

C-TRIC



Clinical Translational
Research and Innovation Centre

Innovating for Healthcare....

Partners



DERRY CITY COUNCIL



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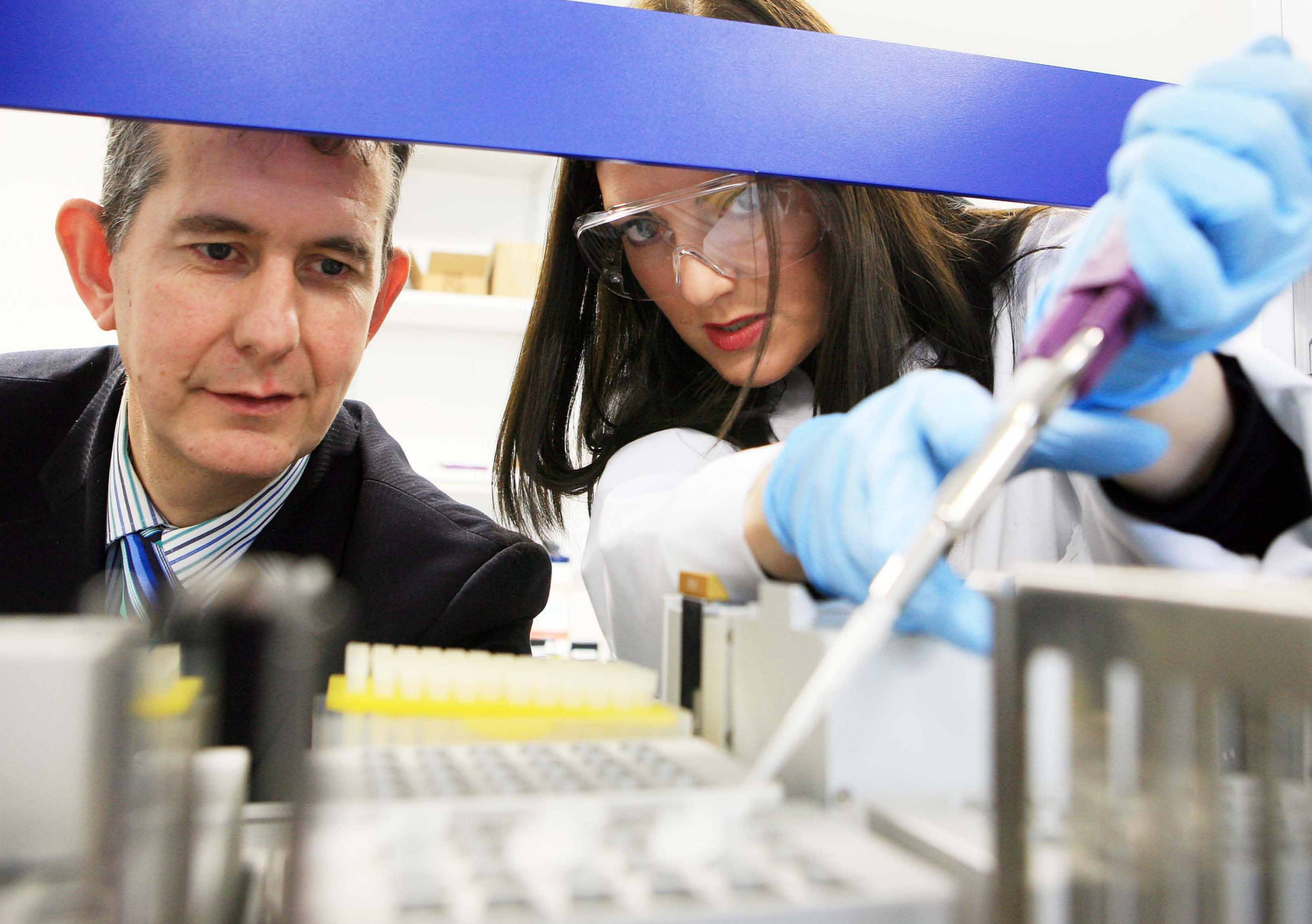
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About C-TRIC

The Clinical Translational Research and Innovation Centre (C-TRIC) is a facility to pioneer clinical and translational research, developed as a joint partnership between the Derry City Council, the University of Ulster and the Western Health and Social Care Trust (WHSCT). C-TRIC draws strength and capability from our three parent organisations.

C-TRIC is a thriving hub for healthcare innovation providing incubation support, innovation services and networking opportunities to researchers, innovators and entrepreneurs who are developing novel product concepts addressing unmet clinical need.

C-TRIC is also Northern Ireland's only purpose built clinical research facility providing direct access to the UK's National Health Service, one of the largest healthcare markets in the world.

C-TRIC's unique infrastructure coupled with its serviceable location on a major acute hospital site, provide the ideal centre to execute high quality clinical research, trials and evaluations. In addition to quantitative clinical research approaches, C-TRIC researchers have expertise in qualitative research methods which helps understand patient experiences of healthcare, treatments and concordance with health professional's recommendations.

Translational Research Groups

Five Translational Research Groups are being established at C-TRIC:-

- Cardiovascular and Stroke Medicine
- Diabetes/Obesity
- Neuro-degenerative Disease
- Oncology
- Rheumatology and Inflammatory Disease

These groups will connect existing thematic areas in biomedical, nursing, psychology, rehabilitation and engineering research within the University of Ulster Research Institutes and existing research active clinicians within the WHSCT.



Personalised Medicine Focus

Personalised Medicine involves the use of genetic testing to ensure that the right treatment, for the right person, at the right time is provided rather than the traditional 'one size fits all' approach.

With key infrastructure and the co-location of clinical, scientific and technical staff within it's facility enabling access to high quality clinical samples and data, C-TRIC is well positioned for R&D in the Personalised Medicine space

CASE STUDY I – Evaluation of Diagnostic Test [Rheumastrat]

Randox Laboratories, the University of Ulster and the Western Trust, at C-TRIC are working jointly on the development of a simple blood test for those suffering from certain inflammatory conditions such as Rheumatoid arthritis. The novel test aims to match "responder" patients to new advanced "biologic" drugs, costing up to per £10,000 per patient per year. By also indentifying "non-responders", the test will mean an end to futile periods of therapy for the sizeable proportion of patients who at present undergo the costly drug treatment without deriving any benefit from it.

The condition costs the NHS an estimated £560 million annually. Around 580,000 adults in England currently have the disease with a further 26,000 new cases diagnosed each year. The estimated cost to the UK economy of sick leave and work-related disability for people with rheumatoid arthritis is £1.8 billion a year.

About 10% of sufferers do not respond to standard drug treatments for rheumatoid arthritis. They are then eligible for expensive biologic drugs such as antibodies to TNFa (Tumour Necrosis Factor-alpha). They combat the effects of joint inflammation by copying the effects of substances naturally made by the body's immune system. This treatment is effective in about two-thirds of those who receive it but the remaining one-third or more fail to benefit from it.

Clinical studies are being conducted in co-operation with 330 volunteer patients, with facilities and staff at C-TRIC playing a key role as one of the two recruitment sites selected.

CASE STUDY I



Connected Health

'Connected Health' is a term used to describe a model for healthcare delivery that uses technology to provide healthcare remotely, it encompasses programs in telehealth, telecare and disease and lifestyle management.

C-TRIC hosts a wide variety of Connected Health studies and companies targeting improved patient care through the adoption of technology and has recently established an ICT Innovation Committee to facilitate of these projects.

C-TRIC has managed range of events and workshops and facilitated a number of collaborative networks including respiratory health, diabetes, obstetrics and gynaecology, bringing together academics, clinicians and businesses to explore opportunities to apply novel technologies to improve patient care

C-TRIC is extremely well placed to take advantage of the trend towards increased technology adoption within healthcare:-

- Close proximity to ICT and Design research excellence at Magee Campus, University of Ulster
- Project Kelvin, the fastest, high capacity city-to-city international telecommunications link from Europe to the east coast of the USA;
- Digital Derry, a vibrant networking organisation supporting, promoting and growing the digital sector in the city
- Connected Health in action - Gestational Diabetes Project



Better Design for Better Health

C-TRIC draws strongly from design expertise based locally at the Magee Campus of the University of Ulster.

The Designers Intra Health initiative at C-TRIC, pioneered by Dr Justin Magee in partnership with other academic and clinical collaborators, is a unique initiative that integrates commercial design practice, design or scientific research and clinical interactions to better address healthcare issues.

A number key innovative product and multimedia design healthcare projects demonstrate this novel approach:

- Cardiovascular device and surgical procedure simulation using 3D animation
- New product development (NPD) of an improved, user-centric drug delivery system
- NPD of a new Infection control station for front line care

With a 'designer in residence' working alongside multidisciplinary teams including key clinical and academic staff, all projects have benefited from the collaborative environment at C-TRIC.

These projects illustrate how strategic collaboration between designers and clinical practitioners, from the outset of a identified problem, can play in providing effective solutions for unmet clinical need.

Based at C-TRIC

Annagh

Annagh develops devices to detect when a diabetic is entering a hypoglycaemic event and alerts nearby carers to check diabetic is medicated

3square

3square have developed a novel healthy eating app for the iPhone, that helps users measure and keep track of all the nutrition you get from your food, so they can enjoy a healthy, balanced diet.

Clearway Medical Limited

Clearway Medical recently received Proof of Concept funding from the NISPO fund managed by e-Synergy to develop a respiratory monitor to detect and report poor breathing patterns.

Crescent Dignostics

Crescent Diagnostics is developing a new prognostic test for hip fracture risk based on measurement of the protein composition and structure of toenails using laser based technologies.

Nurture Design Labs



Digit-Ease

Digit-Ease is a research team formed to address issues around care and treatment of patients with Rheumatoid arthritis (RA).

Gen-X Healthcare Ltd

Gen-X Healthcare have developed an electronic hygiene monitoring and control system which utilizes Radio Frequency Identification (RFID) Technology. Its unique application of RFID, called ACTI/PASS™, together with its flexible reporting software, combine to deliver a powerful Management tool.

Intra-Health Designers

Designers Intra-Health are a collective of designers from various disciplines who provide a design service in new product development, 3d visualisation and design communication within the clinical centre.

I-Innovations

I-Innovations is a company operating within the realms of healthcare and living. They are currently developing a novel Non-Invasive Incontinence Management System designed to remotely detect and alarm care providers of dependents incontinent episodes.

SmartAir Medical

SmartAir Medical is a start-up company in association with Intelligent Systems Research Centre (ISRC) at the University of Ulster (Magee) and C-TRIC. The company has developed a unique spacer device to ensure drug compliance and improved drug delivery for asthma sufferers.



Professor Helene McNulty, Professor of Nutritional Science, Biomedical Sciences Research Institute, University of Ulster

'As one of the lead investigators for a large North-South of Ireland study of ageing - the Trinity Ulster Department of Agriculture (TUDA) study - my research team was very fortunate to have access to the excellent facilities and expertise of C-TRIC. C-TRIC provided a main recruitment hub where we sampled some 1200 participants from the North West. Working in partnership with C-TRIC made all the difference, and ensured that we successfully recruited the required number of study participants more effectively than at any of the other recruitment centres involved in sampling the total of 5300 TUDA participants.'

Dr Paul Thompson, Biomedical Sciences Research Institute, University of Ulster

'Our work examines how vitamin D functions at a molecular level and it is imperative that we extend our knowledge in a clinical context through collaboration with clinicians and access to viable clinical tissue.'

'It would be extremely difficult to undertake this type of research without access to a facility like C-TRIC'

Clinical Research

C-TRIC is facilitating a range clinical trials and evaluations sponsored by both industry and government.

Infrastructure

- Reception / Waiting Area
- Fully Equipped
- Clinical consultation rooms
- Phlebotomy
- Biomedical processing lab
- Physiology lab
- Clinical material storage
 - Electronic sample tracking
 - Remote temperature monitoring
- Office accommodation / Flexible workspace

Personnel

- Research and Development Office
 - Ethics and Governance approvals
- Clinical Research Nurse team
 - Diabetes, Stroke, Cardiology, Critical Care, Paediatrics, Renal Medicine, Oncology
 - Connected to UK Clinical Research Network
- Clinical Support
 - Healthcare Economics, Clinical Study Design, Statistical analysis
- Quality Assurance Technician

CASE STUDY II – TUDA

The TUDA study aimed to collect detailed clinical, lifestyle, dietary, genetic and biochemical data to investigate gene-nutrient interactions in the development of Osteoporosis, Alzheimer's and Cardiovascular disease by studying older adults showing the early stages of these common diseases, namely low bone mineral density, early memory loss and hypertension respectively.

A number of factors are considered to be implicated in these diseases. Lifestyle factors such as diet, body weight, smoking, physical activity and years of education are acknowledged as risk factors for the development of these chronic diseases. Of the nutritional factors, calcium and vitamin D are well-established as important nutrients for the maintenance of bone mineral density and the prevention of osteoporosis. Other nutritional components and genetic factors are increasingly recognised as playing a critical role in disease risk.

Participants in TUDA study were over 60 years of age and had been diagnosed with hypertension, or currently taking hypertensive medication. As part of the study these patients were required to:

- Complete a detailed health and lifestyle questionnaire;
- Complete physiological function tests;
- Have their height, weight and waist/hip measurements taken;
- Provide a blood sample which will be analysed for both clinical markers of health and genetic information.

The TUDA study has just been completed at C-TRIC after recruitment of over 1200 participants in less than 12 months. C-TRIC was capable of facilitating this complex gene-nutrient interaction study that included the administration of cognitive function tests, access to a bone density scanner, laboratory testing of nutritional component levels and genetic testing.

CASE STUDY II



Clinical Research Support

Growing the R&D Culture through Collaboration

C-TRIC plays a key role in facilitating research activities at the Western Health and Social Care Trust (WHSCT) in collaboration with academia and industry.

The WHSCT is comprised of three hospital sites at Altnagelvin, Omagh and Enniskillen providing healthcare services for up to 400,000 people including cross border services in Republic of Ireland. The Trust employs 12,500 staff and invests approximately £422m in the delivery of a comprehensive range of Health and Social Care Services

C-TRIC provides an interface between the biobusiness sector and academic/clinical communities to identify unmet clinical needs and expedite biotechnology product development. Research and Development activities have a high priority within the Western Trust. The Trust recognizes that excellence in research correlates with excellence in clinical care delivery and supports the development of a vibrant research culture.

R&D Discretionary Fund

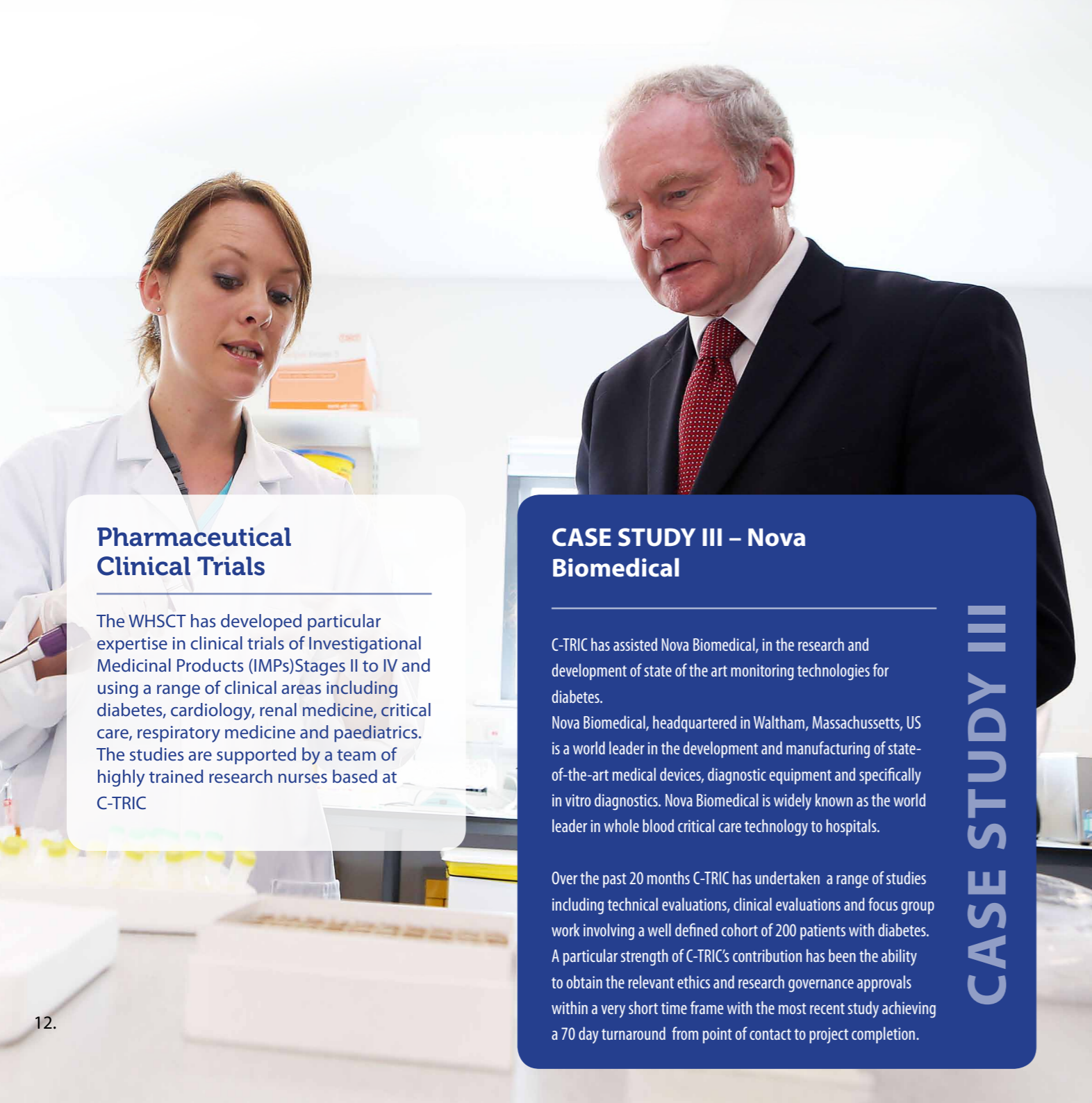
Over 100 new research projects have been commenced since C-TRIC has been established in 2009 covering a broad range of areas including pharmaceutical trials to social services research.

The table opposite shows projects supported recently through the Western Trust's R&D Discretionary Fund. These pilot projects are expected to lead to further more substantial research grant funding applications.

Colette Donaghy, Chief Operating Officer at Medevol (Clinical Research Organisation)

'I am currently working with C-TRIC on a clinical research study and I have been impressed with their efficient infrastructure and committent to the success of the study. I look forward to future collaboration with this group.'

Name of Applicant	Project Title
Professor Finbarr O'Harte University of Ulster	Investigation of Ocular biomarkers in type 2 Diabetes
Dr Ruth Morrissey Western Health and Social Care Trust	Exploration and targeting of pharmaceutical care needs for patients admitted to an acute medical unit
Professor Vivien Coates Western Health and Social Care Trust	An investigation into the self-care management by 'younger' adults with type 2 diabetes, with particular focus on gender differences – a preliminary qualitative study.
Dr Ying Kuan Western Health and Social Care Trust	Use of Bio impedance for longitudinal assessment of nutrition, hydration and residual function in a haemodialysis population: A pilot study
Dr Maurice O'Kane Western Health and Social Care Trust	Prediction of type 2 Diabetes: Shared family environment and lifestyle factors as determinants for health and well being
Dr Maurice O'Kane Western Health and Social Care Trust	Smartlife
Dr Mary Hannon-Fletcher University of Ulster	The effect of a multivitamin and micronutrient supplement on Vitamin D levels and DNA Damage in HD Patients
Cairine Gormley Western Health and Social Care Trust	Recording and evaluating blood assay levels of teicoplanin in patients receiving this drug in Altnagelvin Hospital
Professor Geoff McMullan University of Ulster	A functional genomic study of β -glycosidase and related activities within the human gut microbiota in response to a berry rich diet.
Dr Cathy McGeough University of Ulster	Autoantibody profiling of Rheumatoid Arthritis Patients
Gillian McCorkell Western Health and Social Care Trust	Women's Knowledge and perception of Coronary Heart Disease and the Associated Risk Factors
Professor Helene McNulty University of Ulster	An intervention study to investigate the effect of combined folic acid and vitamin B12 supplementation for 2 years on bone health with Coeliac disease patients
Dr Aine McKillop University of Ulster	Predictive biomarkers for pre-diabetes and early beta cell dysfunction
Dr John Callan University of Ulster	Quantum Dot – Antibody conjugates for the rapid and specific detection
Karen Love Western Health and Social Care Trust	Design of an infection control pod



Pharmaceutical Clinical Trials

The WHSCT has developed particular expertise in clinical trials of Investigational Medicinal Products (IMPs) Stages II to IV and using a range of clinical areas including diabetes, cardiology, renal medicine, critical care, respiratory medicine and paediatrics. The studies are supported by a team of highly trained research nurses based at C-TRIC

CASE STUDY III – Nova Biomedical

C-TRIC has assisted Nova Biomedical, in the research and development of state of the art monitoring technologies for diabetes.

Nova Biomedical, headquartered in Waltham, Massachusetts, US is a world leader in the development and manufacturing of state-of-the-art medical devices, diagnostic equipment and specifically in vitro diagnostics. Nova Biomedical is widely known as the world leader in whole blood critical care technology to hospitals.

Over the past 20 months C-TRIC has undertaken a range of studies including technical evaluations, clinical evaluations and focus group work involving a well defined cohort of 200 patients with diabetes. A particular strength of C-TRIC's contribution has been the ability to obtain the relevant ethics and research governance approvals within a very short time frame with the most recent study achieving a 70 day turnaround from point of contact to project completion.

CASE STUDY III

Dr Siobhan O'Neill, Reader in Psychology, Principal Investigator, University of Ulster

'Our research team utilised the facilities at C-TRIC for accessing patients, collection of data and for team meetings in relation to the evaluation of a pedometer based exercise intervention for patients with cardiovascular disease. The location of C-TRIC on the Altnagelvin Hospital site was ideal for our participant group of cardiac patients. The team at C-TRIC were very helpful in terms of the organisation and management of our research study.'

CASE STUDY IV – Pedometer Study

C-TRIC hosted a feasibility study examining the use of a progressive tailored, pedometer based exercise programme to increase and maintain activity levels in phase IV cardiac rehabilitation.

Regular physical activity is known to improve coronary risk factors and is a core component of cardiac rehabilitation (CR) programmes. Despite the well documented benefits, it appears that the maintenance of physical activity after completing an 8 week CR programme tends to be poor. The study explored the feasibility and acceptability of using pedometers to promote physical activity in phase IV CR participants.

69 participants were recruited following a phase III CR programme and were assigned to a control or pedometer-based intervention group.

The findings from the study indicated that a progressive, tailored pedometer based exercise programme maintains and indeed increases physical activity levels in phase IV CR participants and indicates feasibility to conduct a full randomized controlled trial.

Participants need some type of maintenance plan after 8 weeks completion of the CR programme. The extended duration and ongoing contact with the CR staff enhances confidence and promotes exercising / physical activity when discharged from the service.

This tailored pedometer based exercise programme did motivate the participants to continue physical activity after phase III CR.

CASE STUDY IV





Bio-Entrepreneurs

The 'Bioentrepreneur Programme' is a dynamic new initiative that has been designed to support entrepreneurs, innovators and start-ups develop their innovations for better healthcare whether they are software related, medical devices, diagnostics or therapies.

The programme will provide tailored support comprising of the use of hot-desk and/or lab facilities at C-TRIC for 12 months and support from a mentor or expert to address a specific issue or barrier relating to the development of your business idea. This support can focus on a variety of needs including:-

- **Healthcare Market Feasibility**
- **Prototyping**
- **New Product Development**
- **Applied Research**
- **Testing**
- **Clinical Validation**



Healthcare Innovation

C-TRIC is a thriving hub for healthcare innovation providing incubation support, innovation services and networking opportunities to researchers, innovators and entrepreneurs who are developing novel product concepts addressing unmet clinical need.

What's the next big IDEA in healthcare?

C-TRIC works with academics, clinicians and businesses in the quest to identify the key challenges in modern healthcare and develop innovative solutions.

Insight

Access to clinical expert opinion and market drivers.

Discovery

Observational Studies with Access to High Quality Clinical Materials and Data.

Evidence

Clinical Evaluations and Trials of technology, devices, diagnostics and therapeutics.

Adoption

Introduction of Innovative Healthcare Interventions within UK's National Healthcare System.

Healthcare Innovation

C-TRIC has supported a range of companies through its Bioentrepreneur Programme and has assisted a great number of healthcare innovators and companies whether they are C-TRIC tenants or located right across the globe in Massachusetts-US, Chester- UK, or closer to home in Northern Ireland or the Republic of Ireland.

C-TRIC tenant and client companies are developing a wide range of novel products and services for improved healthcare including imaging technology to measure bone density, improved clinical communication using cloud computing, smart phone apps and devices to manage diseases such as diabetes, rheumatoid arthritis and asthma, technologies to manage and audit patient care and novel cancer diagnostics.

Many C-TRIC based companies and clients have secured Innovation Vouchers from Invest Northern Ireland to further develop their healthcare related product ideas. In a 12 month period C-TRIC provided assistance and support to 5 industry projects enabling them to secure proof of concept finance amounting to £260,000.

In recent years, C-TRIC has also steered innovative healthcare product ideas from 'SmartAir Medical' and 'Clinical Communicator' to success in the Biotech and Digital Media categories respectively, in the Northern Ireland 25K Business Plan Competition





Industry Partnerships

C-TRIC is specifically designed to assist bioscience industry to clinically evaluate and improve their technologies.

C-TRIC's unique infrastructure coupled with its serviceable location on a major acute hospital site, provides the ideal centre to execute high standard clinical research trials and evaluations.

C-TRIC is the centre of an active clinical research community with access to a broad range of clinical services. The locality has a stable and homogeneous population (Northern Ireland population - 1.7 million) facilitating longitudinal and family based research studies.

High levels of participation have allowed efficient recruitment and retention in clinical trials.

C-TRIC is licensed to access, handle, process and store clinical materials and data and the expedition of studies is assisted by formal networks across UK and Ireland.

In addition to quantitative clinical research approaches, C-TRIC researchers have expertise in qualitative research methods which helps understand patient experiences of healthcare, treatments and concordance with health professionals' recommendations.

Jeff DuBois, VP Medical & Scientific Affairs at Nova Biomedical, Boston, USA

The professional services available at C-TRIC have been very beneficial both professionally and personally. Working in partnership with C-TRIC has proved to be a hugely effective strategy in raising awareness of our SMBG products within the European healthcare market. The leadership and staff at C-TRIC are very open and cooperative and access to patients for enrollment in our studies was very straightforward and timely. I highly recommend C-TRIC for product evaluations and clinical trials.

Annual Translational Medicine Conference

C-TRIC held its 4th Annual Translational Medical Conference (TMED4) on 10th and 11th May 2012 at the City Hotel in Derry.

Looking forward now to its 5th successive year, the event is recognised as a leading international conference focusing on Translational Medicine, the translation of ideas from the bench to point-of-care.

The conference targets academics, clinicians, researchers, bioindustry R&D managers and opinion leaders with the aim of encouraging collaboration and communication to inform research and clinical interventions.

With our event in 2012 attracting delegates from USA, UK, Ireland and India, the conference continues to grow in stature each year and we are targeting 200 delegates for our 2013 conference.

Previous TMED conferences have focused on key disease areas such as inflammation, cardiovascular disease, diabetes and mental health.

TMED5 "Enabling Healty Ageing" will take place at the City Hotel 2-3rd May 2013

Dr Peter Donnelly, Chief Executive Officer at BioBusiness 'C-TRIC's Annual TMED Conference has become a signature event in Ireland's biotech calendar'

International Collaboration

Supported initially through EU Interregional funding, C-TRIC targets the global healthcare and biotechnology sectors.

As a previous winner of an Irish Times Innovation Award, C-TRIC continues to promote excellence and work across borders with continued all-island efforts in both the diabetes and cardiovascular disease areas is raising the profile of Irish research and development, North and South.

C-TRIC has strong institutional and industry linkages in the US and Europe and is working towards collaborative R&D projects with key strategic partners.

Dr Susan Whoriskey, Senior Vice President at Moderna Therapeutics, former Entrepreneur in Residence (Life Sciences) at MIT and Principal, Founder at Whoriskey Associates

"I was very impressed by my C-TRIC visit and Northern Ireland is lucky to have such a centre. I have never seen such an excellent convergence of facilities, expertise and partnership under one roof as is present in C-TRIC."



C-TRIC



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