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Clinical Trials

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"Ireland can play a leading role in the provision of clinical trials in Europe."

Dr Rebecca Cramp, Director of Code and Regulatory Affairs, IPHA

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"Trials are the driving force behind improvements in cancer care."

Dr Claire Kilty, Head of Research, Irish Cancer Society

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Critical role of biobanks in clinical trials and how to sustain them

Clinical trials across Ireland are utilising biological samples stored in biobanks to advance understanding of disease and develop tailored medications.

In recent decades, recognition of the central role of biological specimens in disease understanding, biomarker identification and targeted therapy development has surged. This has led to the widespread establishment of biobanks as vital repositories, offering researchers access to essential biological samples and data for various studies.

Biobanks supporting clinical practice

Prof Richard Flavin, Director and Chairman of Biobank Ireland Trust, explains the importance of biobanks for medical research. "A biobank collects patient samples and associated healthcare data, samples are then used to answer important clinical research questions — samples help us to understand how the human body behaves in health and disease, helping us develop new treatments," he says.

Biobank Ireland Trust, a charity established in 2004, facilitates the development of hospital-based biobank networks in Ireland, enabling translational research collaborations and clinical trials. Prof Flavin explains: "We work with a number of biobanks in different areas of health, including cancer research, Covid-19 and more."

Biobank application in breast cancer trial

Biobanks accelerate research aimed at developing medicines and treatments. They bridge the gap between the patient and the development of precise, tailored treatment options. One such example is Trastuzumab, developed through a health research biobank and used in breast cancer treatment.

Challenges in sustaining biobanks

However, accessing samples from biobanks requires researchers to navigate stringent regulations encompassing ethical and legal considerations. Comprehensive patient consent and data regulatory procedures established nationally and at an EU level must be strictly adhered to. Furthermore, the effectiveness of biobanks in facilitating clinical trial delivery hinges on securing adequate funding.

Prof Flavin explains: "Biobanks are the keystone for advancements in medicine, but they are lacking sufficient funding and resources. We need further investment in infrastructure, staffing and equipment."

To sustain the advantages afforded by biobanks, public and patient involvement is key. Strict data confidentiality measures are in place, empowering individuals to engage with biobanks that play a pivotal role in advancing research.

For more information on Biobank Ireland Trust please visit our website: **biobankireland.com**

Dr Richard Flavin
Director,
Biobank Ireland Trust

Clinical trials in Ireland: promoting best care and health expertise

Robert O'Connor
Director, HRB-National Clinical Trials Office

From headaches to life-threatening illnesses, we rely on effective treatments. Clinical trials ensure these work by assessing benefits and identifying risks.

Clinical trials are meticulously designed studies evaluating the safety and effectiveness of medicines, devices and procedures in people — identify what works and what doesn't. Indeed, every treatment we rely on owes its existence to clinical trial evidence.

Why are clinical trials important to Ireland?

Clinical trials lead to better patient outcomes. This improvement stems from the organised and methodical approach inherent in conducting a clinical trial. Ireland boasts a long and proud history of contributing to advancements in healthcare.

For instance, radiotherapy, often used to treat cancer, was first developed and tested over a century ago, right here, in Dublin. Millions of lives have been positively impacted by this work. Medicines, devices and surgeries greatly improve many lives, doubling our life expectancy over the past century. However, many enormous health challenges remain, and trials bring hope for new treatments and cures.

Clinical trials bring economic benefits. As well as being one of the top producers of medicines and devices in the world (if you have a stent, for example, chances are it was made in Ireland), Ireland is now a major global site for organisations that coordinate delivery of trials.

Additionally, trials can reduce the cost of healthcare delivery and may provide sick patients with access to cutting-edge treatments not yet widely available, offering them a potential lifeline and hope for improvement.

Retaining top healthcare expertise

When we fall sick, we want to be treated by the most experienced and up-to-date healthcare professionals. At a time of global shortages in such skills, the ability to be able to contribute to human health advancement in a research-active hospital or clinic can be a major way of retaining and attracting the best and brightest healthcare professionals in our nation and thereby ensuring the most effective and efficient care.

Overcoming challenges through collaboration

Supported by Health Research Board, University College Cork and Enterprise Ireland, the National Clinical Trials Office acts as a crucial facilitator of trial activity. It fosters collaboration between research sites, specialists driving trial development and innovators creating new medical solutions.

Despite challenges like recurrent funding limitations for trial infrastructure, staffing shortages and broader sectoral and legislative hurdles, collaborative efforts within a supportive healthcare system offer the best hope for finding tomorrow's cures.

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Project Manager: **Martha Clarke** *martha.clarke@mediaplanet.com* Business Development Manager: **Lucy Harris** Managing Director - Ireland: **Ross Bannatyne |** Head of Print & Design: **Thomas Kent** Designer: **Aimee Rayment** Content Editor: **Angelica Hackett O'Toole |** Head of Digital Operations: **Harvey O'Donnell** Paid Media Manager: **Jonni Asfaha** Social & Web Editor: **Henry Phillips** Digital Content Editor: **Carolina Galbraith Duarte** All images supplied by Gettyimages, unless otherwise specified **|** Contact information: **ie.info@mediaplanet.com** or **+44 (0) 203 642 0737**

Clinical trials lead to better patient outcomes. This improvement stems from the organised and methodical approach inherent in conducting a clinical trial.

~Robert O'Connor,
Director, HRB-National Clinical Trials Office

Enabling meaningful patient involvement for healthcare innovation and access

Empowering patients can lead to better healthcare access and research innovation. Their voices must be heard through inclusive policies and patient involvement.

Dr Derick Mitchell
CEO, IPPOSI

Irish patients have a right to access the medicines, treatment, devices and procedures they need, including innovations that could be life-changing or life-saving. However, this is not always the case.

Improving access to vital treatments

Irish patients often encounter unequal access to therapies compared to other European countries. Certain treatments may not be approved for reimbursement in the public system or approved treatments experience delays and funding gaps. Additionally, differences exist in available treatments for those with or without private health insurance, particularly oncology treatments.

For patient-centred care, the Department of Health and the HSE must reform the assessment and reimbursement process and ensure sustained access for patients from 2025–2035. This involves partnering with EU Member states to increase treatment access and investing in Irish clinical research infrastructure, facilitating early access to innovative treatments.

Empowering patients through treatment innovation

Patients bring unique insights and perspectives to the healthcare landscape. By actively involving patients in decision-making processes (clinical trial design, drug development, treatment planning), healthcare stakeholders gain a deeper understanding of patient needs, leading to treatment innovation and access.

IPPOSI empowers patients and the public by providing them with inclusive supports, education and tools to become influential partners in healthcare decision-making. Empowered patients are more inclined to engage in decision-making processes at the individual care level plus multiple levels of service delivery.

Fostering inclusive healthcare partnerships

We encourage the Department of Health to integrate patient involvement and person-centredness into legislative, regulatory and policy initiatives, extending this mandate to the HSE and affiliated health agencies.

By incorporating patient feedback and lived experiences, healthcare can pinpoint delivery gaps, enhance resource allocation and broaden access to innovative treatments for a broader range of patients.

Aligned with Sláintecare objectives, patient involvement helps identify access barriers including geography and socioeconomic disparities. This prompts strategies for equitable healthcare access, regardless of background or circumstances.

Establishing a Patient and Carers Advisory Board with direct access to the Minister for Health and the Secretary-General of the Department of Health could enhance national communication.

The research community and health industry must intensify efforts to involve patients and the public, fostering trusted partnerships to advance mutual objectives.

Prioritising patient-centred research and implementation

There should be no debate about whether to involve patients or not. All discussions and decisions around access and research innovation must be person-centred and informed by patients' lived experiences.

The Irish Platform for Patient Organisations, Science and Industry (IPPOSI) is a patient-led organisation that works with patients, government, industry, science and academia to put patients at the heart of health policy and innovation. Learn more: **ipposi.ie**

Developing disease-specific therapies for women with PCOS: a focus on androgen excess

Research aims to understand the long-term impact of androgen excess in women with PCOS, which is associated with increased risk of type 2 diabetes, cardiovascular disease and non-alcoholic fatty liver disease.

Image provided by Royal College of Surgeons Ireland

Polycystic ovary syndrome (PCOS) affects around one in seven women across Ireland. A PCOS study is one of over 70 studies currently taking place at RCSI University of Medicine and Health Sciences, Clinical Research Centre (CRC), based at Dublin's Beaumont Hospital.

Androgens and PCOS research

Principal Investigator in the PCOS study is Prof Mick O'Reilly, a Consultant Endocrinologist at Beaumont Hospital and Honorary Clinical Professor at RCSI with a particular focus on steroid metabolism disorders and, specifically, conditions where androgen hormones are elevated in women's blood.

"The most familiar androgen is testosterone, but there are multiple different types of androgens and although they are typically far lower in women compared to men, there are disorders where androgens such as testosterone can be elevated," he explains.

PCOS affects 10–15% of women and can cause irregular periods, unwanted hair growth and other health conditions. His research group is working on mediating the adverse metabolic health outcomes of androgen excess in women with PCOS, but that involves labour-intensive research.

Secure research environment

Study participants attend the CRC for up to eight hours to be closely monitored with blood samples and biopsies taken, as well as undergoing insulin clamp testing (a marker of insulin sensitivity).

"These complex techniques are embedded within our research pathways and infrastructure," says O'Reilly. "However, this type of research can only be conducted in a secure research environment like the CRC where there is staff, such as a nurse manager and research nurses, working in tandem with doctors conducting the research, plus the equipment needed to deliver it."

The goal is to develop disease-specific therapies to improve long-term health outcomes for women with PCOS and lead to clinical trials of new drugs.

Supporting clinical research expansion

Dr Fionnuala Keane, RCSI CRC Director of Operations, says the centre opened in 2000 and carries out research in diverse therapeutic areas, including respiratory medicine, endocrinology, critical care, neurology, infectious disease and stroke medicine.

"We provide expertise and support services to clinicians who want to do research," she explains. "The centre has consultation rooms, equipment, facilities and highly experienced staff which enables patients to participate in clinical research studies in a calm, professional environment outside of the hospital setting."

The centre is primarily funded by RCSI and secured significant study-specific government and industry funding as it seeks to increase capacity, enabling high-quality clinical research to take place and improve patients' lives.

Dr Fionnuala Keane
Director of Operations, RCSI-CRC

Professor Mick O'Reilly
Clinical Associate Professor, RCSI and Consultant Endocrinologist, Beaumont Hospital

WRITTEN BY
Mark Nicholls

Scan the QR code to find out more

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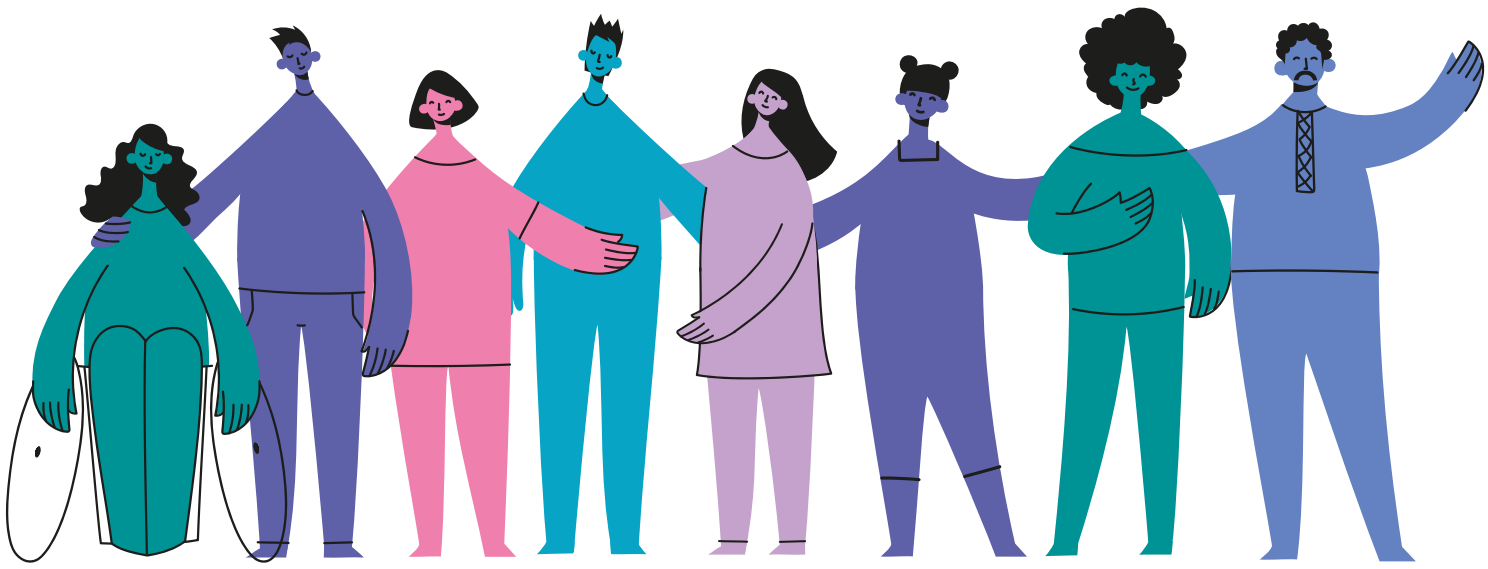
RCSI



Implementation science plays a critical role in facilitating the application of science and research to healthcare practice.

Health Research Institute: meeting the needs of changing patient demographics in Ireland

Discover how patient-centric research at a Health Research Institute in Ireland's Mid-West is revolutionising clinical trials for better medical outcomes within a changing demographic.

Professor Alan Donnelly
HRI Director and Professor in the Department of Physical Education and Sport Sciences, University of Limerick

Professor Rose Galvin
Professor of Physiotherapy, University of Limerick

Paid for by **Health Research Institute, University of Limerick**

Dynamic collaboration among academics, clinicians and healthcare practitioners hailing from University of Limerick's Health Research Institute (HRI) University Hospital Limerick (UHL), and HSE Mid West Community Healthcare is igniting transformative research endeavours with tangible impact.

Supporting this research, the HRI's Clinical Research Support Unit (CRSU) located at UHL streamlines logistical, ethical, regulatory and data protection aspects of clinical trials while fostering patient engagement.

Health Research Institute's strategic expansion

Founded in 2014, the HRI has recently unveiled an ambitious strategic plan to become a leading research institute for Health and Wellness Across the Lifespan by advancing person-centred, technology-enabled, integrated healthcare and treatment. Its Director, Professor Alan Donnelly, explains how the institute integrates a supportive ecosystem to promote interdisciplinary research approaches across seven domains.

These include four priority research areas: cancer, represented by the Limerick Digital Cancer Research Centre (LDCRC); ageing; physical activity for health; food, diet and nutrition. These are underpinned by areas of excellence: digital technology and advanced data analytics; implementation science; and participatory health research.

"Implementation science plays a critical role in facilitating the application of science and research to healthcare practice, meaning that treatment options can change and increase for the patient," says Donnelly, who has a specific interest in measuring physical activity and sedentary behaviour, and their role in influencing long-term risk of non-communicable diseases.

Advancing healthcare for changing demographic

HRI researchers are also working to offer better healthcare for Ireland's migrant population and develop digital solutions with the use of artificial intelligence and bioengineering to deliver novel solutions to specific problems.

Recently, Professor Ruth Clifford of the Cancer Clinical Trials unit at UHL secured a major grant to further develop cancer trials, in conjunction with the HRI.

The HRI's strategic plan takes account of Ireland's changing patient needs and demographics, particularly as the population ages.

This is a key focus for HRI member and Professor of Physiotherapy Rose Galvin, a founding member of the university's Ageing Research Centre (ARC), who has received a national Research Leader Award for exploring models of integrated care for older people.

Enhancing discharge processes for older people

A major study led by Professor Galvin examines the way older people attending emergency departments (ED) are discharged, particularly as they are at risk of poor outcomes, falls and readmission. This meant creating and assessing efficient care paths for older individuals to receive timely and coordinated care tailored to their preferences.

When a dedicated team of health and social care professionals was placed in the ED at UHL and focused on older adults being discharged, researchers saw a significant reduction in ED stay and reduced hospital admission, with home support packages implemented.

Patient-centricity enriches research

Underlining the importance of public and patient involvement in research, Galvin's team established a panel of older people and family carers that meets every six weeks to share ideas and collaborate on research projects.

"Their contribution has hugely enriched and enhanced both the quality and relevance of the work that I do," she says. "These people have a voice and help to shape the relevance of the research. It has also built greater trust and transparency in the research and has been particularly helpful in recruiting and retaining people in trials."

Patient recruitment bridges research and practice

Meanwhile, the CRSU remains the critical conduit between academic researchers and clinical practitioners. CRSU Clinical Research Operations Manager Siobhan Egan explains that the unit offers support to researchers and specialises in the management and coordination of research studies including patient recruitment.

This equally applies to trials of medicines, medical devices, observational and biobanking studies; for example, the CRSU will be involved in the forthcoming National Irish Covid 19 Biobank project. It also facilitates opportunities for patients to participate in research and clinical trials.

"We are passionate and enthusiastic about what we do, with work that will generate new knowledge to ultimately support better healthcare for patients," concludes Egan.

Siobhan Egan
Clinical Research Operations Manager, CRSU, Health Research Institute

WRITTEN BY
Mark Nicholls

Visit **ul.ie/hri** or scan the QR code to find out more.

Ireland's clinical trial approval and safety monitoring process

Find out how clinical trials for medicines and devices are regulated in Ireland.

Dr Donal O'Connor
Clinical Manager, HPRA

The Health Products Regulatory Authority (HPRA) regulates medicines and devices for the protection and benefit of patients and the public. An important part of our role is the review of clinical trials. Trials are conducted to develop medicines and devices intended to benefit patients with new treatments or diagnosis.

Clinical trial approval steps

Many clinical studies involving medicines or devices may require approval from the HPRA as regulated clinical trials before they can commence in Ireland. These include:

- Pre-market studies to assess the safety and benefit of new drugs or devices in development before they receive market approval and are licensed or certified.
- Post-marketing studies on approved drugs or devices to examine their use in other conditions.
- Studies to examine longer-term benefits or potential side effects.

Ensuring safe, valid trials

We review trials conducted in Ireland only as well as larger multinational studies. The latter could include, for example, international trials for a new cancer drug or heart valve that include patients in Irish hospitals. For medicines specifically, there is also a new European Regulation for coordinating the conduct of clinical trials throughout the EU.

Our primary aim is to ensure the safety of trial participants. Data generated must also be scientifically valid and reliable so that the assessment of new treatments is based on good-quality clinical evidence.

For market approval, and before becoming available for wider use, it must be shown that the benefits of new treatments outweigh any risks. As part of this process, we review the medicine or device to check that appropriate testing, such as laboratory studies, was conducted prior to the clinical trial.

Trial design is reviewed to ensure that risks to trial participants are reduced as far as possible. This assessment is conducted by HPRA medical doctors, pharmacists, engineers and other scientists. Trials are also independently assessed by the national research ethics committee.

Safeguarding innovation and public safety

Only studies where potential benefits outweigh the risks involved for participants are permitted. After approval, trials will be monitored carefully to ensure continuing safety. This involves a review of reports of side effects or adverse events, progress reports or inspection visits to study sites.

We are committed to supporting innovation while protecting public and patient safety. We offer support to developers of new and potentially beneficial medicines and devices wishing to conduct clinical trials in Ireland. As well as our guidance documents, we facilitate meetings to assist innovators and clinical investigators in preparing clinical trial applications to the highest standards.

Think accreditation and have confidence in the reliability of **health, safety and environmental services**

Accreditation is the independent assessment of conformity assessment bodies (CABs) to ensure their independence, impartiality and competence to carry out conformity assessment tasks.

Rosemary Hayden
Manager, Irish National Accreditation Board (INAB)

The Irish National Accreditation Board (INAB), a division of the Health and Safety Authority, is the national body with responsibility for accreditation in Ireland. It accredits medical and testing laboratories, biobanks, certification/verification/inspection bodies and reference material producers. It provides accreditation in accordance with the relevant International Organisation for Standardisation ISO 17000 series of standards.

Accreditation for medical laboratories

INAB provides laboratory accreditation for medical laboratories to ISO 15189:2012 or ISO 15189:2022 'Medical Laboratories – Requirements for Quality and Competence'. This standard incorporates essential elements for medical laboratories; in particular, focusing on patient and clinical personnel needs.

It addresses specific issues that include the provision of advisory services to clinicians, collection of patient samples, provision of testing in a medical emergency and the contribution of a medical laboratory service to patient care. Legislation (S.I. 360 of 2005) requires blood bank laboratories to operate to ISO 15189. These laboratories must also comply with additional requirements relating to blood traceability and haemovigilance.

Accreditation for biobanks

Accreditation of biobanks to the standard ISO 20387:2018 'Biotechnology – Biobanking – general requirements for biobanks' is available. This standard applies to all organisations performing biobanking, including biobanking of biological material from multicellular organisms (eg. human, animal, fungus and plant) and microorganisms for research and development.

How and why accreditation can help your business

- Test results are accepted worldwide.
- It ensures public confidence in the reliability of activities that impact health, welfare, security and the environment. Accreditation is used to identify bodies competent for the implementation of government policies and regulations.
- It is a tool for decision-making and risk management.
- It offers consumer confidence by ensuring consistently high-quality and safety standards of products or services purchased.

Manager Rosemary Hayden encourages policymakers to include accreditation as a requirement for policy implementation and advocates that accredited services are considered in the awarding of tenders and funding grants.

Be part of a team of technical assessors/experts

Are you a medical professional looking to expand your knowledge of ISO 15189:2022? INAB is recruiting for contracted technical assessors/experts as follows:

- Consultant pathologists in the areas of blood transfusion, andrology, assisted reproduction, chemical pathology, genetics, haematology, histopathology and cytopathology, immunology and microbiology and virology.
- Experienced medical scientists in the disciplines of assisted reproduction, chemical pathology, genetics, immunology and microbiology and virology.

i For more information on becoming an assessor, log on to **inab.ie/about-us/assessors** If interested, please email **inab@inab.ie** with 'Assessor expression of interest'

Taking actionable steps together to find a cure for **Motor Neurone Disease**

Irish patient participates in trial informing development of new drugs for Motor Neurone Disease.

Photographer - David Coleman - (Bobby Studio)

While on stage at the Dublin Fringe festival, actor and writer Michael Campbell tripped and fell. Eight months later, he was diagnosed with a rare type of inherited Motor Neurone Disease (MND), for which there is no cure.

Motor Neurone Disease

Motor Neurone Disease affects the nerves and brain. Symptoms include muscle weakness, slurred speech and difficulty swallowing, progressively increasing over time; most cases are sporadic with around 10% of cases inherited. Campbell's case was especially rare, stemming from a fault in his FUS gene, occurring in approximately 300 people worldwide.

Campbell's father died from the same disease. Although stunned by the diagnosis, he immediately contacted Professor Orla Hardiman, Ireland's leading neurologist for MND and began seeking clinical trials of new drugs. He found one just beginning at St James's Hospital.

MND clinical research facility

"The standard of care has been nothing short of amazing, I am constantly being checked in on, and I feel like part of the team," Campbell says. Although the outcome is not guaranteed, he knows this is an "actionable step forward to identifying a potential treatment," he says.

Research centres improving outcomes

Opened in May 2013, the Wellcome-HRB purpose-built clinical research facility (CRF) has grown from strength to strength, supporting a wide variety of clinical trials and studies and specialising in early-phase and advanced therapy trials. Professor Martina Hennessy, its Director shines a light on how research improves clinical outcomes. She says: "Evidence shows that research-performing hospitals, including clinical trials, provide greater access to innovative medicines, make better use of evidence, offer more precise care, attract more highly qualified staff, have better facilities and greater capacity to develop novel approaches to the least well-served diseases."

Patient engagement for progress

"With patients and clinicians working in partnership ... we can design better trials that begin to unlock the potential of new medicines. Irish patients are positive about engaging with research and about contributing to the quality of the data, which informs the development of new drugs worldwide," she says.

"They do it for themselves but also their families and society. The outcome is unknown, but CRF staff are with them every step ... to make it as safe as possible," explains Prof Hennessy.

She stresses the importance of working with patients with rare diseases. "With patients like Campbell as part of the team, there is always hope," she insists. Today, Campbell is continuing to write and act — showcasing that life perseveres despite the challenge of disability, thanks to today's research landscape.

Photographer - Gabrielle Masterson

Michael Campbell
Participant in the Motor Neurone Clinical Trial at the Wellcome-HRB Clinical Research facility at St James's Hospital

Professor Martina Hennessy
Director of the Wellcome-HRB Clinical Research facility at St James's Hospital and Trinity College, Dublin

Find out more at **sjhcrf.ie**

Sponsored by **Clinical Research Facility**

Wellcome Trust - HRB **Clinical Research Facility** at St. James's Hospital

Compliance experts ensuring ethical promotion of medicines in Ireland

Pharmaceutical companies are committed to the ethical promotion of medicines, navigating outdated legislation with the help of market-leading compliance experts.

Caroline Kelly
Founder and Managing Director, Pharma Integrity

WRITTEN BY
Bethany Cooper

Clinicians are expected to keep up with all new treatments and advances, which is no easy feat. However, those who choose to collaborate with pharmaceutical companies get direct access to current treatment insight, including efficacy and safety information, to enable informed decisions.

Data compliance in medicine promotion

Companies must adhere to strict regulations regarding the use of data obtained from clinical trials for medicine advertising. They are required to promote the rational use of medicinal products, aligning with approved indications, appropriate patient populations plus correct dosage and administration while emphasising usage precautions. Ultimately, clinicians must balance medicine efficacy with safety considerations.

Commitment to ethical promotion

Caroline Kelly, Founder and Managing Director of Pharma Integrity, a female-led healthcare consultancy, advises pharmaceutical companies on compliance excellence. She explains: "Pharmaceutical companies are unanimous at putting patients front and foremost. To achieve this, the amount of internal resourcing, funding, training of staff, internal structures, processes and standards, which go into all their activities, is vast."

Challenges of outdated legislation

The statutory instrument, which governs the advertising of medicines in Ireland, hasn't been updated since 2007. According to Kelly: "Companies are being provided with new opportunities, systems and manners in which they can engage with healthcare professionals, patients and the public, which do not fit into the structures of existing legislation or industry codes of practice."

It is becoming increasingly difficult for pharmaceutical companies to optimise internal processes while continuing to align with such outdated legislation.

Medicine promotion ethics for public health

Holding extensive industry experience, Kelly is passionate about the work being done behind the scenes to ensure ethical promotion of medicines. Pharma Integrity is uniquely positioned to navigate both the UK and Ireland with operational confidence.

She says: "The industry is under a lot of scrutiny from the regulator for non-compliance of advertising; companies genuinely want to know what they can be doing differently and better, and Pharma Integrity provide the forum for them to achieve that."

Providing a host of innovative services, events and programmes are tailored to individual companies'needs, including a cross-industry compliance network championing good practice between all. "Today, stakeholders — health professionals, payers, patients and the public — care about 'how' you have achieved successes, not just 'what' you have achieved. Reputation matters," she adds.

With market-leading compliance experts helping behind the scenes, we can have confidence that the pharmaceutical industry is ensuring the best for patients, healthcare professionals and the public.

Paid for by **Pharma Integrity**

PHARMA INTEGRITY
Driving Excellence in Compliance

Find out more at **pharma integrity.com**

Clinical trial standardisation can bring health and innovation advantages to Ireland

A robust clinical research setup grants patients access to life-saving therapies. However, Ireland must improve its appeal for trials, as it lags behind European countries with similar populations and economies.

Dr Rebecca Cramp
Director of Code and Regulatory Affairs, IPHA

Ireland can play a leading role in the provision of clinical trials in Europe. To do that, a predictable, transparent and efficient clinical research system is essential to compete internationally and attract clinical trials. Healthcare providers in Irish hospitals and academic institutions have shown that they have the ability to participate and drive world-class research.

Clinical trial standardisation benefits

Ireland's decision to join the European Clinical Research Infrastructure Network has the potential to widen access to clinical research networks in Europe. Aligned with this and to accelerate the conduct of clinical trials and increase delivery in Ireland, the Irish Pharmaceutical Healthcare Association (IPHA) developed a new standardised Clinical Trial Agreement between the Site and the Sponsor.

The Model Clinical Trial Agreement (mCTA) is an efficiency initiative, which can reduce delays in hospitals, cut costs, increase efficiencies and enable the faster start of more trials — all aimed at improving patient outcomes. Through the mCTA, we have moved to standardise the approach to conducting clinical research.

This standardisation means speed in terms of the number of rounds of discussion and review for contracts being reduced. This, in turn, reduces the administrative and financial burden for hospitals and companies.

Alongside the positive human health impact, clinical trials also enhance the value proposition for innovation in Ireland.

Critically, it can reduce the time taken to start clinical trials in Ireland, thus improving trial competitiveness and, most importantly, improving individual patient health.

Increasing clinical trial competitiveness in Europe

Alongside the positive human health impact, clinical trials also enhance the value proposition for innovation in Ireland, with potential to secure future global investment in manufacturing and discovery activity against significant competition. This drive towards competitiveness is not just of concern to Ireland, but across Europe.

According to a 2022 report published by Charles River Associates for the European Federation of Pharmaceutical Industries and Associations, the US and China are gradually dominating clinical trials globally. In 2022, the US spent $2 billion more than Europe on R&D. Today, that figure is €25 billion.

With regard to clinical trial activity for advanced therapy medicinal products, it is twice as high in the US and almost three times as high in China than Europe. State and industry must work together, adopting best practices across the life science ecosystem to ensure a thriving R&D sector for the future of patients and medicines development in Ireland and Europe.

The future of intensive care research shaped by **leading Irish critical care network**

A critical care research network is shaping the future of intensive care medicine across Ireland, with increased patient engagement and global collaboration, preparing for future pandemics.

Prof Alistair Nichol
Director of the Irish Critical Care - Clinical Trials Network (ICC-CTN), and Chair of Critical Care Medicine, University College Dublin

Irish Critical Care Clinical Trials Network

Amid the Covid-19 pandemic, robust research and innovation in critical care have never been more imperative. The global surge in critical care admissions profoundly strained intensive care units (ICU) and beyond.

Comprehensive critical care research network

Funded by the Health Research Board, the Irish Critical Care–Clinical Trials Network (ICC-CTN) is harnessing the knock-on effects of the pandemic to expand research efforts in critical care. Prof Alistair Nichol, Director, and Dr Leanne Hays, Pandemic Programme Manager, explain the importance of such a comprehensive research network.

"We have established an Irish methodological hub, which coordinates many trials throughout ICUs in Ireland from start to finish, providing all the scientific, technological and logistical resources necessary to run clinical trials within any Irish ICU — all under one roof," explains Prof Nichol.

Advancing intensive care patient outcomes

"We are continuously working towards improving outcomes for our patients who find themselves in the ICU," says Dr Hays. "We had a number of studies generate significant results for the Covid-19 pandemic, including results of 16 treatment options, improving patient care and the identification for the first time of how a person's genetics can affect them becoming severely ill."

The network aims to produce real, impactful results that have the potential to revolutionise clinical practice globally. "We hope to further develop our ongoing studies to design a coordinated, more rapid response for future pandemics," adds Dr Hays.

Hearing the patient voice

The HRB ICC-CTN engages with past critical care patients and their relatives in its aim to carry out accessible, patient-centred trials. Clodagh Rock, leading member of the HRB ICC-CTN Public and Patient Involvement group, recounted her own story of being an ICU patient and how that led to her involvement.

"Having been through the experience of being admitted into the ICU, I am able to provide the patient's perspective on many areas of critical care medicine, including my views on taking biological samples and precision medicine approaches, gaining consent and treatment options," she explains. This can then help researchers improve how they do research.

Global health impact on critical care environment

From academic publications to conference presentations, social media and podcasts, sharing knowledge is fundamental to the network.

Following on from recent international research agenda meetings, the work has just begun. Ireland emerges as a significant force in critical care research through enhanced patient engagement, streamlined trial structures and precision medicine.

Dr Leanne Hays
Pandemic Programme Manager, the Irish Critical Care-Clinical Trials Network (ICC-CTN)

Clodagh Rock
Leading Member of the ICC-CTN Public and Patient Involvement (PPI) Group, Former ICU Patient and Trial Participant

WRITTEN BY
Bethany Cooper

Find out more at **iccctn.org**

Why patient-centred trials lead the way in developing treatment

Leveraging academic and clinical expertise centred on patient involvement can draw forth better clinical outcomes and more effective, innovative treatments.

Professor Fai Ng
Director, CRF-UCC

Professor Barry Plant
Consultant Respiratory Physician and Clinical Lead, Respiratory Medicine, CUH

WRITTEN BY
Mark Nicholls

As the incoming director of the Clinical Research Facility at University College Cork (CRF-UCC), Professor Fai Ng believes there is a huge opportunity to develop the centre's research infrastructure, with people from all sectors at the core.

Benefits of patient-centred trials

As Professor of Rheumatology and former Director of the NIHR Newcastle CRF, Ng underlines the importance of staff, Principal Investigators (PIs), industry partners and patients working together. He believes that CRF-UCC has the potential to become country-leading in Ireland, and internationally, as researchers develop new therapies.

The facility is co-funded by the Health Research Board and the College of Medicine and Health and can thus leverage academic and scientific excellence alongside clinical expertise across all medical specialties.

"Clinical trials are important if we want to develop new and better medicines, but there are economic benefits as well," adds Ng, who takes up his new post on April 15.

Clinical trials for revolutionary drugs

The facility has an established track record in developing treatments in all therapeutic areas from laboratory through clinical trials. For instance, from its initial work with the cystic fibrosis (CF) drug ivacaftor in 2011, it has continued to engage with clinical trials, including with ETI (elexacaftor-tezacaftor-ivacaftor) for CF, explains Professor Barry Plant, Consultant Respiratory Physician, Clinical Director for Medicine and Director of the Adult Cystic Fibrosis Centre at Cork University Hospital (CUH).

"These new CF drugs are transformative and revolutionising patient care," he adds.

Several CF patients being treated at CUH are involved in trials with new drugs and studies. Many participated in the CFMATTERS trial assessing how best to use intravenous antibiotics for infections in CF patients.

Professor Plant explains telehealth and telemedicine approaches have also been supported to expand options for care delivery. His group is working with European bodies on these initiatives and looking at new ways of microbiology sampling to minimise cross-contamination and infection risk for patients, using next-generation bronchoscopy.

> **These new CF drugs are transformative and revolutionising patient care.**

Patient-focused research

The CRF-UCC endeavours to deliver an infrastructure that enables busy academics and clinicians to conduct high-quality clinical research by providing access to expert staff including research nurses and statisticians, plus support around governance and ethics, and a patient-centred research environment

Professor Sinead Harney, Consultant Rheumatologist at CUH and Honorary Clinical Professor at UCC, highlighted how CRF-UCC has enabled her to remain active in clinical trials and address ongoing 'unmet needs' for rheumatology patients.

She is PI in Cork for the IDEA-FAST study that covers 14 other European countries investigating fatigue across inflammatory and neurodegenerative conditions. Other research areas include psoriatic arthritis and lupus.

Relevant outcomes for patients

Dr Frances Shiely, Director of Education at the CRF, says patients are playing increasing roles in clinical trials. "Twenty years ago, we used to do trials on patients," she says. "Now, we do trials with patients."

Patient and Public Involvement (PPI) sees patients working with researchers on trial design, recruitment, communication and dissemination of study findings ranging from new drugs to community-based interventions. There is also a move towards more decentralised clinical trials.

PPI leads to better-quality, more efficient trials with better recruitment and design, delivering more relevant outcomes for patients. "You can only do that when you work with the patients," adds Dr Shiely.

Clinical trials previously involved patients as passive subjects. Today, trials engage with patients as active collaborators. This shift empowers patients, fostering a deeper partnership between researchers and those with lived experiences.

The CRF also offers a postgraduate certificate, postgraduate diploma and master's degrees in clinical trials (online) and conducts funded research projects to create inclusive clinical trials, plus training and education on increasing involvement in underserved groups.

Professor Sinead Harney
Consultant Rheumatologist, CUH

Dr Frances Shiely
Director of Education, CRF-UCC

Find out more at **crf.ucc.ie**

Paediatric clinical trials: improving outcomes for sick children

Clinical research in children is essential if we are to find new ways of preventing, diagnosing and treating childhood diseases.

Most of the medicines currently given to children have only been tested in adults.

Most of the medicines currently given to children have only been tested in adults. However, young adults, children and newborn babies often react differently to medicines than adults. They are not simply 'small adults.' Having access to clinical trials enables children in Ireland to benefit from the latest advances in medicines and treatments for children.

Facilitating paediatric clinical trials

Children's Health Ireland (CHI) is a hospital group currently participating in over 80 clinical trials. These span across 15 different therapeutic areas and include trials assessing new treatments for a range of rare and common childhood illnesses including paediatric cancer, cystic fibrosis, haemophilia, paediatric heart failure, peanut allergy, achondroplasia and Duchenne muscular dystrophy.

The move to the new hospital in 2025 means new state-of-the-art research facilities.

Clinical Research Centre and Cancer Clinical Trials Unit

Trials are conducted through CHI's Clinical Research Centre (CHI-CRC) and Cancer Clinical Trials Unit (CCTU), both HRB-funded clinical research infrastructures. Together, they provide dedicated staff and expertise to enable clinical teams and study sponsors to carry out trials for new drugs, medical devices and other medical advancements.

Already operating across four clinical sites Crumlin, Temple Street, Connolly and Tallaght, it is an exciting time for research. Our hospital charity partners have merged into the Children's Health Foundation, a key supporter of the development of our trials capability in CHI. The move to the new hospital in 2025 means new state-of-the-art research facilities and, bringing more opportunities to participate in innovative trials.

Collaboration is central to this work

CHI is connected to national and international networks to share ideas and best practices and provide children in Ireland with access to large multinational clinical trials. One such network is In4kids, the HRB-funded Irish Network for Children's Clinical Trials.

In4Kids is the Irish hub of c4c (conect4children), a large collaborative European network that aims to facilitate the development of new treatments for the entire paediatric population. With In4kids, the CHI-CRC will launch a new National Young Patient Advisory Group (YPAG) in 2024 to drive the involvement of young people in the design of new clinical trials. Paediatric research across Ireland has also been supported over many years by the Children's Health Foundation.

Paul McNally
Director of Research & Innovation, Children's Health Ireland

Mary Costello
Research Programme Manager, Children's Health Ireland

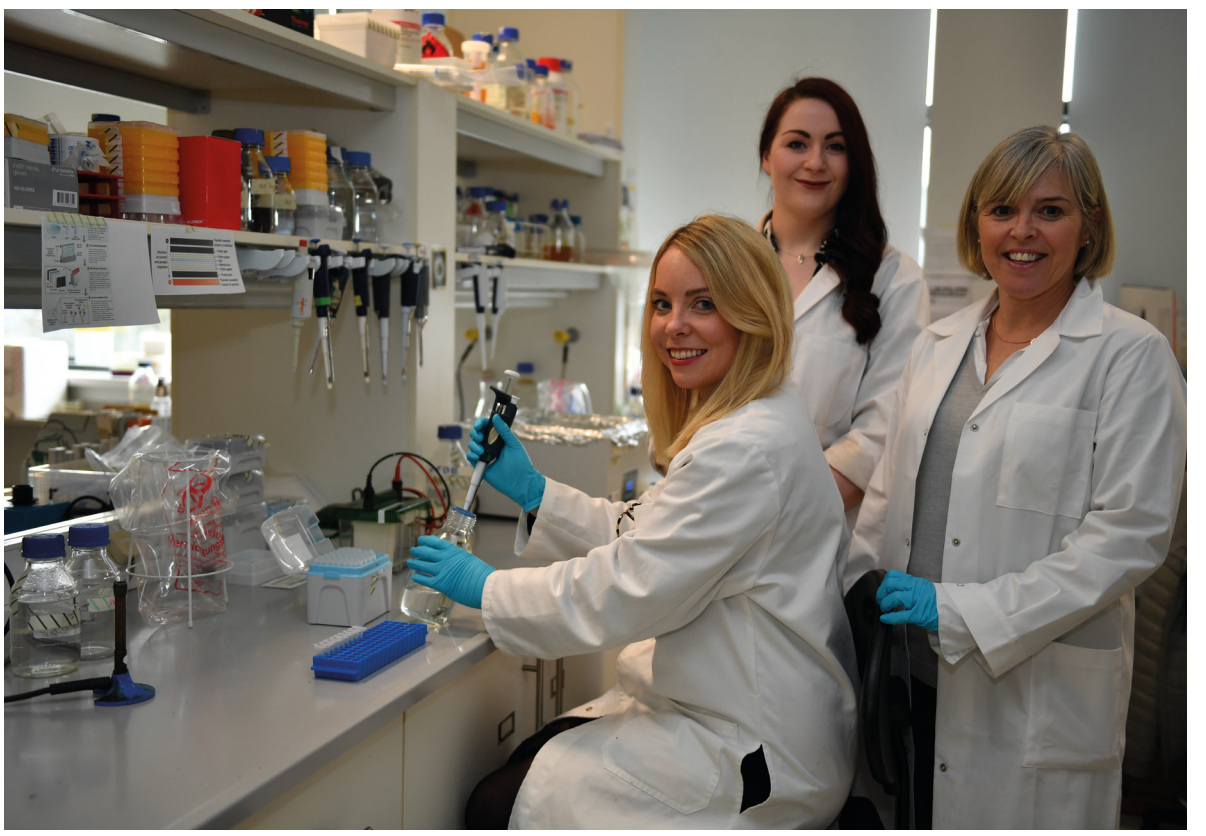
Supporting a research-active **healthcare system**

Clinical trials can be linked to improving the diagnostic capabilities of our clinical laboratories or developing novel testing strategies to detect disease.

Clinical pathology laboratories support the diagnosis of disease through testing of blood, other bodily fluids, tissues and cells. Medical scientists in these laboratories work tirelessly to provide a high-quality service in what is acknowledged as an increasingly busy and challenging national healthcare service.

Providing clinical pathology support

Even in this challenging environment, medical scientists develop and support projects that identify more efficient and effective ways to improve laboratory services. To support them, researchers in Munster Technological University (MTU) are engaged in a number of collaborative research projects, involving clinical trials, which aim to improve the diagnostic services of clinical pathology laboratories. Patient-focused research activity in hospitals can help improve patient care quality and support better patient outcomes.



From left to right: Jessica Neville, Aisling O Brien, Fiona O Halloran. Image provided by MTU.

More than half a billion adults are living with diabetes worldwide and its incidence in Ireland is increasing.

Novel strategies for diagnosing diabetes

More than half a billion adults are living with diabetes worldwide and its incidence in Ireland is increasing. It is also becoming more challenging to differentiate between different types of diabetes, particularly in children and young adults. Early detection and differentiation are key to help direct appropriate treatment and prevent long-term complications.

Jessica Neville, Department of Clinical Biochemistry, Cork University Hospital (CUH), is collaborating with Dr Seán Costelloe (CUH) and Dr Fiona O Halloran (MTU) to investigate current clinical practice in Ireland for diagnosing diabetes. They are exploring the potential of novel testing strategies and predictive clinical biomarkers for early detection of disease.

Clinical trial work is at the centre of this project, and patient recruitment is essential to assess the effectiveness of any new testing strategy. A major aim is to identify new methods of testing for type 2 diabetes and gestational diabetes, which are easier for patients and more feasible to tolerate and schedule. This would improve diagnostic turnaround times and ease footfall in hospitals.

Improving clinical detection of cancer

Multiple myeloma (MM) is the second most common blood cancer in adults, and its incidence continues to increase. In Ireland, almost 400 people are diagnosed with MM every year. While there is currently no cure for this disease, early clinical detection and treatment intervention can significantly improve patient wellbeing and prognosis.

Despite developments in treatment options, most patients will relapse; and this is usually caused by residual drug-resistant cancer cells. The ability to detect these residual cells relies on the sensitivity of the testing methods.

Aisling O Brien, Department of Immunology, Cork University Hospital (CUH), in collaboration with Dr Vitaliy Mykytiv (CUH) and Dr Fiona O Halloran, is investigating ways to improve the diagnostic capabilities of clinical laboratories for MM.

Clinical trials that involve the collection of bone marrow and blood samples from MM-positive patients are central to the success of the project and the development of more sensitive clinical tests for MM cancer cells. Using sophisticated equipment, a major aim of this project is to investigate the potential use of blood-based methods to allow more frequent, less-invasive testing for MM patients.

Patient contribution key to clinical trials

Clinical trials rely on patient participation. We want to take the opportunity to thank all the patients who contribute to our clinical trials. We are acutely aware that our studies rely on patients who have been diagnosed with chronic, sometimes life-threatening conditions, and we are grateful for their support. Keeping the patients at the centre of our research is a priority and keeps us focused and committed.

Acknowledging colleagues and sponsors

These projects and clinical trial work are supported by a multidisciplinary team of healthcare professionals, including clinicians, nurses and nutritionists. Funding support for these projects is through the Irish Research Council, Breakthrough Cancer Research and the Haematology and Education Research Trust. These projects are also sponsored by the Higher Education Authority Technological Transformation Fund and MTU.

Dr Fiona O Halloran
Lecturer and researcher with Dept Biological Sciences, MTU

Dr Seán Costelloe
Dept Clinical Biochemistry, CUH

Dr Vitaliy Mykytiv
Department of Haematology, CUH

WRITTEN BY
Bethany Cooper

Trials bring access to latest treatments **for oncology patients**

Streamlining our processes and regulations around clinical trials is vital for keeping Ireland globally competitive. We're only as fast as our slowest part.

Professor Seamus O'Reilly
Medical Oncologist & Clinical Lead, Cancer Trials Ireland

Cancer clinical trials allow patients access to the latest available treatments. They create an environment of inquiry and standards, and they accelerate innovation. They enable us to bring patients newer treatments years before they would come into place if we waited until they were approved and reimbursed by the Government.

Oncology research in Ireland

Oncology is also at an exciting stage within Ireland, with many new agents in the pipeline. For example, there is a drug class called antibody-drug conjugates, and there are 160 of these in development globally. Creating an environment in our hospitals where patients have access to this innovation is of great significance.

Streamlining processes and regulations

Cancer Trials Ireland has four themes for the next four years, the first of which is 'streamlining.' We need to be efficient in bringing trials into Ireland and remove as many barriers as possible. We are competing with other countries, so our processes and regulations — particularly around GDPR — must be streamlined. Much like other enterprises, you're only as good as your weakest link, and you're only as fast as your slowest part.

The second theme is bringing more studies into Ireland. Getting patients access to the studies arising from the 160 antibody-drug conjugates is a key objective for our organisation.

Growth through succession

The third theme is succession. In any organisation, we need to nurture the next generation. We look at ways of nurturing the next generations so they can you know be involved in clinical trials. It is not just about doctors.

Building an infrastructure where we can encourage, recruit and retain nurses and data managers in our system is also hugely important. If you don't have a team, you can't build around it.

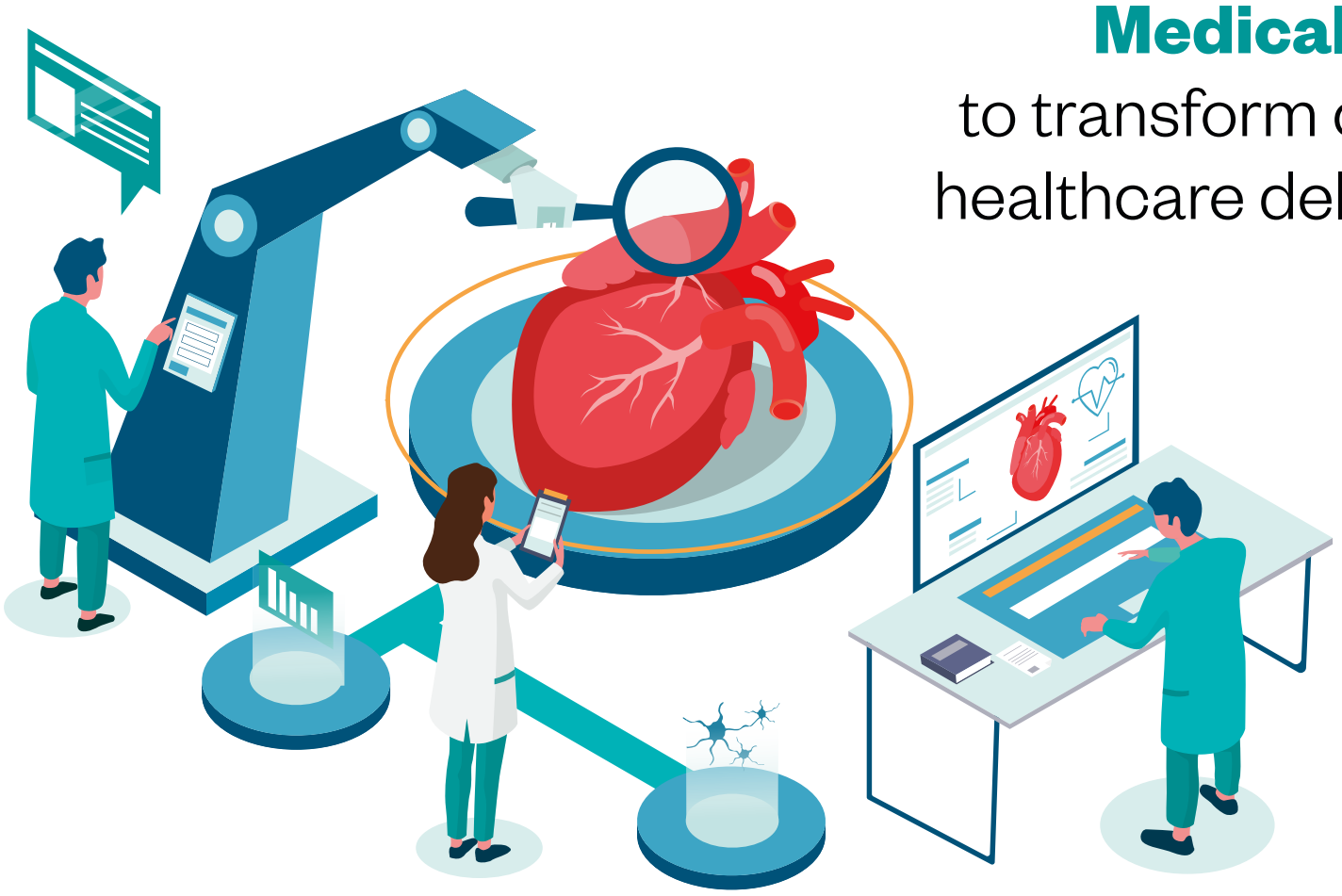
Getting patients access to the studies arising from the 160 antibody-drug conjugates is a key objective.

Sustainability initiatives

The final theme is sustainability. Healthcare itself is very climate-unfriendly, while fossil fuel pollution contributes to cancer. In France, they calculated that 3% of their breast cancer cases are due to fossil fuel pollution from cars. It's a worsening problem that we are all affected by.

In 2022, we set up the National Green Cancer Clinical Trials initiative, and we've established a green charter for cancer trials in Ireland. Our group also published a paper last year called 'Climate Toxicity'— the first time the term has been used in medical literature.

Medical device trials to transform cardiovascular healthcare delivery in Ireland



Clinical trials underway across Ireland are putting advancements in cardiovascular medical technology to the test, allowing groundbreaking new medical devices to be brought to market.

Ronan Rogers
Senior Research & Development Director, Medtronic

Dr Faisal Sharif
Professor of Cardiovascular Translational Research and Innovation; Consultant Interventional Cardiologist; Non-Executive Director BioInnovate Ireland

WRITTEN BY
Bethany Cooper

As advancements in technology move faster than ever, healthcare technology companies bridge the gap between the ever-growing burden of disease and the need for efficient healthcare solutions.

Medical devices improving cardiac conditions

Prof Faisal Sharif, Professor of Cardiovascular Translational Research and Innovation, pioneered two groundbreaking medical devices, showcasing the work being developed in the cardiology space.

1. Remote monitoring device for heart failure

"Cardiac pressures are known to change for one week before a patient gets unwell. With use of a remote patient cardiac pressure measurement device, frail and elderly patients with heart failure can be monitored at home. Changes to their cardiac pressures can be identified and treated before the patient gets to the point of emergency hospitalisation," explains Dr Sharif.

2. Renal artery denervation for uncontrolled blood pressure

Hypertension or high blood pressure is a health concern affecting one in three people globally. Healthcare technology company Medtronic has developed an innovative device to treat hypertension, which can produce a much-needed drop in blood pressure. "Long-term high blood pressure causes heart disease, stroke and other health complications; development of this new therapy creates an innovative approach to treating a widespread problem," says Prof Sharif.

How clinical trials transform healthcare

Medical devices can be transformative but must be patient-friendly in their application. They offer a chance to revolutionise healthcare by enabling innovative treatments and remote patient monitoring, potentially reducing hospitalisations and preventing health deterioration.

They also offer alternative treatments, which can work synergistically with pharmaceutical options. Clinical trials provide strong scientific evidence of safety and benefit to the patient prior to a device attaining approval for widespread population use.

Ronan Rogers, Senior Research and Development Director of Medtronic, discusses the scale and extent of bringing medical devices to market, with the help of clinicians like Dr Sharif. "Our technology improves the lives of around two patients every second. At any one time, we are running around 400 clinical trials globally," insists Rogers. "Trials are producing the evidence needed to establish best clinical practice, informing strategy and future policy."

Networks for enhanced clinical outcomes

Conducting clinical trial activity in Ireland requires national collaboration to operate at scale, according to Rogers. "We are fortunate in Ireland to have highly skilled healthcare professionals, a widespread research network and meaningful links to academic institutes allowing us to achieve this," he says.

"Medtronic has conducted a number of clinical trials in Ireland, including one focused on the treatment of hypertension, and has benefited from a really strong clinical research team, including highly-trained research nurses, data managers and researchers, allowing us to produce high-quality clinical research data."

In environments prioritising clinical research, the quality and capacity of care are elevated, leading to enhanced clinical outcomes for patients. Rogers and Sharif specifically acknowledge the significant contribution of the Irish community, highlighting their pivotal role in these advancements. "We want clinical trials to be meaningful, and patients are regularly involved in the design of our trials across Ireland," says Dr Sharif.

Ireland's medical technology landscape

With extensive government support from the Department of Further and Higher Education, Research, Innovation and Science, the Department of Health and the Health Research Board, Ireland's clinical research infrastructure continues to expand.

Rogers emphasises: "We have all the necessary components of the ecosystem in Ireland; we have the ability to do more. If we can align the various stakeholders involved and speed up the process to get the clinical trials started and provide sustainable research posts, the possibilities could be endless."

In Ireland, medtech companies are at the forefront of groundbreaking advancements in medical technology, harnessing a unique blend of cutting-edge technology, scientific expertise and a connected ecosystem. These collaborative efforts are driving the development of innovative solutions to tackle complex medical conditions.

Laura Clifton-Hadley
Associate Director, Clinical Operations UK & Ireland, Bristol Myers Squibb

Jill Mullan
Senior Medical Science Liaison, Innovative Medicines, Bristol Myers Squibb

WRITTEN BY
Bethany Cooper

Drive for patient participation to advance lupus clinical trials in Ireland

A global biopharmaceutical company is empowering patient involvement in clinical trials, for the advancement of new treatments.

Lupus, a widespread chronic autoimmune illness, impacts millions globally (Lupus UK), affecting various organs and systems. It arises when the immune system attacks one's own tissues and organs. Its cause remains unknown, necessitating additional research for new treatments that can change the course of the disease.

Lupus research in Ireland

Ireland stands at the forefront of pioneering efforts to combat lupus. With an extensive research infrastructure, strong collaborative networks, government support and ongoing academic excellence, Ireland is primed to conduct clinical trials focused on key areas of unmet patient need.

Treating lupus poses challenges due to its symptoms often resembling those of other conditions and its varied impact on individuals' immune systems. Finding the right treatment for each person's lupus is crucial. Insights gained from studying lupus could also help us understand and treat other autoimmune conditions.

Global pharmaceutical involvement

Laura Clifton-Hadley, Associate Director of Clinical Operations and Jill Mullan, Senior Medical Science Liaison of Bristol Myers Squibb, highlight the clinical trials underway to develop potential treatments, ranging from small molecules and biologics to cell therapies.

"We are investigating potential new medicines for Systemic Lupus Erythematosus (SLE), which is a very complex disease affecting more women than men and disproportionately impacting ethnic minorities," says Clifton-Hadley.

By advancing lupus research, such disparities in healthcare outcomes can be addressed, ensuring all individuals affected by the disease receive equitable access to effective treatments and care.

"We are trying to bring the right medicines to the right patients faster," adds Mullan. "Lupus is currently treated using a wide variety of medicines. Not all currently approved treatment options work for everyone, making this an important area in which to keep looking for potential new treatments."

Patient engagement and awareness

Clinical trials are being conducted nationally, ensuring their accessibility to patients across Ireland. Patient involvement is the cornerstone of all clinical trials. "Patients are playing a part in science for themselves and future patients, getting a sense of comfort and an increased sense of physician involvement throughout," insists Clifton-Hadley.

Stressing the importance of encouraging patient involvement, she says: "Raising awareness of clinical trials is vital to ensure uptake."

Mullan adds: "We actively welcome participant diversity, going above and beyond to make sure participants from a variety of ethnic backgrounds and cultures have access to the information they need."

Whether lupus, or another condition with limited treatment options, Clifton-Hadley and Mullan encourage people affected to explore their options, as clinical trials are underway across Ireland.

> Speak to your doctor about available trials, or go to **clinicaltrials.gov**

Tackling challenges and taking **clinical trial design into the future**

Robert O'Connor
Director, HRB-National Clinical Trials Office

Decades of research are yielding promising avenues to manage and potentially cure numerous severe diseases. However, significant challenges lie ahead.

Rapid advancements in medical science are leading to exciting possibilities in clinical trials. New treatments like immune system enhancers for previously untreatable cancers offer hope for long-term remission.

While complete eradication of diseases might not always be the outcome, gradual progress is already clearly evident in the increasing number of individuals surviving serious illnesses like cardiovascular disease.

Evolutions in trial design

Trial methodologies are also evolving. Traditionally, trials focused on one medicine/technology addressing a single disease. Now, complex approaches like platform, umbrella and basket trials allow for simultaneous testing of various approaches against multiple aspects of a disease, leading to faster and more efficient results.

Additionally, with a deeper understanding of diseases, we're witnessing a shift towards individualised medicine and once common illnesses are being classified into unique subtypes, paving the way for personalised treatment plans.

Truly personalised medicine

Gene editing, cellular therapies and novel vaccines are at the forefront of revolutionary advancements. Trials are exploring the potential of correcting faulty genes within the body or engineering immune cells or the wider immune system to combat diseases. Such trials are already underway in specialist centres in our nation.

It is also likely that we will increasingly see technology and medical approaches merged to give the best performance for a particular individual, and there is no doubt that machine learning (often misnamed AI) will increasingly figure, too.

Patients leading the way

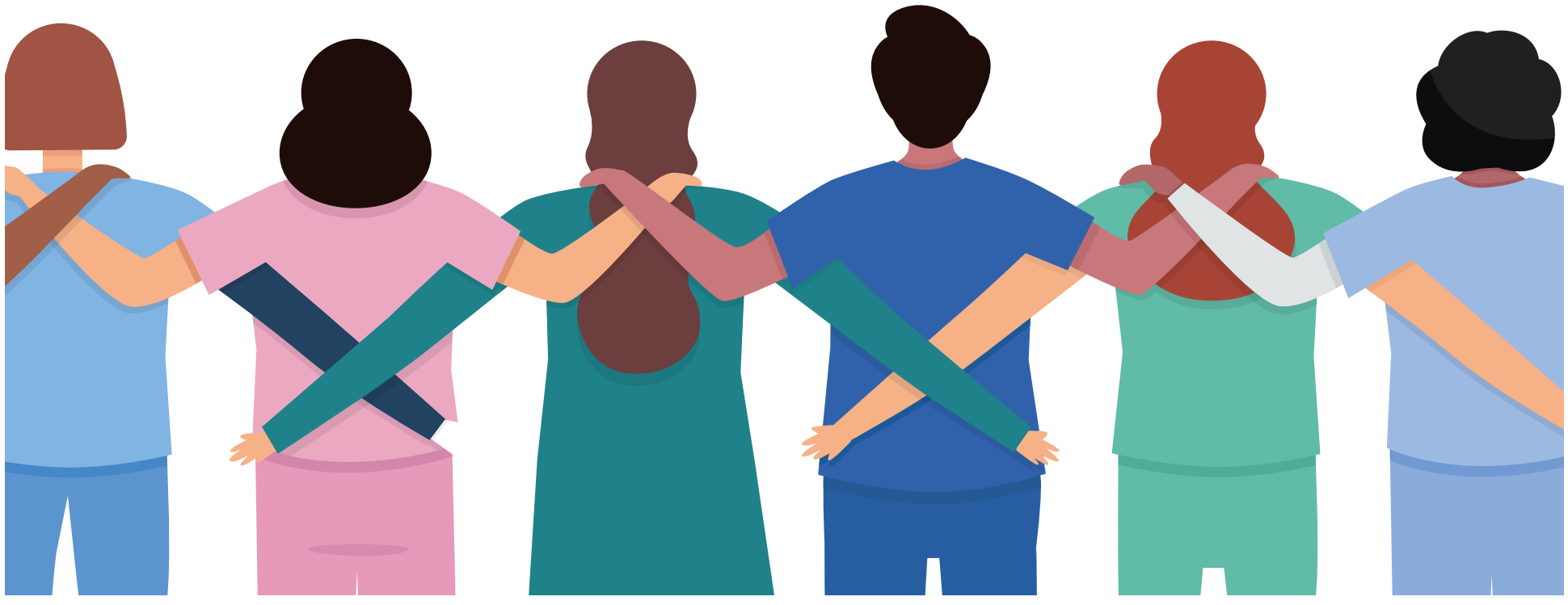
Patient-centric trials are another crucial development. Previously often overlooked, patient needs and perspectives are now being increasingly prioritised. Patients actively participate in shaping trial design, ensuring clear communication and helping identify outcomes that directly impact their human wellbeing rather than the disease itself.

Advances come with challenges

Trial regulation grows ever more complex and costly. Regulations are vital. However, increasingly, lack of investment in the extra cost of regulation is impeding progress, and regulation without resourcing can wreck purpose.

Lifesaving technology comes at an increasing cost and, indeed, the first multimillion-euro treatment has recently been approved for a rare condition in Ireland. The economics of a 'cure' will increasingly tax us intellectually and practically, as will the growing tide of patients who can have great extensions to their lives but require ongoing and costly treatment.

Hence, arguably, we are reaching a new frontier where the challenges around trials and health technology are increasingly societal rather than scientific.



Empowering hope by investing in lifesaving cancer trials

We must support clinical trial research to ensure that Irish cancer patients have access to innovative and novel cancer treatments and approaches.

A key priority for the Irish Cancer Society is investing in world-class cancer research that will have an impact on people affected by cancer in Ireland.

Improving cancer care in Ireland

The Irish Cancer Society is the largest voluntary funder of cancer research in Ireland. Every year, we invest €3.7 million, on average, in over 100 researchers working all across the country to improve cancer outcomes.

We provide over €1 million of funding every year to Cancer Trials Ireland, the leading cancer research trials organisation in Ireland. Through this investment, the Cancer Trials Ireland team work hard to drive and attract a broad trial portfolio to Ireland across a range of cancer types.

Trials improve patient outcomes today

Each year in Ireland, thousands of people affected by cancer are participating in hundreds of clinical trials across the island. For some cancer patients, trials may be the best treatment option for them, especially those who may have exhausted previous treatment options.

In addition to trials focused on improving patient outcomes through new treatment modalities, we are also passionate about ensuring Irish patients have access to cutting-edge studies centred on improvements in their cancer care and quality of life. For example, trials focusing on diet and exercise interventions have shown success for some individuals living with and beyond cancer.

Research talent and expertise

Alongside a direct focus on cancer trials, it is also vital to foster and cultivate research talent and create an environment where pioneering clinical trials research can be developed. To do this, the Irish Cancer Society provide dedicated research buy-out time for oncology-based clinicians to allow them the time to develop new research ideas. Ultimately, we want people affected by cancer nationwide to have access to the best clinical research expertise.

Each year in Ireland, thousands of people affected by cancer are participating in hundreds of clinical trials across the island.

Trials are the driving force behind improvements in cancer care and the hero of happy endings. We know that cancer research both in Ireland and globally lost valuable time during Covid — time that we can't afford and need to catch up on as soon as possible.

To do this, we, as a community, all need to work together to do everything we can to ensure that people affected by cancer in Ireland have access to world-class clinical trials and expertise.

Dr Claire Kilty
Head of Research,
Irish Cancer Society

There is still time to support the Irish Cancer Society's Daffodil Day by making a donation: **cancer.ie**

Conducting clinical trials is an essential step in providing an evidence base for improved medicines and treatments for children.

~Mary Costello, Research Programme Manager, Children's Health Ireland & Paul McNally, Director of Research & Innovation, Children's Health Ireland