Ollscoil na Gaillimhe
University of Galway

An Institiúid do Thrialacha Cliniciúla
Institute for Clinical Trials

Future*Trials*
Strategy 2023-26

Context

The University of Galway **Institute for Clinical Trials** will transform the clinical research landscape in Ireland by creating a comprehensive end-to-end programme that supports the development and delivery of clinical trials, from concept to implementation of findings. The Institute, which is led from the College of Medicine, Nursing and Health Sciences, will consolidate our resources, build on our clinical research expertise and improve the lives of patients and the health of our population, leveraging the academic strengths of the University and its healthcare partner Saolta University Healthcare Group. Additionally, the Institute will focus on developing sustained, mutually beneficial partnerships with industry and academic partners, positioning the West and Northwest as the medtech centre of Ireland. The cross-sectoral activities of the Institute for Clinical Trials will be nationally distinctive, will align with Ireland's regional development strategies and will enhance economic competitiveness by attracting investment, jobs and talent, in addition to its core mission of improving the health of the population.

Mission

To improve health by supporting the development of better and safer treatments and diagnostics for disease management and prevention.

Vision

An Institute for Clinical Trials, where scientific and operational excellence guide our ambition to rapidly translate research into impact, is inclusive, is driven by need, and committed to enhancing the global health.

Alignment

The development of the Institute for Clinical Trials is part of an ambitious cross college vision to achieve a step change in research activity at the University of Galway. The College of Medicine, Nursing and Health Sciences in partnership with the College of Science and Engineering worked closely to propose the establishment of two new cross-college research institutes with both institutes underpinned by an integrated and professionally managed Core Facilities Unit. In addition to the Institute for clinical trials, a research institute for ***Medical Technologies and Advanced Therapeutics Discovery*** with a primary affiliation to the College of Science and Engineering will be established.

The Medical Technologies and Advanced Therapeutics Discovery Research Institute is a discovery and applied institute. Its scope encompasses the breadth of biomedical science and engineering research, including fundamental science and discovery, biomedical engineering and medical technologies, regenerative medicine, diagnostics and advanced therapeutics. Together, the two Institutes will provide a cohesive platform for future expansion, as well as a strategic distinctness to University of Galway's research agenda, putting Galway on the map as destination of choice for clinical trials.

Prioritisation Criteria

Our strategic priorities have been identified through a careful appraisal of both the current landscape and the unique opportunity at the University of Galway. In identifying our strategic priorities, we have used the following prioritisation criteria to ensure that our work drives our overall mission.

The criteria are:

i. Excellence: We will compete internationally and benchmark ourselves against leaders in the field
ii. Partnership: Our partnerships will underpin our research impact
iii. Clinical Need: We will focus on areas of greatest relevance to our population
iv. Clinical and Translational Focus: We will facilitate research translation from discovery to evidence-based policy and practice applications, enhancing healthcare outcomes.
v. Integration: We will align our programmes with the Medical Technologies and Advanced Therapeutics Discovery Research Institute to improve patient outcomes.
vi. Inclusion: We will prioritise areas that provide opportunities for the widest cohort of patients, general public and investigators, with an emphasis on inter-professionalism and multidisciplinary
vii. Sustainability: We will develop an organisation that supports sustainable delivery of high-class research to patients.

Our Values

The University of Galway's strategic Plan 2020-25; Shared Vision, shaped values commits the University to being a force for transformation and public good, whose commitment to the core values of respect, excellence, openness and sustainability are a standard by which we choose, define and measure our priorities and behaviours. At the Institute for Clinical Trials we acknowledge these values and commit to them guiding everything we do. In particular this values led approach commits us to

1. Embedding the patient and community experience in all that we do. From establishing an advisory council, to involving patients in our trial steering committees, we will set a new standard for engagement
2. We will ensure our clinical trials are representative of the needs of our community, are inclusive of our diverse population and delivers on our regional needs
3. We will advocate for our patients, ensuring clinical trials are an accessible option for patients and supporting the clinical advancement of the region
4. We will strive to create an environment which is supportive of Medical Technology, Digital Health and Pharmaceutical companies; a place where we are a beacon of excellence, supporting economic development and job creation

Strategic Direction

Our strategic direction encompasses five pillars

Developing
Building Partnerships For Growth

Delivering
Excelling in Trial Completion

Innovating
Creating the Trials of the Future

Training
Advancing the Workforce and Future Trialists

Influencing
Translating Findings and Shaping Policy

Developing – Building Partnerships for Growth

We will grow our trials portfolio by developing and deepening relationships with partners in health care, industry and academia. By developing pathways for industry engagement, we will position ourselves to be Industry's partner of choice. We will develop bespoke supports for different partners, providing access to clinical specialists and experienced trial staff. We will act as a connector for these networks, driving regional, national and international impact. Through these actions, we will develop sustained relationships that support our industry partners, grow our trial activity, enhance our academic reputation and impact our patients.

Delivering – Excelling in Trial Delivery

We will provide comprehensive supports for clinical trial execution, from study design to clinical report writing. Our expert staff will ensure trials meet the highest standards, are compliant with regulation, focused on efficiency, and are completed in the shortest possible time. Our partners will benefit from comprehensive academic led assistance, spanning from design to conduct to reporting and translation, including trial design, statistical planning, regulatory and ethics approvals, trial conduct data collection and processing, trial and site management and all reporting requirements. Through the establishment of the Institute for Clinical Trials we will address the current deficit of a full service Clinical trials Unit in Ireland. We will specifically develop trial delivery capacity in digital health and medical technologies, supporting our regional expertise.

Innovating – Creating the Trials of the Future

Building on our research track record, we will be a centre for excellence in trial innovation. Focusing on improving trials methodology, which includes creating novel trial designs, developing new biomarker-based outcome measures and deploying advanced health technologies, our trials will spearhead scientific progress and be designed to be efficient, fast and impactful. In collaboration with our partners, we will develop methods tailored to their requirements, ensuring that their goals are achieved.

Influencing – Translating Findings and Shaping Policy Impact

We understand that the successful translation of clinical trials to clinical practice and policy demands expertise in report writing, evidence synthesis, policy development and advocacy. We will collaborate closely with our partners to ensure effective communication of trial findings, leveraging our expertise to bridge the gap between research results and real-world applications, ultimately driving meaningful advancements in clinical care and policy implementation.

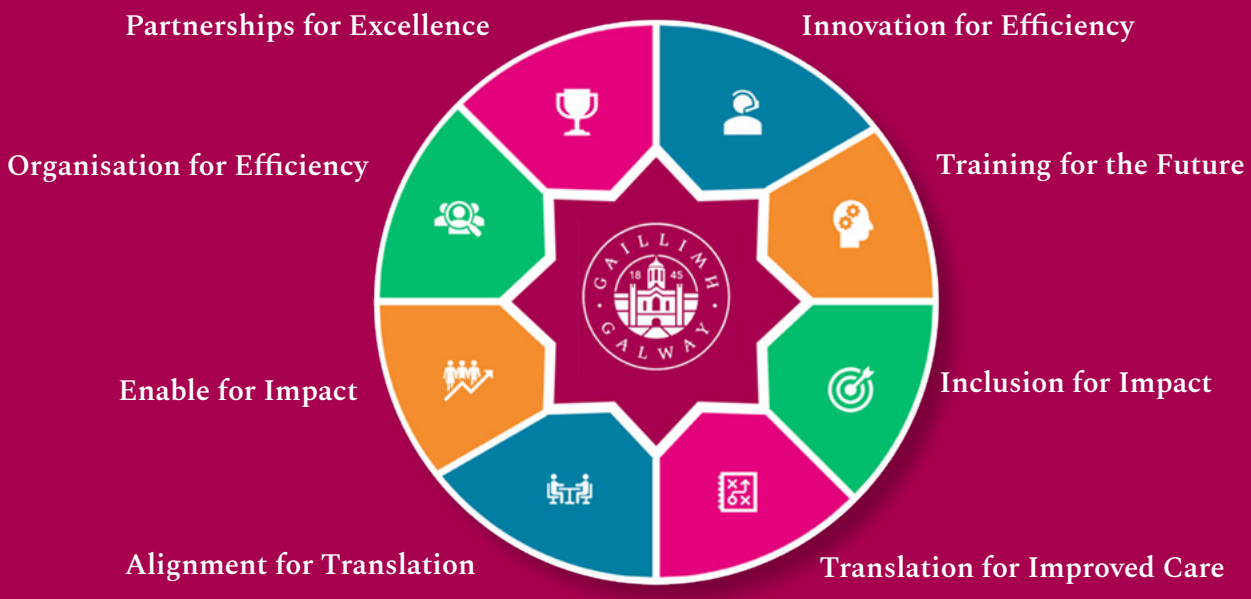
Training – Advancing the Workforce and Future Trialists

Our Institute consolidates significant academic and operational expertise, creating an ideal environment offer training programmes that strengthen the workforce and train the investigators of the future. We will work with health care, industry and academic partners to build human capital, identify training requirements and knowledge gaps, for which we will design and deliver customised continuing professional development (CPD) programmes. Through our Trialist programme, we will train our hospitals clinical staff, establishing a pipeline of experienced investigators capable of driving trial activities.

Through these Pillars we will develop an institute that is characterised by excellence, that is responsive to the needs of our partners, and is positioned to deliver best impact on our patients and our community. These Pillars underpin our overarching Strategic objectives.

Strategic Priorities

1. Create an international beacon for high impact clinical research activity where partnerships are created, and excellence is delivered
2. Organise and expand our research assets and expertise to support investigators and improve trial efficiency. We will connect with the regional MedTech community to strengthen the ecosystem, supporting innovation and comercialisation
3. Maintain a focus on science by Identifying and minimizing obstacles to impact through our Research Enablement Programme
4. Lead research in emerging priority domains including connected and digital health, ensuring these vital healthcare innovations are evaluated and applied in an evidence based manner and provide a pipleline for discovery to preclinical to clinical evaluation
5. Be a centre for trial innovation, where the trials of tomorrow are developed and applied
6. Promote equality, diversity, and inclusion in clinical trials, both from a participant/patient perspective and in the number investigators from all disciplines who conduct research across the translational pipeline
7. Mentor, educate and train the clinical research workforce, to support delivery of increased clinical trial activity creating opportunities for regional and national economic development
8. Ensure the evidence generated from clinical trials is incorporated into guidelines and policies, and that it informs clinical decision-making and practice



Partnership for Excellence

We recognise that a strong vibrant, impactful research institute is externally connected and partners with world leaders. As confident partners, we will contribute proactively to advancing innovative research. We acknowledge that a sustained focus on partnership is vital to our success and enables participation in trials and provides opportunities for funding. To achieve this ambition, we will complete the following key actions:

Goal

Create an international beacon for high impact clinical research activity where partnerships are and excellence is.

1. We will implement a research agreement with Saolta University Health Care group, frontloaded by a collaboration between the Institute and the Clinical Research Development Office, which enables research, ensures efficiency, and aligns our resources
2. We will identify, prioritise and pursue joint research projects that drive innovation and create a significant impact
3. We will establish strategic partnerships with leading research institutions, organisations and industry leaders worldwide
4. We will partner with key stakeholders across the clinical research enterprise, from funders to representative bodies, from collaborative networks to patient groups. This ensures our institute remains dynamic, responsive and engaged with the diverse perspectives and evolving needs of the community
5. We will support emerging domains, such as Artificial Intelligence in Healthcare, by creating a cluster of academic and industry investigators, aligned to evaluating digital health interventions
6. Enhance regional competitiveness through partnership with regional development groups and state bodies

Organisation for Efficiency

At the Institute for Clinical Trials, we recognize that trials must de designed, developed and delivered in the most efficient way, enabling rapid translation of findings to care and overall health improvement. By integrating efficiency and excellence we will be an engine for research excellence. Through our infrastructure, our facilities, and our expert staff, we have created an environment where state of the art research will be delivered. We will enhance our trial delivery through:

Goal

Organise and expand our research assets and expertise to support investigators and improve trial efficiency.

1. Aligning our research infrastructures, including the Clinical Research Facility to provide the best environment for our patients, staff and investigators
2. Establishing a Clinical Trials Unit, to provide end-to-end support for investigators and positioning us as the collaborator of choice
3. Harmonising our processes for trial selection and registration to make sure we prioritise the most impactful research and ensure best oversight
4. Integrating our quality and operational processes across all clinical research activity to ensure consistency and drive excellence
5. Expanding our core capabilities in data science and analytics, ensuring our trials are up to date, relevant and responsive
6. We will leverage our partnerships to create specific trial groups, serving the needs of our population. For example, with the Cancer MCAN we will develop a Cancer Trials Strategy. We will work closely with the MedTech Industry and Academic Community to create specific supports
7. We will establish an early phase clinical trials programme in Ireland, offering opportunities for the evaluation of both pharmaceutical products and medical devices thereby promoting a comprehensive landscape for innovative healthcare solutions
8. Continuously monitor and evaluate our progress, ensuring our strategies remain aligned with the ambition of building a vibrant, impactful research institute

Enablement for Impact

At the Institute for Clinical Trials, we prioritise science for impact. By optimising the way our investigators, our research partners and our research team spend time, we will ensure that progress continues, and patients are impacted. Our Research Enablement Programme will unburden researchers from the administrative tasks that cause delay and frustration and ultimately hinder productivity. Specifically, we will provide:

Goal

Maintain a focus on scientific excellence by identifying and minimizing barriers to impact through our Research Enablement Programme.

1. Capability Signposting. We will develop resources that clarify our supports and infrastructure for investigators and external partners
2. Investigator Onboarding. We will work with investigators and groups, so they have early, facilitated access to our supports and resources
3. Challenge Profiling. We recognize that to remove barriers and unburden investigators, we must first develop a deep understanding of the challenges they face. We will systematically profile these barriers facilitating the development of effective solutions to overcome them
4. Legal and financial expertise. We will appoint legal and financial leaders, who will develop effective partnerships with the University Research Office and the CRDO, to ensure contracting and financial processes are smooth, consistent and efficient
5. Study Start Up. We understand the importance of accelerated study start up. We will standardise processes, and appoint a Study Start Up specialist to guide project mobilization and deliver best study start up times
6. Lifecycle study coordination. Through our Clinical Trials Unit, we will offer dedicated coordination and project management services for investigator led projects, from grant application to close out

Alignment for Translation

The co-creation of the Institute for Clinical Trials and the Medical Technologies and Advanced Therapeutics Discovery Research Institute provides an unprecedented opportunity to establish Galway as the place where discoveries are made and translated into changed healthcare practice and policy, benefiting our patients, our research ecosystem and wider society. We will seize this opportunity through:

Goal

Through partnership with the Medical Technologies and Advanced Therapeutics Discovery Research Institute, we will establish a pipeline for innovation, from discovery, preclinical and clinical evaluation.

1. Profiling Activity for synergy- We will review research opportunities across the University, to identify opportunities to develop partnerships between University,clinical partners, and industry
2. Clinical Expert Collaboration-Collaboration with clinical experts to design and implement clinical trials that effectively test the potential of these novel interventions
3. Supporting existing staff- We will provide access to current staff across the translational pipeline to ensure they can capitalize on research opportunities. From early phase to biomarker driven trials, we will integrate our best preclinical scientists into our trials programme
4. Direct Recruitment- We will work closely with the College and Schools to recruit investigators and staff who contribute to our research vision, creating an institute aligned faculty of world leaders
5. Investment in core services and resources- We will ensure that our core translational research facilities, equipment and systems are available to our research community, creating an environment where trials are underpinned by molecular and cellular biology
6. Translational Research Journey – We will provide engagement opportunities for Translational Researchers, clinical researchers and population researchers, providing a continuum of supports from preclinical to health services research

Innovation for Efficiency

Whilst the last two decades have seen unparalleled advancement in clinical trial methods and activity, it is increasingly appreciated that current trials are inefficient, costly, time consuming and contribute to research waste. For example, advancements in technological wearables, machine learning, and data mining have prompted the transformation of clinical research and is bringing next-generation trials to the fore. The Institute for Clinical trials will be at the centre of advancing trials methodology so that we accelerate discovery and deliver trials that are better, safer and serve the needs of all stakeholders. Specifically we will:

Goal

Be a centre for trial innovation, where the trials of tomorrow are developed and applied.

1. Develop approaches to enhance patient participation in trial design, conduct and reporting, including using approaches for patient enrolment and engagement
2. Embed digital strategies in our trials- from wearable devices, to remote data collection to patient specific portals
3. Create a Clinical Research Data Hub, within our Clinical trials unit, where databases can be rapidly deployed, where analysis can be conducted and data integration and aggregation enabled
4. Partner with the Data Science Institute and the Curam Medical Device Centre at University of Galway, and other relevant research centres, to align our assets in digital and connected health
5. Actively promote the integration of primary trials methodology research within all our trial activities so that we can refine how clinical trials are designed, analysed, reported and translated to practice and policy
6. Develop master protocols for specific populations, allowing large cohorts of patients to be enrolled to platform, umbrella, basket or window trials, ensuring we maximise participation in our studies
7. We will integrate molecular analysis into our trials, enabling phenotype and event driven iterative trial designs
8. We will focus on the design and conduct of N of 1 trials in rare disease, utilising state of the art methodologies to ensure rare disease patients are prioritised and included
9. We will utilise technology to enhance our management, ensuring that our processes are as cutting edge as our science

Inclusion for Impact

Clinical trials are a potent means to transform lives. By ensuring new interventions are developed and diffused into healthcare practice, trials represent a better future for all. Given their impact, it is vital that our trials programme is inclusive and impacts all patients, their families, and communities. It is also critical that all our investigators can be part of and lead clinical trials. We will make equality, inclusion and diversity guiding principles of the Institute for Clinical Trials. We will action this through the following initiatives:

Goal

Promote equality, diversity, inclusion and access in clinical trials, both from a participant/patient perspective and in the number investigators from all disciplines who conduct research across the translational pipeline.

1. We will create a Patient Council and employ a Research Participant Advocate, ensuring that the patient voice is present and heard, throughout all aspects of trial design and conduct
2. We will maximise trial generalizability by enabling the inclusion of diverse research participants in all our trials
3. We will develop a process for validation of all protocols, to ensure they are inclusive and representative
4. We will create dedicated supports for all investigators, regardless of career stage or discipline, to ensure they have maximum opportunities for contribution to advancing healthcare
5. We will connect with our communities, by ensuring we disseminate our activity and our presence, through all appropriate communication channels
6. We will open the Institute for Clinical Trials to the wider community, through open days, school engagement programmes and a public lecture series

Training for the Future

As clinical trials continue to transform into a data and technology intensive enterprise, where speed of response and excellence of execution are our trademarks, we recognize the requirement to train the next generation of clinical trial staff and investigators. Learners will learn in a research-intensive environment, training alongside our excellent teams and learning from our expert staff. The institute for Clinical Trials will be the preferred destination for students at under and postgraduate level who aspire to be part of the transformed clinical research landscape we are creating. Specifically, we will:

Goal

Mentor, educate and train the clinical research workforce, to support delivery of increased clinical trial activity creating opportunities for regional and national economic development.

1. Continue to innovate in graduate education, through our MSc in Applied Clinical Data Analytics, our MSc in Clinical Research and our MSc in Evidence Based Future Health Care. These programs will develop a diverse range of health professionals, including trialists, data analysts, clinicians, healthcare administrators, and policy experts for shaping the future of healthcare
2. We will create Ireland's first undergraduate programme in Clinical Trials. Offering direct entry to school leavers, it will graduate professionals who will be the workforce of the growing clinical trials industry in our region
3. We will provide bespoke CPD offerings for industry partners, providing direct access to our expert led programmes enabling upskilling to the latest methodologies and techniques in Irelands flagship Clinical Trials Institute
4. We effect leadership development by mentorship and training of new investigators, through our investigator onboarding programme
5. Our community engagement will include providing bespoke training programmes for patients, community groups and the public- offering insights into clinical trials and how our work transforms lives

Translation for Improved Care

We are committed to ensuring the findings of our clinical trials are translated into changes in healthcare delivery, that will impact our patients for the better. The Institute for Clinical Trials will lead the development of innovative treatments and therapies that can improve the health outcomes and quality of life for people receiving care in Ireland and around the world. To achieve this, the institute is committed to ensuring that the evidence generated from clinical trials is incorporated into guidelines, policies and clinical decision-making processes. This will include:

Goal

Ensure the evidence generated from clinical trials drives meaningful improvements in healthcare by integrating findings into guidelines, policies, and clinical decision-making processes.

1. Develop and expand a specialised unit that addresses the needs of the medical device community. It will provide a dedicated service to conduct high quality systematic reviews of the global body of evidence for medical device clinical evaluations, post market surveillance and risk management reports. This dedicated service will support evidence-based decision- making in the health technology sector
2. Enhance capacity within the regional and national medical device community by offering tailored, high-quality programs to these training initiatives, led by international experts and accredited by Cochrane, will cover essential skills such as searching for evidence, critical appraisal, evidence synthesis, and reporting. Programs can be delivered on-site at company locations or at the University of Galway, ensuring accessibility and flexibility
3. Engage in active advocacy efforts to support policies and guidelines that prioritise the integration of evidence-based research from clinical trials into healthcare including health systems
4. Increase public awareness and understanding of clinical trials and trial outcomes by regularly sharing informative materials and engaging with people receiving care, their families, and the public in accessible, meaningful ways
5. Provide training and capacity-building programs for researchers within the institute to enhance their skills in evidence synthesis, ensuring that findings from clinical trials are effectively and rigorously incorporated into healthcare guidelines and policies
6. Create a specialised evidence synthesis unit within the institute that focuses on synthesising clinical evidence, using methods such as systematic reviews and meta-analyses. This unit will work collaboratively with researchers, healthcare professionals, and policymakers to produce high-quality, contextually relevant syntheses
7. Develop a comprehensive program within the Institute that focuses on implementation research. This program will aim to bridge the gap between evidence generated from clinical trials and its adoption in real-world healthcare settings

Ollscoil na Gaillimhe
University of Galway

University *of* Galway