaptive and less dependent on static treatment plans," Matsopoulos concludes. "Used properly, they can help clinicians extend their reach and support patients more consistently."

In doing so, projects like TELEREHAB are not simply introducing new technologies; they are redefining what rehabilitation can be: continuous, personalised and connected to the realities of how people live their lives.

PROJECT INFORMATION

Project Title
TeleRehabilitation of Balance clinical and economic Decision Support System (TeleRehaB DSS)

Project Objective
Assess fall risk, treatment effectiveness and patient outcomes. Remotely monitor patients through wearables and IoT devices. Create personalised rehabilitation plans based on clinical and socio-economic factors. Ensure patient adherence by evaluating eHealth and digital literacy.

Project Duration and Timing
Duration: 45 months
Start: 01.12.2022, End: 31.08.2026

Project Funding
HORIZON EUROPE (HORIZON-HLTH-2021-DISEASE-04)
Funding: € 5.060.562,00

Project Partners
Institute of Communication and Computer Systems (GR). University of Ioannina (GR). Chulalongkorn University (TH). VILABS OE (GR). Istrazivacko Razvojni Centar Za Bioinzenjering BioIRC Doo (RS). Active Ageing Association (ES). Medtronic Iberica SA (ES). National and Kapodistrian University of Athens (GR). BRIDG OU (EE). UNINOVA-Instituto de Desenvolvimento de Novas Tecnologias-Associacao (PT). QUANTITAS Srl (IT). University Hospital Freiburg (DE). University College London (UK). Guys and St Thomas' NHS Foundation Trust (UK). Secretaria Regional da Saude (PT). IDEA – Institute for Development and Innovation in Technology (PT).

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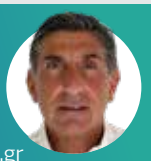

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TeleRehaB

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UniHealth: Delivering diagnostics where they are needed most

Developing portable, adaptable and connected testing platforms, UniHealth is shifting molecular diagnostics from centralised laboratories to the point of care – improving sensitivity, access, accelerating response times and strengthening global health preparedness. Key project partners explain how this shift could redefine preparedness and reshape the future of healthcare delivery.

For decades, modern healthcare has relied on a centralised model of diagnostics. When illness strikes, patients often travel to hospitals or clinics, where samples are collected and processed in specialist facilities before results are returned hours or even days later. It is a system that has delivered remarkable advances in clinical accuracy and disease detection, but it is also built around controlled environments, fixed infrastructure and predictable demand. When rapidly evolving global health emergencies strike, these models can be tested to breaking point.

The COVID-19 pandemic exposed these limitations with unprecedented clarity. Systems designed for stability were suddenly required to operate at global scale, under pressure and in real time. "COVID showcased the fact that we could not reach reliable, effective and inexpensive diagnostics quickly enough," says Stamatiki Kritas, Managing Director of CEBR and Cluster Manager of the Hellenic BioCluster and the UniHealth project's dissemination lead. "We couldn't manage the crisis in the usual way, in one hospital or as one country. We needed to look at it collectively, globally and we were not set up for that."

For Professor Electra Gizeli, coordinator of UniHealth and Group Leader at the Institute of Molecular Biology and Biotechnology (IMBB) at FORTH, the pandemic brought into sharp focus many of the challenges she has spent years trying to address. "When the pandemic came, the world was not prepared," she reflects. "Not just in diagnosing the virus, but in providing drugs, delivering devices, monitoring the

PEBBLE qcLAMP Platform

spread through surveillance-tools and managing the whole pipeline; we were simply not prepared for what we faced."

These systemic weaknesses highlighted a more specific challenge: the gap between scientific capability and practical readiness. "We realised that health threats can come again and so we have to be better prepared."

This gap between technological capability and real-world delivery is the starting point for this project. UniHealth is a European research initiative focused on the development of molecular diagnostic solutions that are based on the detection of genetic biomarkers; molecular diagnostics outperform the standard antibody/antigen rapid tests by detecting directly the nucleic acid of the virus upon enzymatic amplification. As a result, several million nucleic acids can be produced that are identical to the viral RNA, starting from just a few copies of the virus in the patient's sample. The detection of the genetic material is a laboratory-based method, requiring the use of several dedicated instruments.

However, one of the current challenges is the ability to perform the same test in an environment outside the lab, at the point-of-care, with equal sensitivity and reliability, offering, in addition, portability, fast results, simplicity in operation and low cost. UniHealth's aim is to deliver a broad range of molecular diagnostic solutions for point-of-care applications, with a focus on detecting emerging pathogens.

"We don't want the next pandemic to find us again unprepared," says Gizeli. "Let's face the challenge of being able to deliver fast diagnostic solutions at the beginning of the next outbreak. We should have already investigated and figured out which methods are the best depending on the pathogen and sample, how fast we can prepare them, and how best they can be deployed to slow down the spread of disease."

Distributed solutions

At the centre of the UniHealth approach is a portable diagnostic platform, building on technology developed by SME partner BIOPIX DNA Technology, a spin-out from FORTH. "The initial idea is based on the PEBBLE device," explains Dr. Anastasia Galanopoulou, Scientific Manager of UniHealth. "It's a smart portable device that can be used for molecular diagnostics at the point of care."

In practical terms, the system brings laboratory-level testing into a compact, self-contained unit. Using isothermal amplification techniques, it can detect viral or bacterial genetic material directly from patient samples without the need for complex laboratory infrastructure or time-consuming preparation steps. The process itself is designed to be simple and fast. A sample is mixed with reagents and placed into the device, where it is heated to enable the reaction to take place while an integrated optical system monitors changes in real time. Normally, in 30-40min, a result is available.

Crucially, the system is designed not just for portability, but for connectivity and immediacy. "It can be inexpensive, rapid and connected," says Galanopoulou. "It can connect the data to a server instantly, so you don't have to wait for the outcome from centralised laboratories, which usually takes a lot of time."

This combination of speed, simplicity and connectivity underpins a different model of diagnostics, one that removes delays between testing and decision-making and enables results to be generated and shared wherever the patient happens to be.

The importance of this shift lies in the role diagnostics play in the broader healthcare pathway. Delays in testing can directly affect how quickly diseases are identified, contained and treated. By moving diagnostics closer to the point of care, UniHealth shortens that chain.

Designing for the unknown

If decentralisation addresses the limitations of current systems, UniHealth's focus on adaptability addresses the uncertainty of future threats. One of the defining challenges in diagnostics is not only detecting known diseases but responding rapidly to new ones. Each emerging pathogen typically requires the development of new assays, protocols and validation processes, a process that takes time and limits how quickly health systems can respond.

"What we are trying to do is advance this technology so that it is ready for the next pandemic," says Galanopoulou. "At the moment, you need time to develop new protocols for different targets and different matrices – human samples, mosquito samples and environmental samples, for example. Under UniHealth, we are creating ,. pipelines that can be adapted instantly."

For Gizeli, preparedness is not an abstract hope; it is a measurable scientific objective. "It means that when the next health threat appears, we should be able to rely on already

UniHealth Partners

Stamatiki Kritas
Managing Director of CEBR and Cluster Manager of the Hellenic BioCluster

Professor Electra Gizeli
Coordinator of UniHealth and Group Leader at the Institute of Molecular Biology and Biotechnology (IMBB) at FORTH

Dr. Anastasia Galanopoulou
Scientific Manager of UniHealth

developed and mature solutions which can be deployed to the end user very fast, ideally within less than a month, relying on a fast certification route," she explains. "Before, it took us 18 months to prepare and deliver our first innovative molecular diagnostic solution. Reducing this time to one month would be a huge improvement and a huge step forward.

"To achieve a fast response, we cannot rely on rapid innovation in the moment of crisis," she continues. "It depends on systematic and collaborative work carried out in advance. We need validated methods, tested systems and reliable processes developed in collaboration with all stakeholders – researchers, engineers, clinicians, certification consultants, entrepreneurs and end users.

"We cannot start research at the next moment of crisis. We need technologies that are already in the lab and have been validated and accepted by clinicians and end users."

Central to this is the idea of a pipeline – a structured, repeatable process that allows new diagnostic tests to be designed and deployed as soon as an emerging pathogen is identified. "Once we know the genome sequence, we can deliver the test", Gizeli says. "Because we have already done the steps. We know which methods work, which samples they work with. We are investigating each case and collecting this important information in advance."

In practice, this means creating standardised workflows that connect bioinformatic data, assay design and device integration into a coherent system. Instead of starting from scratch whenever a new pathogen emerges, researchers can adapt and deploy existing processes, dramatically reducing development time.

The approach also reflects a broader understanding of how diseases emerge and spread. UniHealth is grounded in the One Health perspective. This is a concept that recognises that human health, animal health and environmental conditions are closely connected, and that emerging threats often move between these domains. "We want to be able to rapidly develop assays to detect novel diseases, not only for humans, but also for animals and the environment," says Galanopoulou. "Because these are all interconnected."

By integrating this perspective into its design, UniHealth extends the role of diagnostics beyond clinical settings, enabling earlier detection of threats wherever they originate.

From vision to application

For Gizeli, this is not simply about improving speed or efficiency. It is about fundamentally changing how diagnostics are used. Rather than being confined to laboratories and triggered only once symptoms appear, diagnostics should become more immediate, more accessible and more closely integrated into everyday healthcare. "We need to give the doctors, patients and all end-users the ability to manage their health or just to know whether they're healthy or not," she explains.

"Uncertainty has real consequences in any pandemic. Without timely, reliable diagnostics, people are forced to make decisions based on incomplete information, increasing the risk of transmission and delaying intervention."

UniHealth addresses this challenge by bringing rapid, accurate testing closer to the point of need. "We are creating tools that allow people to act quickly and appropriately, supported by reliable information," Gizeli continues. "Our vision is to have solutions that are ready before any new pandemic arrives and technologies that can operate reliably beyond the laboratory, in the everyday settings where decisions are made and where early intervention matters most."

Speed and sensitivity

A critical challenge in moving diagnostics closer to the patient is maintaining the balance between speed and accuracy. "From COVID, we know that there are two different technologies that we all use," says Galanopoulou. "On the one hand, there are antigen-based tests, which are inexpensive and very rapid. On the other hand, there are highly sensitive molecular diagnostics in centralised laboratories, which are very expensive.

"We want an approachable diagnostic tool that can be performed as easily as the rapid antigen test that we buy from the pharmacy, but which has the sensitivity of the assays that take place in centralised laboratories."

This ability to deliver laboratory-level performance in a portable format is central to the project's impact, ensuring that decentralisation does not come at the expense of reliability.

Population insight

While the immediate benefit of point-of-care diagnostics is faster individual testing, the broader impact lies in how data is generated and used. "Surveillance is crucial, not only to know who is sick, but also for prediction models," says Galanopoulou.

Traditional testing models tend to capture only those

who actively seek testing, introducing bias into the data. Distributed diagnostics offer a different perspective. "With portable testing, devices can be used in airports or on public transport, for example," she explains. "This provides a more representative view of the population and opens up new possibilities for real-time monitoring and early detection."

This ability to generate data closer to where people live, work and travel could significantly improve preparedness. "If you know where you're at, you can respond," adds Kritas. "That's why it is called preparedness."

Real-world deployment

Unlike many research initiatives, UniHealth builds on an existing commercial foundation. BIOPIX DNA TECHNOLOGY SME partner has already launched diagnostic products for COVID-19 and influenza using the same underlying technology. This has allowed the project to focus not only on innovation, but on scaling up and expansion – extending the platform to new diseases, new markets and new healthcare environments. "The commercial entity is already there," says Kritas. "What we are trying to do now is add value to the products they already have, create new products and enter the market quicker."

For Gizeli, however, entrepreneurship has never been about commercialisation for its own sake. She is now focused on the impact this commercial technology can deliver. "Challenge-driven research has always been of particular interest to me," she says. "In my group we are continuously striving to adapt new scientific concepts and innovations to solve global problems. We are passionate about translating laboratory results to useful solutions for society.

PEBBLE qcLAMP Platform performing test analysis.

"It is no good to do all this work and just leave it there. It is not fair for the researchers involved, the funding body and society as a whole. I have always felt it my obligation to go beyond the lab, translate the results and deliver a solution. When you see that there are results with exploitation potential, it is inspiring to move forward, write a patent and ideally give it to the people who can develop it," she explains. "Otherwise, important work can stay in the lab as internal knowhow; beyond publishing, it is of paramount importance to reach the people who can benefit from this work.

"BioPix, a FORTH spin out, is a perfect example of technology transfer. This is what I mean by delivering useful solutions – BioPix IP and technological solutions are now making a real difference in POC diagnostics, from Africa to Europe and the US."

Accessibility and equity

At the same time, the project is tackling the challenge of global accessibility by supporting regional production capabilities. "We want production to be autonomous in every region," says Galanopoulou. "Not only in Europe, but also in underserved communities, including Africa."

This ambition reflects a broader understanding of what it takes to make diagnostic innovation truly accessible. "The technology is simple in the sense it can be produced easily," explains Gizeli. "It does not require sophisticated parts or manufacturing methods thanks to the novel detection methodology we are employing. Manufacturing can take place in Europe, Africa or anywhere else in the world as long as there is a 3D printer and a computer.

"We want everyone to have access to powerful and robust technologies wherever they are based," she adds, and for her that means going beyond practicality. It is her guiding principle. "I am not so keen on technologies that are suitable only for one part of the world," she says. "I prefer to develop technologies that can have a large impact and be applied globally, equitably."

Collaboration

Making this vision a reality requires much more than technological excellence.

"To bring a product to the market, you need a lot of different people with different expertise," says Kritas. "Researchers, clinicians, commercial partners, regulatory experts."

This multidisciplinary approach ensures that innovation is translated into solutions that function in real-world settings and across different healthcare systems. It also extends beyond traditional stakeholders to include the people who will ultimately use the technology. "The end users co-shape the final product with us," explains Galanopoulou. "We take into consideration their feedback, whether it is easy to use,

whether they trust the technology, to make the product more user- and society-friendly."

A new diagnostic paradigm

Taken together, these elements point towards a broader transformation in healthcare — one in which diagnostics are no longer centralised and reactive, but embedded in everyday life. "I think in 15 years, most things will be next to the patient," says Kritas. "We give patients their dignity, their quality of life and we can deliver diagnosis and treatment where they are."

For Galanopoulou, the long-term implications extend well beyond pandemic preparedness. "This technology will become a standard technology for point-of-care testing," she says. "It will also be useful for other aspects like antimicrobial resistance, food safety and sexually transmitted diseases."

For Gizeli, however, the future is ultimately about thinking beyond individual technologies and towards the systems they support. "I believe that you always need to think a few years ahead and be several steps ahead," she says.

UNIHEALTH is not simply developing new diagnostic technologies. It is helping to build the foundations of a more responsive, more equitable and more resilient healthcare system. "We are looking at a very big picture," says Gizeli. "A full ecosystem."

Size comparison in a lab bench of the PEBBLE qcLAMP Platform and a real time PCR.

PROJECT INFORMATION

Project Title
UniHealth: Development of a diagnostic ecosystem for detecting and monitoring emergency-prone pathogens across species, globally and in a unified way.

Project Objective
UniHealth is developing accessible point-of-care diagnostics for emerging pathogens, supporting pandemic preparedness through a One Health approach.

Project Duration and Timing
Duration: 36-months.
Timing: 1 December 2023 - 31 May 2027

Project Funding
Funded by the EU under the Horizon Europe Health programme. Total cost €5,345,960.00/ EU contribution €4,887,345.13.

Project Partners
Coordinator
Foundation for Research & Technology, Hellas — Greece
Participants
BIOPIX-T — Greece; CHARITE - UNIVERSITAETSMEDIZIN BERLIN — Germany; INSTITUT PASTEUR DE TUNIS — Tunisia; INSTITUT PASTEUR — France; HARALDSPLASS DIAKONALE SYKEHUS AS — Norway; KIARA HEALTH (PTY) LTD — South Africa; UNIVERSITETET I BERGEN — Norway; Hellenic Bio Cluster (HBio) — Greece
Partner organisations; PKNM SOLUTIONS SARL — Switzerland; UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST — United Kingdom

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UniHealth
POINT-OF-CARE INNOVATION

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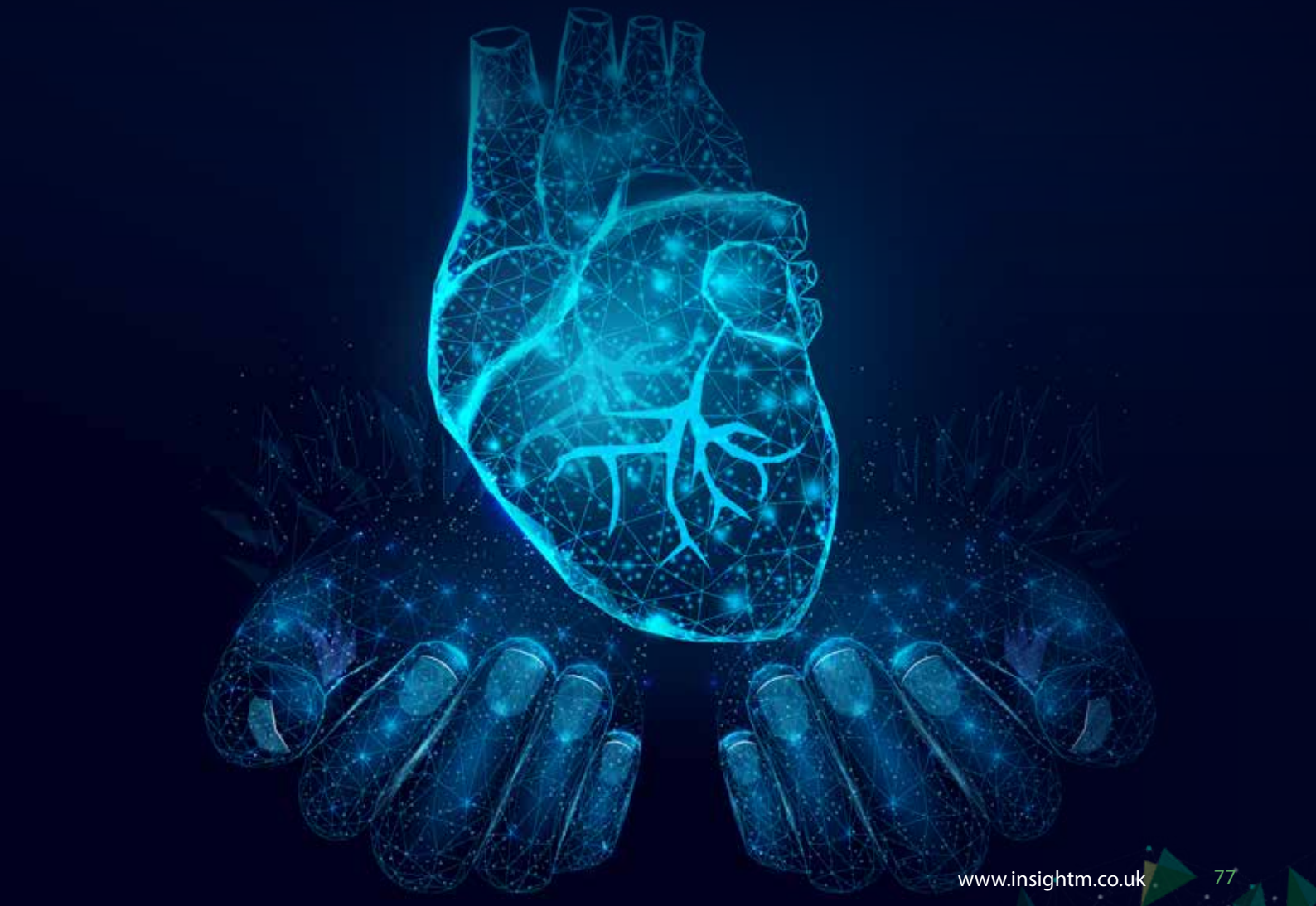
GEREMY: Correcting the genetic roots of inherited heart disease

Gene therapy could transform the treatment of rare inherited heart diseases such as arrhythmogenic cardiomyopathy. **Professor Pieter Doevendans** of UMC Utrecht and **Professor Eva van Rooij** of the Hubrecht Institute and Heartbeat.Bio explain how the GEREMY project is combining clinical insight, molecular biology and cutting-edge gene therapy to address these conditions at their genetic source.

For clinicians treating arrhythmogenic cardiomyopathy, the challenge has long been both urgent and frustrating. The condition, a rare inherited disease affecting the heart muscle, can lead to severe arrhythmias, progressive heart failure and, in some cases, sudden cardiac death. Yet despite major advances in cardiovascular medicine, treatments remain largely reactive, addressing the consequences of the disease rather than the genetic defects that cause it.

The GEREMY project aims to change that. By harnessing advances in gene therapy and molecular biology, researchers are working to develop new treatments that target inherited



forms of arrhythmogenic cardiomyopathy at their source – the DNA itself.

For Professor Pieter Doevendans, a cardiologist at UMC Utrecht who has spent decades studying inherited heart disease, the ambition represents the culmination of a long scientific journey. Over the years, his work has been shaped by the stark reality of the disease and the people affected by it.

"For many of these patients, the first symptom can actually be sudden death," he explains. "That is why these diseases are so serious. We can treat the complications, but we have never really been able to correct the underlying cause."

Together with Professor Eva van Rooij, a leading researcher in cardiovascular gene therapy, of the Hubrecht Institute and Heartbeat.Bio, Doevendans is helping to lead a consortium exploring whether gene-based treatments could offer a fundamentally new approach to treating arrhythmogenic cardiomyopathy and other inherited heart diseases. Combining clinical insight with advances in molecular and gene therapy technologies, the team is working to address these conditions at their genetic source.

Understanding a hidden genetic disease

Arrhythmogenic cardiomyopathy (ACM) is caused by mutations in genes that control the structure and stability of heart muscle cells. When these genes malfunction, the architecture of the heart begins to deteriorate, disrupting electrical signals and weakening the muscle itself.

"ACM is actually a relatively new name for the condition," Doevendans says. "It used to be called arrhythmogenic right ventricular dysplasia, but we now recognise that the disease can affect different parts of the heart. Increasingly, understanding ACM means understanding its genetic origins and the mutations that disrupt the structure and function of heart muscle cells."

Two genetic mutations are particularly important in inherited forms of the disease: PKP2 and PLN. PKP2 mutations are the most common globally and often affect the right ventricle of the heart. Patients frequently present with severe arrhythmias, which can lead to sudden cardiac arrest. PLN mutations, however, tell a slightly different story. Patients may develop both arrhythmias and heart failure, often involving the left ventricle. What makes PLN cardiomyopathy especially unusual is its genetic history.

"All the patients with this mutation can essentially be traced back to a single founding mutation centuries ago," Doevendans explains. "If you go back far enough, they are all related."

The mutation is particularly prevalent in the Netherlands, where large extended families carry the same genetic change. "Over the years, we have been able to identify many of these families and follow them across generations," he adds. "That has allowed us to build very detailed patient registries and family networks."

For researchers, this shared genetic origin provides a rare opportunity to understand how the disease develops and progresses. "Because so many patients carry exactly the same mutation, we can study the disease in a very systematic way. That also gives us a unique opportunity to explore how targeted therapies might one day correct it."

Treating symptoms rather than causes

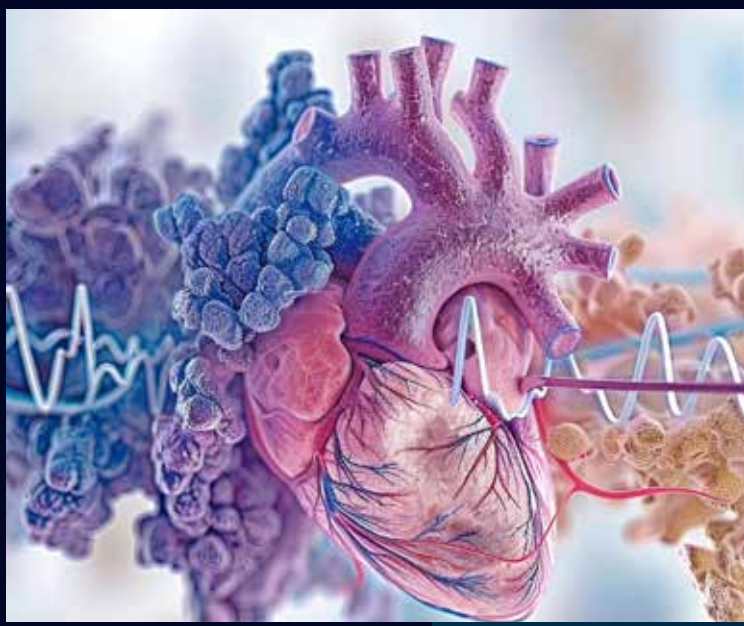
Although clinicians are increasingly able to identify patients with inherited cardiomyopathies, the available treatments remain limited. For patients suffering from arrhythmias, doctors often implant an implantable cardioverter defibrillator (ICD), a device that monitors the heart's rhythm and delivers a shock if a dangerous arrhythmia occurs. "It's something we do very frequently," says Doevendans. "The goal is to prevent sudden death."

But ICDs do not stop the disease itself from progressing. "In essence, we are managing the consequences rather than the disease," he says.

For patients who develop heart failure, the situation can become even more complex. Many eventually require mechanical circulatory support while waiting for a heart transplant. "These devices can take over the circulation completely," Doevendans explains. "But your life depends on the battery you are carrying around. It is a very intense treatment, and ultimately patients are waiting for a new heart." Even transplantation is not a permanent solution, particularly for younger patients. "There is still no curative treatment available," he adds.

From disease modelling to gene therapy

The possibility of changing that reality has emerged only recently, thanks to rapid advances in molecular biology and gene editing. One of the key breakthroughs has been the



development of induced pluripotent stem cell technologies, which allow researchers to create patient-specific heart cells in the laboratory.

"We can now model these diseases very precisely," says van Rooij. "We take stem cells from patients with a mutation in PKP2 or PLN and generate heart muscle cells that carry the exact same genetic defect."

These patient-derived cells allow researchers to recreate the disease in the laboratory and study how it develops at the cellular level. "It means we can study what actually happens in the heart muscle cells when these mutations are present," she explains. "We can see how the cells behave, how the disease progresses and how different interventions might change that."

The models also provide a powerful platform for testing potential therapies before they ever reach patients. In parallel, advances in genome engineering, particularly technologies such as CRISPR gene editing, now allow researchers to modify the DNA of these cells with unprecedented precision.

"In principle, if we correct the error in the DNA, we could restore healthy heart cells again," van Rooij explains. "That means we are not just treating symptoms – we are addressing the cause of the disease."

The ability to model the disease in this way is now shaping the work of the GEREMY project. Using these systems, researchers are able to test a range of complementary therapeutic strategies, from approaches that aim to correct the mutation directly, to others designed to restore the normal function of key proteins disrupted by the genetic defect.

For PKP2 mutations, for example, the disease often arises because heart cells produce too little of the healthy protein. This situation, known as haploinsufficiency, means that although one copy of the gene still functions, it does not produce enough protein to maintain the normal structure and stability of heart muscle cells. "In many of these patients, the problem is simply that there isn't enough of the healthy protein," says van Rooij. "So one strategy is to use gene therapy to restore that level in the heart."

By delivering a healthy copy of the gene to cardiac cells, researchers hope to increase the amount of functional protein produced in the heart muscle and stabilise the affected cells. "If we restore the normal level of that protein in the heart, we can potentially correct the disease mechanism."

Encouragingly, similar approaches are already beginning to move beyond the laboratory. Several biotechnology companies in the United States are now testing gene therapies targeting arrhythmogenic cardiomyopathy and related conditions in early clinical trials, reflecting the rapid pace at which the field is advancing.

"While we were working on these models, several companies developed comparable therapies," van Rooij notes. "And recently we heard that the first patients treated with these approaches are already showing benefit."

For the researchers involved in GEREMY, these developments

are both encouraging and instructive. The progress being made in clinical trials provides valuable insight into how gene therapies might ultimately be delivered to patients and highlights the increasingly collaborative nature of research in this field, where academic laboratories, clinicians and biotechnology companies are working in parallel.

"It really shows the potential power of what we are trying to do," van Rooij says. "The field is moving very quickly, and we are learning a lot from the work that is already being done in patients."

As she explains, this exchange of knowledge between academic researchers and industry partners is helping accelerate progress across the field. "Many groups are working on similar questions at the same time," she adds. "By sharing insights and learning from each other's work, we can move much faster towards therapies that can really help patients."

The delivery challenge

Designing gene therapies in the laboratory is only part of the challenge. Delivering them safely and effectively to the heart is one of the field's biggest hurdles. Most current strategies rely on adeno-associated viruses (AAV) as delivery vehicles that transport therapeutic genetic material into cells. "The virus itself is simply the carrier," Doevendans explains. "What matters is the genetic construct inside it, which produces the beneficial effect in the cell."

Once injected into the bloodstream, these viral vectors travel through the body and deliver their genetic cargo to target tissues. However, directing them specifically to heart cells, while avoiding other organs to avoid side effects, remains complex. "In the lab we can design very powerful tools," van Rooij adds. "But getting those tools safely into the patient, and specifically into the heart, is still the biggest challenge we face."

The project is therefore working to refine viral vectors so they target heart tissue more efficiently and minimise side effects. Improving this precision is crucial: the more effectively a therapy can be directed to heart cells, the lower the dose required and the smaller the risk of unintended effects elsewhere in the body.

This is not simply about delivering genetic material, but doing so in a way that is both safe and efficient enough for clinical use. Progress in this area is advancing rapidly, as researchers experiment with new viral capsids, delivery strategies and targeting mechanisms designed specifically for cardiac tissue. "Solving this challenge will be a critical step in translating promising discoveries into treatments that can be reliably delivered to patients," says van Rooij.

Collaboration across disciplines

Progress in such a complex and rapidly evolving field depends on collaboration across multiple areas of expertise. The GEREMY consortium brings together cardiologists, molecular biologists, gene therapy specialists, animal model researchers, clinical trial designers, biotechnology partners and patient organisations, each contributing a different perspective to the challenge of developing gene-based therapies for inherited heart disease.

Patient organisations play a particularly important role within this ecosystem, helping researchers stay closely connected to the experiences and priorities of those living with the disease. "We want to understand what patients are willing to undergo and what they expect from these therapies," says Doevendans. "That dialogue is essential, because ultimately these treatments are being developed for them."

Because gene therapy represents a fundamentally new approach, understanding patient attitudes towards testing and potential treatments is a crucial part of the research process. Many of the individuals affected by inherited cardiomyopathies have lived with the condition, or the risk of it, for many years, often within families where multiple generations are affected. "These are families who know the disease very well," Doevendans explains. "Some have seen relatives experience serious arrhythmias, heart failure or even sudden cardiac death. So they understand both the risks of the disease and the potential benefits of new treatments."

That experience also shapes how patients view experimental therapies. "We have to ask very carefully what people are comfortable with," he adds. "Would they be willing to participate in a clinical trial? What level of risk would they accept? How do they feel about genetic therapies? These are important conversations to have early on."

For the GEREMY team, this dialogue is not only about ethics but also about designing realistic and effective clinical pathways. "If these therapies move towards clinical trials, patients will ultimately be the ones deciding whether they want to take part," Doevendans adds: "Understanding their perspectives helps us design studies that are both scientifically sound and meaningful for the people we are trying to help."

The project also collaborates closely with biotechnology companies that are already testing gene therapies in clinical trials, allowing academic researchers to learn from emerging clinical experience while contributing new insights from laboratory research. "It's a very open exchange of information," Doevendans says. "We are constantly learning from each other."

For van Rooij, this collaborative environment is essential to turning scientific discoveries into viable treatments. "We really have the full spectrum of expertise within the project, from laboratory research to clinical development, working with partners Mauro Giacca in the UK, Christian Kupatt in Germany, Seppo Ylä-Herttuala and Peter van der Meer in the Netherlands and Pascal Borry in Belgium," she says. "That is what makes it possible to translate discoveries into real treatments."

A step towards the future of cardiac medicine

Although GEREMY focuses primarily on rare inherited cardiomyopathies, its implications could extend far beyond these conditions. The genetic mechanisms being studied may help researchers better understand other forms of heart failure and open new avenues for treating cardiovascular disease more broadly.

For Doevendans, the project also reflects decades of work dedicated to understanding PLN cardiomyopathy and the families affected by it. "It has been a long-term goal," he says. "For many years we have been trying to understand how this disease develops and how we might intervene earlier and more effectively."

For many patients, the stakes are extremely high. Arrhythmogenic cardiomyopathy can remain silent for years before suddenly manifesting as severe arrhythmia or cardiac arrest, and even when the disease is diagnosed early, current treatments largely focus on managing risk rather than curing the condition. "If we can address the mutation at its source, then we are no longer simply managing the consequences of the disease," Doevendans says. "We are trying to correct the mechanism that causes it."

That possibility represents a profound shift in the way inherited heart diseases might one day be treated. "There is still nothing truly curative for these patients today," van Rooij adds. "We can treat symptoms and try to manage the disease, but we cannot yet fix the underlying genetic problem. That is why gene therapy offers such hope."

The road ahead remains complex, and significant scientific and regulatory challenges must still be overcome before these therapies reach patients. But for researchers and the families affected by these conditions, the progress being made offers a glimpse of what the future of cardiac medicine might look like. If successful, GEREMY could mark an important step towards a future where inherited heart diseases are no longer managed only through lifelong treatment, but corrected at the level of their underlying genetic mutations.

PROJECT INFORMATION

Project Title
Gene Therapy for treatment of rare inherited Arrhythmogenic CardioMyopathy

Project Objective
The GEREMY consortium aims to develop the first cardiac gene therapies for rare inherited arrhythmogenic cardiomyopathy caused by PLN and PKP2 mutations, using advanced preclinical models, novel delivery vehicles, gene editing and pig models, while integrating stakeholder input, modern trial design and commercialisation strategies to accelerate clinical translation and reduce disease burden.

Project Duration and Timing
48 months 1/5/2023 – 1/5/2027

Project Funding
Horizon Europe Framework Programme, 8 million

Project Partners
Netherlands Heart Institute
Hubrecht Institute
University Medical Center Groningen
Technische Universität München
University of Eastern Finland
EUPATI
PLN Foundation
KU Leuven
King's College London
Exom Group

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Gene Therapy for treatment of rare inherited Arrhythmogenic CardioMyopathy

This project has received funding from the European Union's Horizon Europe research and innovation program under the grant agreement **No 101080204**.

Insight Feature

AAL: A legacy of innovation shaping ageing well in Europe

Since its launch in 2008, the AAL Programme has pursued the simple but ambitious goal of enabling people to age well in a digital world. Over the course of the programme, it has funded more than 300 projects across 18 countries, involving around 2,000 SMEs, 700 research organisations and more than 100 end-user organisations.

The latest Impact Assessment and Legacy Study highlights measurable impact across AAL's three core objectives: improving quality of life, supporting more sustainable health and care systems, and strengthening Europe's AgeTech sector.

One of the clearest indicators of success has been the programme's expanding real-world reach. During the latest reporting period alone, AAL-supported solutions reached an estimated 23,550 end users, compared with 4,268 in 2023 and 1,855 in 2021. Around two-thirds of beneficiaries were older adults, demonstrating how innovations developed through AAL are increasingly moving beyond pilot projects into everyday use.

Commercial impact has grown alongside societal benefit. Around 250 paying customers are now using AAL-developed solutions, most of them care organisations, while 55% of participating organisations report achieving substantial commercialisation goals. Many products have successfully entered the market, and participants report that, without AAL support, revenues would have been significantly lower or products may never have reached commercial deployment. SMEs have played a particularly important role, leading almost two-thirds of projects during the programme's later years.

The programme's greatest success, however, lies in the difference it has made to people's lives. Among users who had adopted AAL-supported technologies for more than a year, over half reported improvements in physical and mental wellbeing, greater independence, reduced reliance on others and increased confidence and social participation. These findings demonstrate how digital innovation can support not only everyday tasks, but also healthier, more connected and more independent lives.

The Legacy Study, based on an AI-supported analysis of more than 30,000 documents, also provides a broader perspective on the challenges addressed through AAL. Social isolation, independent living, cognitive decline,

mobility and personal safety emerged as the programme's principal areas of focus. In response, projects developed a wide range of solutions, including monitoring technologies, telehealth services, social interaction platforms, wearable devices and assistive technologies that together have helped shape today's rapidly expanding ageing well innovation landscape.

The study also charts the technological evolution of the programme. Early projects focused largely on sensors and alert systems, while later innovations increasingly adopted predictive artificial intelligence, interoperable digital platforms and open standards, allowing solutions to become more scalable and better integrated within health and care services.

Central to AAL's success has been its collaborative approach. More than 60,000 older adults and 14,000 caregivers contributed throughout the programme, helping to co-design technologies that better reflect real-world needs. Continuous user involvement consistently resulted in higher levels of adoption and usability, while 59% of participants reported significant long-term benefits from the partnerships and networks created through the programme.

The studies also acknowledge that challenges remain. Access to investment, technology maturity, business development and regulatory complexity continue to slow the adoption of many innovations. Yet one of the clearest conclusions is that meaningful impact often takes time, with many of the programme's most successful innovations reaching significant market adoption five to ten years after project completion.

Ultimately, AAL leaves behind far more than an impressive portfolio of projects. It has demonstrated how technology, business, researchers, healthcare providers and end users can work together to develop solutions that genuinely improve people's lives. In doing so, it has helped create a stronger European ecosystem for innovation in healthy ageing, one whose influence will continue long after the programme itself has concluded.

Building on the AAL legacy

Although the AAL Programme has reached its conclusion, its influence continues through the European Partnership on Transforming Health and Care Systems (THCS), which is building on many of the principles established by AAL.

While AAL focused on developing innovative technologies and services that enable people to age well, THCS takes a broader systems perspective, working to transform how health and care services are organised, integrated and delivered across Europe. In doing so, it carries forward many of the approaches pioneered through AAL, including co-creation with end users, cross-sector collaboration, ecosystem development and the translation of research into practical, scalable solutions.

The partnerships, expertise and innovation culture created through AAL continue to inform new research collaborations and future health initiatives. Rather than marking an endpoint, the programme has laid important foundations for the next generation of European health and care innovation, ensuring that its lessons and achievements continue to shape healthier, more resilient and more person-centred health and care systems.

RETENTION: From reactive care to predictive precision in advanced heart failure

Advanced heart failure remains one of the most complex and resource-intensive conditions in modern medicine. The RETENTION project is bringing together clinical expertise, data science and digital health technologies to transform how patients with the condition are monitored and treated. We talk to the project's three coordinators about how this work is shifting care from reactive intervention to predictive, personalised management.

For clinicians working in advanced heart failure, uncertainty is a constant part of everyday clinical practice. Patients present with highly variable conditions, unpredictable trajectories and a need for continuous, lifelong management. "Advanced heart failure is not a single predictable condition," explains the RETENTION project's clinical coordinator Dr. Aggeliki Gkouziouta, heart failure and transplant cardiologist at the Onassis Cardiac Surgery Centre in Greece. "We deal with a whole spectrum of patients – those in heart failure, those who undergo transplantation and those supported with ventricular assist devices. Each of these groups has distinct clinical trajectories and therapeutic needs, making management inherently complex and highly individualised. Managing these patients is extremely complex."

This complexity is not just clinical, but also systemic in how it impacts on every aspect of health and care. Patients may experience repeated hospitalisations or sudden deterioration, while the burden of managing complex therapies in their daily lives can be overwhelming. For many, access to specialist care is limited by geography, while for clinicians, decision-making

is often constrained by fragmented data and limited tools that accurately chart the likely progression of the disease.

"It is more complex because the challenges are multidimensional," Dr Gkouziouta Continues. "You must deal simultaneously with haemodynamics, clinical instability, treatment adherence and psychosocial factors in the here and now, all within the context of a condition that requires continuous, lifelong monitoring.

"The problem is exacerbated by the fact that though a great deal of data is generated across healthcare systems, it is rarely available in a form that can support real-time clinical decision-making", Dr Gkouziouta continues. "We realised that although the data exists, it is difficult to synthesise it in real time and at the point of care. This is why continuous monitoring is so important – it helps bridge the gap between available data and actionable clinical insight."

Closing the gap

It is precisely this gap between available data and actionable insight that RETENTION addresses. At its core, the project aims to shift care from reactive intervention to more proactive management. "What RETENTION fundamentally aims to do is to close the gap from reactive to proactive," says Dr Gkouziouta. "The goal is to enable earlier, more informed intervention, before clinical deterioration becomes evident."

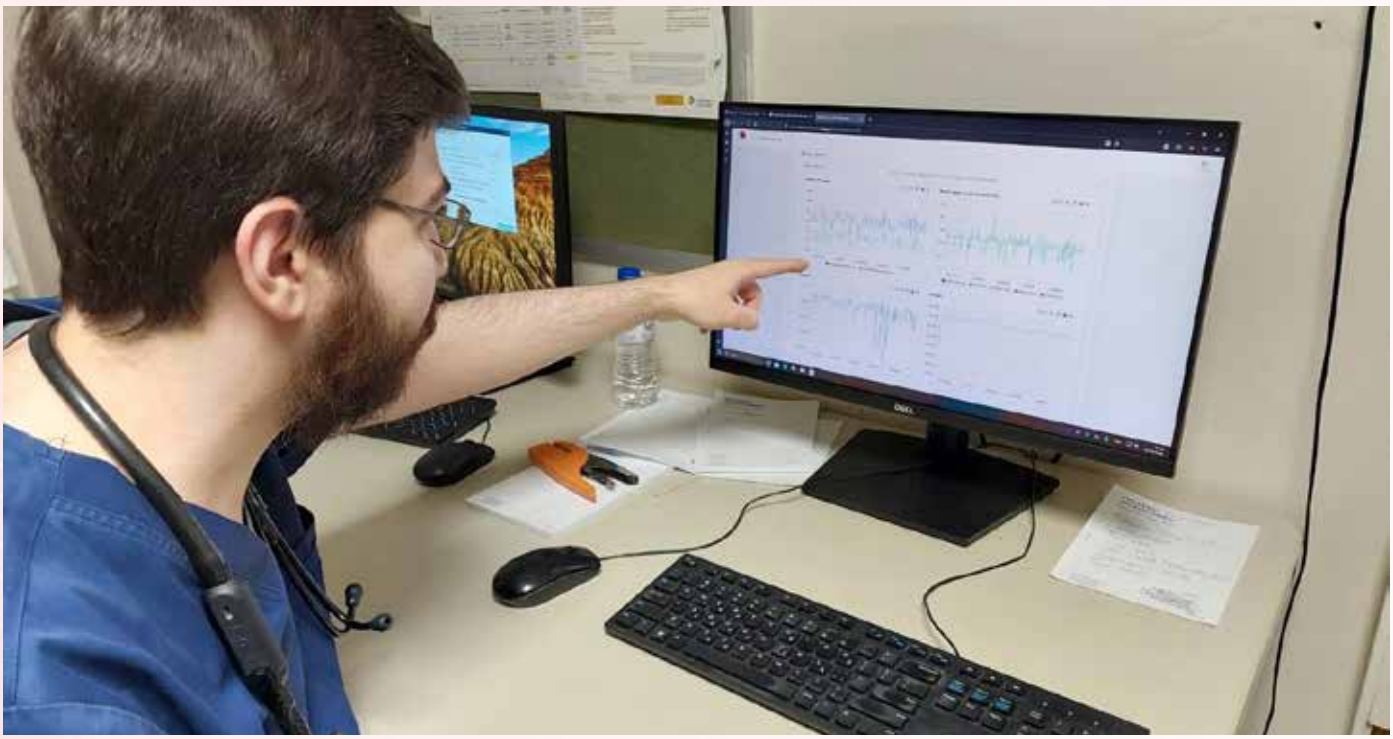
For project coordinator Dr. Maria Haritou, Research Director at the Institute of Communication and Computer Systems in Greece, this represents a pivotal moment for the care of heart disease. "We now believe we are at a point where we have both the data and the technology to use it meaningfully in daily clinical practice," she explains. "Advanced heart failure is a dynamic condition influenced by many interacting factors like the clinical status of the patient, any comorbidities they have and even their biology. The devices they may have fitted also influence the progress of the condition and its ongoing management.

"Traditional models cannot fully capture this complexity, and so clinicians often rely on their experience and what fragmented data they have available to make critical decisions. We want RETENTION to give these experts a big boost with integrated, data-driven insights."

A data ecosystem

So, at the heart of RETENTION is a comprehensive data ecosystem that captures the full reality of a patient's condition, not just within a hospital setting, but in everyday life. "We use a number of devices that patients already have at home to capture this data," Haritou explains. "We collect measurements such as blood pressure, oxygen levels and body weight automatically. For heart failure patients, even subtle changes, especially in weight, can provide an early warning that something is wrong, often before the patient feels it themselves."

But the system goes further than collecting clinical data about a patient. It also integrates additional layers of information that are rarely considered in traditional care models, but add a critical layer to disease monitoring and management. "We collect environmental data, like temperature, humidity and pollution, for example, using sensors in the patient's home," Haritou explains further. "And we use a smartwatch to monitor activity, including sleep patterns and periods of activity and



RETENTION Partners

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inactivity. Patients also self-report how they feel."

The result is a multi-dimensional dataset that combines clinical, behavioural and environmental inputs, offering a far richer picture of patient health as it evolves. Importantly, the system is built using commercially available and certified medical devices. "These devices already exist on the market," Haritou adds. "We have tested them and integrated them into our system."

From monitoring to prediction

Collecting data, however, is only part of the RETENTION story. The real innovation lies in how that data is used. "There are two main parts to this," explains technical coordinator Dr. Lefteris Koumakis, Assistant Professor in Data Science and Machine Learning at Sphynx Technology Solutions in Switzerland. "First, clinicians use the three sources of data to monitor patients through a dashboard, which provides a continuous overview of their condition. Second, the data is analysed using machine learning and artificial intelligence models to generate predictive insights."

These models are trained on longitudinal patient data, which is information collected continuously over time, rather than at a single point during a clinical visit. This data builds a dynamic picture of how a patient's condition evolves and is combined with historical data from many other patients, enabling the system to learn from patterns observed across larger populations.

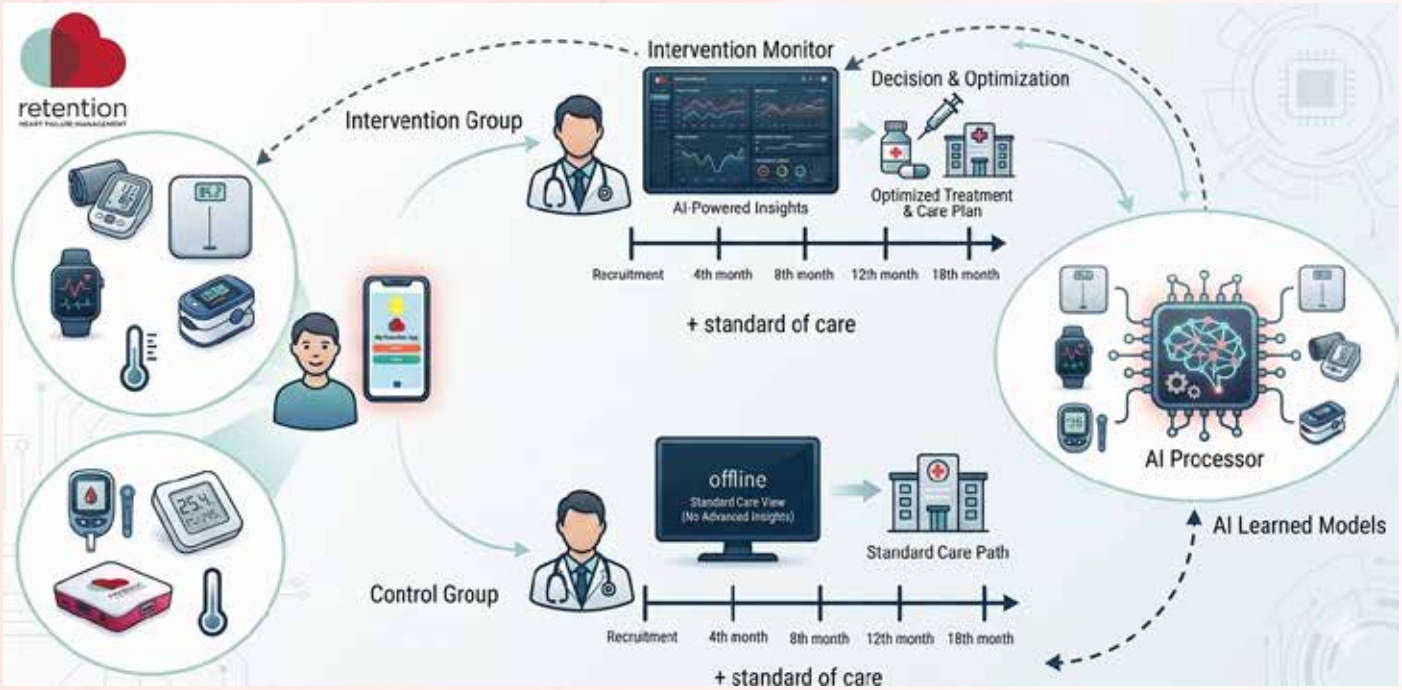
"We use temporal information throughout the course of the disease to train our models," Koumakis explains. "This means looking not just at individual measurements, but at how those measurements change over time, how a patient's condition develops, stabilises or worsens. Based on this, and by learning from similar patterns seen in other patients, we can begin to predict whether a patient is likely to be admitted again or experience a cardiovascular event."

In effect, RETENTION is not just monitoring patients; it is learning from them, with its primary focus being on preventing deterioration before it becomes critical. "We are trying to predict unplanned hospitalisations and clinical destabilisation," Haritou explains. "So clinicians can intervene earlier."

For Dr Gkouziouta, this represents a fundamental shift in care. "Early detection means fewer admissions and fewer complications," she says. "An efficient healthcare system is one that intervenes at the right time with the right treatment for the right patient."

Clinicians at the centre

Despite its reliance on advanced analytics, RETENTION is not about replacing clinical judgement. In fact, its motivation is simply to help clinicians make better decisions. "It is a human-in-the-loop approach," Dr Haritou emphasises. "The system provides recommendations and predictions, but nothing is



automated and all decisions are made by clinicians."

Crucially, the system also explains its predictions, ensuring transparency and trust. "We provide explainability – why the model suggests something," she continues. "Clinicians can assess the prediction, compare it with their own observations, and decide whether to act."

This balance between technology and human expertise is essential for adoption. "The key factor here is trust," says Dr Gkouziouta. "Clinicians need to trust the system, patients trust their doctors, and doctors must trust the technology. So, we all work together, for the benefit of the patient."

Supporting patients

While RETENTION is designed to support clinicians in making better decisions, its impact on people living with advanced heart failure may be even more profound. For many patients, the burden of their condition is not confined to hospital visits, but shapes every aspect of daily life. "One of our major challenges is adherence," explains Dr Gkouziouta. "Patients suffer a lot. They see doctors, nurses, emergency departments repeatedly, and sometimes they reach a point where they say, 'I give up.'"

This is not simply a matter of missed medication or forgotten measurements, but the cumulative effect of living for years with a long-term and often debilitating condition. Many patients face significant physical limitations, while also coping with uncertainty about their future and, in some cases, the long wait for life-saving interventions such as transplantation.

RETENTION introduces a structured and continuous layer of support into this reality, helping patients to manage their condition more consistently and with greater confidence. "We can monitor whether they follow their routine – checking their vital signs, and confirming that they are taking their medication, for example" Dr Gkouziouta says. "This is critical, because if a transplant patient does not take immunosuppressants, they may reject the graft. If a VAD patient does not take anticoagulants, they risk thrombosis. And if a heart failure patient does not manage their fluid balance, clinical decompensation can rapidly occur. They will deteriorate."

By making these routines visible and trackable, the platform helps reinforce compliance with recommended routines and treatments, while also allowing clinicians to intervene early when patterns begin to shift. At the same time, continuous monitoring provides reassurance for the patients, which is something equally important. "Patients feel safer knowing they are being monitored," says Dr Haritou. "Especially those who live far from specialist centres. It also provides reassurance to their families."

For patients who may be living many miles from the nearest transplant or cardiology centre, this connection to their care team can be transformative. Rather than relying solely on periodic appointments or reacting to symptoms once they become severe, they are supported through a system that is constantly observing and ready to respond.

And these benefits extend beyond the patient themselves. Caregivers, who are often family members who play a crucial and demanding role in supporting daily care, are also an integral part of the RETENTION approach. "It is very important

to acknowledge caregivers," Dr Gkouziouta adds. "And the monitoring and connection to the clinical team helps them feel less alone and, in a condition where the trajectory can change quickly and unpredictably, this sense of shared oversight can reduce anxiety and provide a greater sense of control."

The system at work

In practice, RETENTION operates across three interconnected layers. At home, patients use simple, familiar devices to collect data. In the clinic, healthcare professionals access a web-based dashboard that provides real-time insights into patient status. And, behind the scenes, a central "Global Insights Cloud" aggregates anonymised data for analysis and model training. "These are the three core components," Haritou explains. "The patient environment, the clinical dashboard, and the central cloud where analytics take place."

This architecture allows clinicians to monitor patients continuously, regardless of location. "They can access the system from anywhere," she says. "They can see if there is any alert or change and act accordingly."

When issues are detected, intervention remains personal and direct. "If we see changes, we contact the patient directly," Dr Gkouziouta explains. "We ask what is happening, whether they are taking their medication. Sometimes we act before the patient even realises there is a problem."

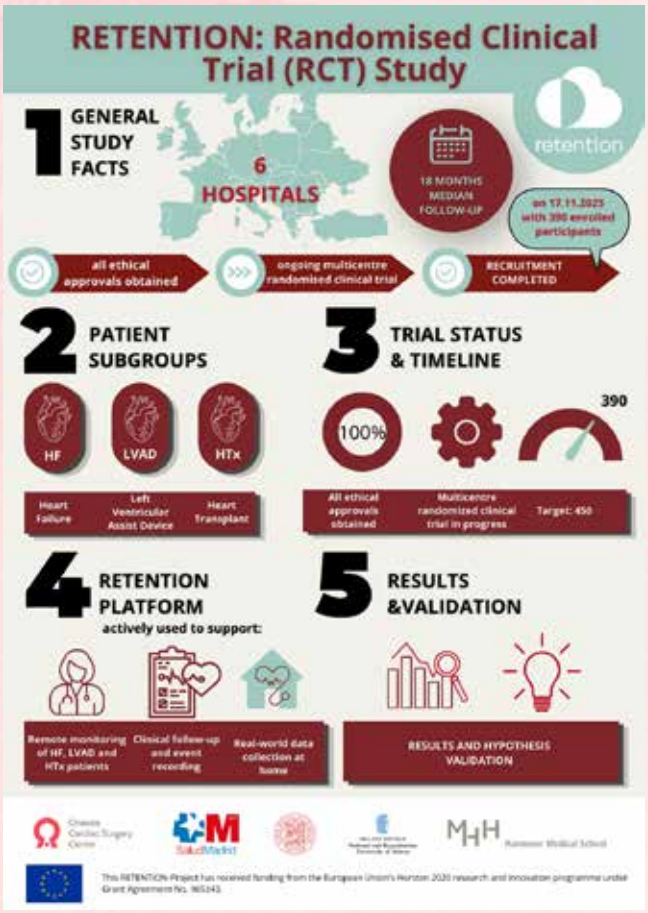
Next steps

As a project, RETENTION is now in its final phase, following a challenging journey shaped by the COVID-19 pandemic, which saw it extend into a fifth year. "We lost about a year and a half due to COVID, but now we are running the clinical trial, which began in 2024 and is now nearing completion," Dr Haritou says. "We have two groups – an intervention group and a control group – and we will analyse the results after the study finishes.

When issues are detected, intervention remains personal and direct. "If we see changes, we contact the patient directly," Dr Gkouziouta explains. "We ask what is happening, whether they are taking their medication, and in many cases, we are able to intervene before the patient is even aware of a problem".

Looking beyond the project, the pathway to implementation is already being considered. "We designed the system to be interoperable and scalable from the beginning," says Koumakis. "We use standards such as FHIR, and each hospital can operate independently."

However, the partners are clear that adoption will require more than simply having a working technology. Introducing any new system into healthcare environments is notoriously complex, with certification, integration into existing infrastructures and acceptance by healthcare professionals all essential steps



along the way. What gives RETENTION a distinct advantage in this context is its flexible underlying architecture. Rather than being built as a single-purpose solution, the platform has been designed to adapt to different clinical scenarios and patient groups. "Our system is not limited to heart failure," Koumakis explains. "It can be adapted to other chronic conditions, meaning a separate system is not needed for each disease."

This ability to generalise across conditions is particularly significant. Chronic diseases often share similar challenges. Long-term monitoring, fluctuating symptoms, the need for early intervention and the importance of patient compliance are all common features. By allowing clinicians to define and monitor different sets of parameters, RETENTION can be reconfigured to support a wide range of conditions without fundamentally changing the system itself.

In practical terms, this reduces fragmentation within healthcare systems, where multiple disconnected tools are often used for different diseases. Instead, a smaller number of flexible, interoperable platforms can support multiple care pathways, improving efficiency for clinicians and simplifying integration for healthcare providers.

This broader applicability also aligns closely with the European Union's strategic priorities for healthcare. "I think it is fully aligned with European priorities," Haritou adds. "There is a

strong focus on digital transformation and data sharing and RETENTION directly supports this vision."

Across Europe, there is a growing emphasis on creating integrated digital health ecosystems, including initiatives such as the European Health Data Space, which aim to enable the secure sharing and reuse of health data across borders and disciplines. Solutions like RETENTION fit well within this evolving landscape. By enabling data to be collected, analysed and reused in a consistent and scalable way, the project contributes not only to improving outcomes for individual patients, but also to building the kind of connected, data-driven healthcare system that the EU continues to promote through its research funding efforts.

Legacy

As the project now approaches the conclusion of its clinical trial phase, the focus is firmly on gathering the evidence on whether the system can meaningfully reduce hospitalisations, support earlier intervention and improve outcomes for patients with advanced heart failure. For clinicians working in this field, even incremental improvements can translate into significant gains in quality of life and reductions in the burden on healthcare systems.

RETENTION's ambition is therefore not to replace clinical judgement, but to strengthen it by providing a clearer, more continuous picture of patient status in real time and enabling decisions to be made with greater confidence and at an earlier stage. For Dr Gkouziouta, that objective remains straightforward: "We have aimed to develop an efficient system that intervenes at the right time with the right treatment for the right patient.

"Whether RETENTION can consistently deliver that outcome will be determined in the months ahead," she concludes. "But if it does, it will offer a good example of how data-driven approaches to healthcare can effectively support the sustainable, day-to-day management of chronic diseases within our healthcare systems."

PROJECT INFORMATION

Project Title
Heart Failure Patient Management And Interventions Using Continuous Patient Monitoring Outside Hospitals And Real World Data (RETENTION)

Project Objective
RETENTION aims to support clinical decision making and evidenced based personalised interventions for patients with advanced Heart Failure (HF).

Project Duration and Timing
66 months Start: 01.05.2021, End: 31.10.2026

Project Funding
HORIZON 2020 (SC1-DTH-12-2020)
Funding: € 5.983.243,94

Project Partners
Institute Of Communication And Computer Systems (GR); Onassis Cardiac Surgery Centre (GR); Alma Mater Studiorum - Universita Di Bologna (IT); Servicio Madrileno De Salud (ES); National And Kapodistrian University Of Athens (GR); Forth Institute Of Research And Technology (GR); London School Of Economics And Political Science (UK); Sphynx Technology Solutions Ag (CH) Datamed Sa (GR); I2grow Innovation To Grow Srl (IT); Aegis It Research Gmbh (DE); Siemens Srl (RO); Eunomia Limited (IE); Hannover Medical School (DE)

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retention

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SHIFT-HUB: A pan-European smart health hub turning fragmentation into connected impact

SHIFT-HUB is building a pan-European smart health innovation community and hub, connecting fragmented ecosystems and helping digital solutions move from concept to real-world use. By bringing together innovators, healthcare organisations, decision makers and patients to accelerate smart health solution development and overcome long-standing barriers to market, coordinator **Alena Bubeck** of **Steinbeis Europa Zentrum** believes the project's approach will deliver lasting health impacts.

Despite huge progress in AI, data analytics and smart devices, it is clear that digital tools are still nowhere near as embedded in everyday health and care as they could or should be. Many promising technologies remain stuck in labs, pilots or fragmented regional programmes, while innovators and healthcare stakeholders sometimes find it difficult to work together on developing solutions to meet specific needs.

For **Alena Bubeck**, Project Manager at **Steinbeis Europa Zentrum** – a long recognised innovation and ecosystem builder for SMEs and research actors in Europe – and coordinator of the SHIFT-HUB project, this gap between innovation and implementation emerged as a critical challenge in the project. A key aim for the consortium was, therefore, to find ways to close the gap, bring stakeholders together and to get innovative digital solutions out of the development stage and into real-world use.

"The idea is really about bringing smart health innovation to people," she explains. "Along the development chain, there are a lot of stakeholders involved, and many people need to be brought together to make sure innovations actually reach end users."

SHIFT-HUB, funded under the Horizon Europe programme, is doing exactly that: building a pan-European Smart Health Innovation Hub that brings together healthcare providers, patients, SMEs, researchers, investors, public authorities and other actors to co-develop and adopt smart health technologies.

Why we need a smart health hub

The health challenges SHIFT-HUB set out to address when it started three years ago are not new. They have been with us for many years and they remain among the most persistent pressures on Europe's health systems. As **Bubeck** explains, the project was framed around the major health challenges: the rising incidence of non-communicable diseases such as chronic diseases, cancer, cardiovascular conditions, but also the need for disease prevention.

"Prevention is critical, but is often overlooked. It's often the least attractive topic, even though it has the biggest potential impact," she says. "Prevention starts with end-users – clinicians, citizens and patients – but human nature gets in the way – because when there is no direct pain point, people rarely act on it. If you're not sick, you don't think about preventing illness."

Smart health applications could help change that equation, using data, decision support and personalised feedback to nudge people towards healthier behaviours and earlier interventions. Yet too many promising tools never make it past the prototype or pilot phase.

When **Bubeck** and her colleagues looked at why this is the case, one problem appeared everywhere: fragmentation. "Ecosystems differ in maturity, infrastructure, stakeholder types, barriers," she explains. "Our idea was to overcome this by creating a Europe-wide hub that connects fragmented ecosystems, providing a contact point where they can build communities, share ideas and data and collaborate across borders."

From EDIH principles to a living knowledge hub

SHIFT-HUB does not start from scratch in developing this hub. It builds on the European Digital Innovation Hub (EDIH) concept – physical and virtual one-stop shops that provide digitalisation services to industry and the public sector.

"We are aligned with the structure of innovation hubs like the EDIHs," says **Bubeck**. These provide services to stakeholders within innovation ecosystems, but SHIFT-HUB pushes the idea further across regional borders. SHIFT-HUBs aim is to build and connect the Smart Health Community across Europe in one place.

Rather than being another service provider, SHIFT-HUB acts as a **knowledge hub** and **facilitator**, helping innovators navigate a complex maze of stakeholders, regulations, data and funding opportunities across European borders. "We want to be the contact point for Smart Health innovators offering a comprehensive portfolio and say: 'Here is what we can do depending on your stage, how can we help and who we can connect you with?'," says **Burbeck**.

As a researcher herself, **Bubeck** knows how easy it is to get stuck in the lab: "You believe in your innovation, focus intensely on the small steps, and sometimes loose track of the big picture. Later, all the aspects you didn't consider can become overwhelming, and motivation drops. Innovations then stall. SHIFT-HUB aims to support this whole journey so that doesn't happen."

Mapping the landscape

Turning that ambition into something concrete started from the beginning of the project. "In the concept design phase we mapped existing hubs and facilities to understand what already works," **Bubeck** explains. "We didn't want to reinvent the wheel, so we reviewed existing service structures in other digital innovation hubs and performed a thorough stakeholder mapping to better understand the needs of all stakeholders."

This led to an initial portfolio built around three types of services:

- Involvement services – community building, engagement, facilitation
- Growth services – support for SMEs, startups and tech providers

- Route-to-market services – access to funding, demonstration, test-before-investment

Different stakeholder groups, from innovation hubs and public authorities to tech providers, clinicians, patients and policymakers, were brought into co-design sessions. Over time, feedback led to the fine-tuning of the concept further. "Through multi-stakeholder co-design, we reorganised the services into three clearer pillars," says **Bubeck**. These, which now define how SHIFT-HUB works day to day, are labelled: Build & Boost, Connect & Thrive, and Learn & Grow.

Pillar 1: Build & Boost – helping innovations grow

The first pillar, Build & Boost, is focused on the innovators themselves: tech providers, SMEs and startups working on smart health solutions. Services under this pillar aims to helping technology providers and startups develop and co-create solutions, from idea generation to near-market readiness. Services include:

- **Open Innovation Workshops** – where multidisciplinary stakeholders co-create new ideas around healthcare challenges
- **Matchmaking and Brokerage Events** – finding the right partners for R&D, pilots or scale-up
- **Pitch Sessions and Access-to-finance Support** – helping teams refine their proposition and connect with investors or funding schemes
- **Demo Days** – showcasing mature solutions to healthcare organisations, patients and other potential users

The impact is already tangible: SHIFT-HUB has run nine Open Innovation workshops involving more than 400 participants, generating more than 40 concrete ideas. Eighteen of these have led to the building of consortia applying for calls, together requesting more than €15 million.

Pillar 2: Connect & Thrive – a European smart health community

If Build & Boost is about nurturing individual innovations, Connect & Thrive is about building the ecosystem around them. The pillar aims to foster collaboration and build a European smart health community. At its heart is SHIFT-HUB's community platform – an online space where members can register for free, host events, advertise services and connect with. The platform offers:

- Matchmaking and networking
- Direct messaging without sharing personal contact details
- A marketplace where members can list available services, infrastructure (such as Living Labs), or collaboration offers
- Event promotion, and hosting

"Currently our community platform has more than 700 members, and within our project, we have counted more than 730 matchmaking opportunities, with more than 300 effective collaborations," says **Bubeck**. "It really shows that people are using the platform to reach out to one another."

The Connect & Thrive pillar also brings the ecosystem together through a series of structured activities. SHIFT-HUB's international conferences – hybrid and on-site events featuring policymakers, regional authorities, clinicians, innovators, researchers and citizens – create spaces where different stakeholders of the health innovation system can openly exchange perspectives. Alongside these, the project runs a focus group on priority eHealth topics such as AI in healthcare, data security, secure data sharing, European Health Data Spaces(EHDS) and cybersecurity. This group allow experts to compare approaches, identify gaps and work towards shared policy recommendations.

A third strand, the Entrepreneurial Discovery Workshops, digs deeper at the regional level. Held in places like Central Macedonia, Northern Portugal and Southwest Germany, these sessions bring all ecosystem stakeholders together to map their local structures, needs and barriers, and to co-design the policy recommendations that might help address these.

This policy aspect of the project has been a key component, yet when the findings have been compared, a striking familiarity has become apparent. As **Bubeck** puts it: "Looking at the policy recommendations that have emerged from the workshops, there are none that you have never heard of, which is actually quite shocking as it shows they have not been addressed fully over many years. We seem to be talking about these things over and over again, but not acting."

The persistent obstacles that SHIFT-HUB has found resurfacing in the policy recommendations are: early-stage

funding gaps, the familiar 'valley of death' for startups, insufficient and inconsistent mentoring networks, and an urgent need for interoperable health data infrastructures capable of supporting digital innovation at scale.

Pillar 3: Learn & Grow – literacy, trust and capacity

This third pillar addresses another critical barrier, knowledge and trust, by supporting knowledge exchange and capacity building across different stakeholder groups. Its flagship output is an educational resources catalogue – almost 190 resources across 15 themes such as AI, data science, smart health applications and training formats.

The catalogue targets patients, citizens and healthcare professionals and aims to build trust and improve digital literacy, which are essential for data sharing and the uptake of digital solutions. Importantly, it will remain freely accessible via the SHIFT-HUB website even after the project ends – and for **Bubeck**, this is fundamental. "We were also lucky that our SHIFT-HUB partner, the University of Porto, who lead the development of the catalogue, secured follow-up funding via the INNOV4LIFE Interreg-project, which will continue to update the educational resources available,"she says.

"Building trust is essential – patients and citizens need to know their data is being handled correctly and securely. Without that trust, they won't share their data, and without data, smart health solutions simply cannot be developed. These technologies depend on it."

The involvement of COPAC, the Coalition of Organisations of Patients with Chronic Diseases in Romania, as a patient organisation and project partner has also been crucial in this aspect of the project. Their networks give SHIFT-HUB fast access to large groups of patients and carers for feedback, co-design and testing. "Having patients or patient representatives included in European funded projects is essential," says **Bubeck**. "Our main goal is to help people with these solutions. But in order for them to use them, they need to accept and trust them. Therefore, it is important to involve patients from the get go and listen to their feedback. This allows us to do that. In fact, I would probably never plan another European health project without having a patient representative organisation involved. "

Real-world testing

Beyond frameworks and platforms, SHIFT-HUB has also generated concrete results. Alongside the Open Innovation workshops and consortia, the project has organised five Living Labs with more than 200 participants – patients, citizens and healthcare professionals – all testing solutions on topics like health literacy for seniors, frailty prevention and digital health training.

For more mature solutions, SHIFT-HUB has run six Demo Days with more than 300 participants and around 20 startups. One standout is MedRadar, an app that helps patients locate pharmacies that have specific medicines in stock, providing a clear example of how SHIFT-HUB is already helping to turn ideas into solutions on the market.

"Our event helped MedRadar speed up their journey from idea to market solution," says **Bubeck**. "They now have more than 20,000 users and 2,500 pharmacies that are listed and using the app, which is very encouraging."

At the same time, more structural initiatives have emerged, such as a Living Lab being set up in Bucharest by COPAC with the local medical university.

Lessons learned

Among the most revealing outcomes of SHIFT-HUB's work are the insights it has gathered on Europe's investment culture. Despite the abundance of smart health ideas emerging across the continent, many struggle to progress beyond early stages, not because of a lack of creativity or market viability, but because of an over-cautious investment culture.

As **Bubeck** explains, investor feedback was surprisingly consistent: "They agreed that the innovation ecosystem in Europe will often not take too many risks, so we are holding ourselves back a bit. But this risk aversion is compounded by bureaucracy, regulatory complexity and fragmented national frameworks, all of which make market entry even harder," she reports.

The absence of a unified European pathway, particularly for regulatory and data-related requirements, leaves innovators navigating a patchwork of systems at the very moment they most need clarity. For the experts, part of the solution here lies in embracing a more experimental mindset. Europe, they suggest, must become more comfortable with iteration, rapid decision-making and letting go of innovations that aren't working.

It seems this is precisely where SHIFT-HUB can add value. By bringing innovators together with reviewers, investors, patients and other stakeholders early in the process, the hub helps make those difficult decisions clearer and less costly.

"We need to connect the innovators with the end users, the investors and the entrepreneurs that have gone through all of these stages, to provide critical feedback," **Bubeck** continues.

Through its pitch programmes, brokerage events, Living Labs and multi-stakeholder workshops, SHIFT-HUB creates the spaces where that candid feedback can happen. In doing so, it helps de-risk innovation not by eliminating uncertainty, but by ensuring that innovators have the information, insight and connections they need to deal with bureaucracy and regulations and to make informed decisions faster.

Growing the hub

Despite the project coming to an end, **Bubeck** is refreshingly realistic about its longevity and for the hub to keep delivering. On the business side, ideally they would love to establish an innovation cluster that is independent of public funding, but the likelihood is that more public funding will be needed. The team is, therefore, actively seeking follow-up funding to evolve into a fully funded European innovation hub or join forces with other related innovation ecosystems.

In the meantime, all SHIFT-HUB partners are dedicated to keeping the services alive and accessible. The community platform will remain open for at least five years, replication and best-practice sheets are being prepared for all services and partners have committed to being reachable as contact points.

On the topic side, one of the most promising growth areas now is secure health data sharing. Rather than building its own platform, SHIFT-HUB has chosen to collaborate with the RAISE project, an EOSC project, which is piloting data sharing infrastructure aligned with the future European Health Data Space.

"There is no point in replicating it," **Bubeck** says. "Instead, our role will be to make sure our community knows that such a platform exists and can use it, especially technology providers and entrepreneurs who can access available datasets to test their ideas and trial their prototypes."

As SHIFT-HUB transitions beyond its funded period, and with much of its activity continuing, the project has also already left a durable legacy, at the centre of which is the community platform, which **Bubeck** describes as essential for bringing diverse stakeholders together for the marketplace and the matchmaking opportunities.

Around this sits a set of practical tools and methods that will also outlive the project: structured approaches for Demo Days, test-before-investment activities, and Capacity-Building Workshops; the project's targeted value-creation methods that help other innovation hubs evaluate and strengthen their own services; and the educational resources catalogue, which consolidates smart-health training materials in one accessible place. Equally important is the growing network of collaborating hubs and innovation intermediaries now able to guide innovators across regions and sectors.

Of course, no one expected a three-year project to remake Europe's innovation landscape, but **Bubeck** is clear that SHIFT-HUB has shifted the ground in this time: "The project has created a space where European smart health innovation is likely to be more effective, and to thrive more than it was before the project happened, particularly in partner regions and countries such as Portugal, Central Macedonia and Romania," she says.

"I see SHIFT-HUB as a real contact and connection point; a valuable community. It's not just about offering services, but about being the place people can turn to whenever they need support."

For innovators, healthcare providers, patients, authorities and investors across Europe, the message is straightforward: Join this community, use the services, bring your challenges and your skills and help co-create the digital health solutions Europe urgently needs.

Visit ***https://shift-hub.eu/*** for information about joining the hub and gaining access to more than 700 members in the community.

PROJECT INFORMATION

Project Title
SHIFT-HUB: Smart Health Innovation & Future Technologies Hub

Project Objective
SHIFT-HUB aims to create a pan-European Smart Health Innovation Hub fostering collaboration among quadruple helix stakeholders. It drives technology development, uptake, awareness, and trust through community building, data sharing, demonstrations, education, and gamified experiences, while ensuring sustainability via policy activities and peer partnerships—paving the way for proactive, personalized healthcare.

Project Duration and Timing
3 years, January 2023 until December 2025

Project Funding
European Commission, Horizon Europe, Coordination Support Action, €1,999,999.00

Project Partners
Steinbeis Europa Zentrum, KiNNO Innovation Intermediaries Ltd, University of Porto, University Hospital Cologne, Aristotle University of Thessaloniki, European DIGITAL SME Alliance, IPPOCRATE AS, BOOSTER Labs S.A.S, BEIA Consult International SRL, Coalition of Organisations patients with chronic diseases in Romania, Cleyrop, Numih France

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SHIFT-HUB

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Partnership for better health

Transforming healthcare requires more than scientific excellence alone. It demands collaboration between researchers, clinicians, policymakers, patients, industry and communicators to ensure that innovation reaches the people who need it most. Across Europe, health research is delivering remarkable advances in prevention, diagnosis, treatment and care. This magazine celebrates those achievements and highlights the partnerships that turn promising discoveries into real-world impact.

Whether developing new vaccines, improving diagnostics, harnessing artificial intelligence, advancing rehabilitation technologies or creating more sustainable healthcare systems, good health research is built on strong partnerships. It's a relatively simple concept – meaningful progress depends on the right people and organisations working together towards a common goal.

It is an approach that Europe has refined over decades through its research and innovation programmes. By bringing together universities, hospitals, research institutes, healthcare providers, SMEs, industry partners and policymakers, Europe has created a world-leading ecosystem capable of addressing some of society's most pressing health challenges.

As preparations continue for the next Framework Programme (FP10), health research stands at the forefront of Europe's ambitions. Ageing populations, rising healthcare costs, workforce shortages, chronic disease, growing inequalities in access to care and the continuing threat of future pandemics all demand innovative solutions. The EU is rightly focused on these challenges, but meeting them effectively will require not only excellent science but also effective collaboration and the ability to translate research into practice.

The projects featured throughout this edition demonstrate exactly what can be achieved when expertise is brought together. Researchers, clinicians, engineers, behavioural scientists, public health experts, patient groups and healthcare innovators are working collectively to improve prevention, personalise treatment, strengthen healthcare systems and ultimately improve quality of life for citizens across Europe and beyond.

At Insight Media, we are proud to support this ambition. For more than 15 years, we have worked alongside some of Europe's leading research and innovation projects, helping them communicate their work, demonstrate impact and engage the audiences that matter most. In health research, effective communication is particularly important. The journey from scientific discovery to patient benefit often depends on engaging healthcare professionals, policymakers, regulators, healthcare providers, industry stakeholders and the wider public.

Partnership sits at the heart of everything we do and every project we support becomes a partner. We work closely with consortia to understand their objectives, identify their target audiences and develop communication, dissemination and exploitation strategies that deliver measurable outcomes. Our role is not simply to share information, but to help research achieve the visibility, engagement and uptake needed to maximise impact.

Bringing this magazine together is itself an example of that partnership approach. Each article is the result of close collaboration with project coordinators, researchers, clinicians and communication teams across Europe and further afield. Together, we transform complex scientific work into accessible, engaging stories that can be understood and appreciated by a wider audience.

But our support extends far beyond the printed page. Projects featured in this publication benefit from a whole range of targeted activities designed to extend the reach of their research. These include distribution through carefully selected European events, targeted outreach to specialist and mainstream media, tailored project publications, digital campaigns and strategic stakeholder engagement activities that help projects connect with the

audiences most relevant to their goals. We work hard to ensure communication becomes impact. In health research, reaching the right audience can be just as important as generating the research itself. A breakthrough innovation cannot improve lives if healthcare professionals are unaware of it. A new policy recommendation cannot influence decision-making if it never reaches policymakers. A promising technology cannot achieve uptake if potential adopters are not engaged.

Recognising this challenge, Insight Media has developed a new way for organisations to access specialist research communication expertise.

Insight Access provides research organisations, universities, institutes and projects with direct access to Europe's leading research communication specialists at Insight Media, through a flexible, embedded support model.

Rather than commissioning individual activities in isolation, organisations gain access to a dedicated team capable of supporting strategic communication, dissemination, stakeholder engagement, content creation, digital communications, media relations, exploitation planning and impact generation as an integrated service.

For health research organisations, this approach offers a particularly powerful advantage. Research environments are increasingly complex and fast-moving. Communication teams are often under pressure to demonstrate impact, support multiple projects simultaneously and engage a diverse range of audiences. Insight Access provides additional capacity, specialist expertise and strategic guidance precisely when it is needed, helping organisations strengthen their communication activities without the need to expand internal teams. The result is a more consistent, effective and impactful approach to research communication.

Alongside Insight Access, Insight Media continues to work as a full consortium partner within Horizon Europe and other major research programmes. From proposal development through to project implementation, we lead communication, dissemination and exploitation activities designed to maximise visibility, engagement and long-term impact.

As European funding programmes place increasing emphasis on impact, exploitation and measurable outcomes, effective communication has never been more important. Strong dissemination strategies are no longer an optional extra; they are a critical component of successful research and innovation.

Our approach combines evidence-based audience mapping, strategic planning, targeted stakeholder engagement and high-quality content creation to ensure that research reaches the people who can benefit from it most.

Whether producing project films, developing websites, creating podcasts, delivering social media campaigns, organising events or supporting exploitation activities, our focus remains the same: helping excellent research achieve meaningful impact.

It is the partnership between researchers and clinicians, innovators and healthcare providers, policymakers and practitioners and scientific excellence and effective communication. Most importantly, it is the partnership between research and society itself. It is through these relationships that we really see how important partnerships are and why we relish being part of these stories.

We hope this edition has provided not only a fascinating insight into the health innovations shaping our future, but also a clear demonstration of how collaboration, communication and engagement can help transform research into better health outcomes for all. That is partnership for better health in action.

INSIGHT MEDIA

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