2018 IN NUMBERS

1. NEW ACADEMIC PARTNER IN CRDI BRINGING TOTAL TO 6
   - 31% INCREASE IN NEW USERS ON CRDI WEBSITE IN 2018
   - 197 FEASIBILITY ASSESSMENTS PROCESSED
   - 120 STAKEHOLDERS ATTENDED CORPORATE ENABLING OF CLINICAL RESEARCH CONFERENCE IN MAY 2018
   - 16 ICAT FELLOWS UNDERTAKING ICAT PROGRAMME
   - 45 PARTICIPANTS IN CRDI/CÚRAM MEDICAL DEVICE e-LEARNING MODULE
   - 16 HRB CRCI WORKING GROUPS
   - 4,800 DIAGNOSTIC JOURNEYS OF MEN WITH PROSTATE CANCER DETAILED IN IPCOR ANNUAL REPORT
   - 2 NEW CRF/CS IN HRB CRCI NETWORK BRINGING TOTAL TO 8
   - 2nd ANNUAL ICTD SEMINAR HELD
   - 155 ATTENDEES OF TECHNIQUES & STRATEGIES COURSE

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Clinical Research Development Ireland (CRDI) is a not-for-profit research partnership comprising NUI Galway, Royal College of Surgeons in Ireland, Trinity College Dublin, University College Cork, University College Dublin and the University of Limerick, their medical schools, associated academic hospitals and clinical research facilities, with the objective of accelerating the translation of biomedical research into improved diagnostics, therapies and devices for patients.

CRDI builds on the achievements of Molecular Medicine Ireland which was established in 2008 by the five aforementioned universities, together with its predecessor the Dublin Molecular Medicine Centre (DMMC), a partnership initiated by UCD and Trinity College Dublin in 2002, with the inclusion of Royal College of Surgeons in Ireland in 2005. The University of Limerick joined in June 2018.

CRDI is funded by the six universities along with programme funding from a number of sources including the Health Research Board, Enterprise Ireland, Wellcome Trust, Science Foundation Ireland, Irish Cancer Society, Movember Foundation and the Health Service Executive.
2018 HIGHLIGHTS

UNIVERSITY OF LIMERICK JOINS CRDI PARTNERSHIP

In June 2018, the University of Limerick joined Clinical Research Development Ireland, becoming the sixth partner of this leading academic research partnership.

For more see page 14 »

FUTURE INVESTMENT IN CLINICAL RESEARCH

In March 2018, Clinical Research Development Ireland brought together senior executives from stakeholder organisations in clinical research in Ireland for an exciting new initiative entitled the Future Investment in Clinical Research (FICR) that aims to enhance the level of clinical research in Ireland for the benefit of the patient and the wider economy.

For more see page 16 »

CRDI FUNDED FOR FOUR NEW PROGRAMMES

CRDI was successfully awarded funding for four new programmes during 2018: HRB NEPTuNE, in4kids, connect4children and Erasmus+ CONSCIOUS.

For more see page 16 »
2018 HIGHLIGHTS

**HRB CRCI LEADS ICTD CELEBRATIONS IN IRELAND**

The second national seminar to celebrate International Clinical Trials Day was hosted by HRB CRCI on 10 May 2018 in the historical Round Room at the Mansion House in Dublin.

For more see page 28 »

**CORPORATE ENABLING OF CLINICAL RESEARCH CONFERENCE**

The Corporate Enabling of Clinical Research initiative held a full-day conference on Wednesday 30 May 2018 in the Liffey Suite at the Ashling Hotel in Dublin.

For more see page 32 »

**WELLCOME-HRB ICAT PROGRAMME SECOND ANNUAL SCIENTIFIC RETREAT**

The second annual ICAT Retreat took place in Malahide on 15 and 16 November 2018 gathering together the ICAT Fellows, Directors, PhD supervisors, members of the ICAT Steering Committee and Independent Advisory Board, as well as aspiring clinician scientists.

For more see page 44 »
Chairman’s Statement

On behalf of the Board of CRDI, I was delighted to welcome the University of Limerick to the partnership on 18 June 2018. This fulfilled an important strategic objective and was marked with a gathering hosted by Professor Des Fitzgerald, President of the University of Limerick, and attended by representatives of all six members including the newly appointed directors from UL, Professors Rachel Msetfi and Calvin Coffey.

During 2018 CRDI, in collaboration with its partners and stakeholders across the academic, public and private health sectors, continued to make progress on its mission to advance patient care and health service delivery by supporting the development of clinical and translational research across our partner academic institutions, their medical schools and associated hospitals.

This progress was aided by the Irish Government’s ongoing investment in the clinical research ecosystem, premised on strong evidence that an active clinical research system not only benefits patients but also contributes to the national economy in terms of investment and job creation. In particular, we welcome the renewal of funding to HRB Clinical Research Coordination Ireland via the Health Research Board and Enterprise Ireland for the coordination and conduct of research including clinical trials in medicines, medical devices and diagnostics. CRDI also received new funding as a core partner in a HRB Collaborative Doctoral Award for the collaborative Neonatal Encephalopathy PhD Training Network (HRB NEPTuNE) which aims to produce a cohort of experts who will advance patient-focused research in neonatal encephalopathy.

We are delighted that the Government’s future policy commitments also include the improvement and enhancement of an enabling environment for health research as outlined in Ireland’s Strategy for Research and Development, Science and Technology, Innovation 2020, and echoed in the Slaintecare Implementation Strategy and Next Steps (2018). Slaintecare presents a vision for healthcare in Ireland that advocates the development of a broad-based national health research strategy with input from a new R&D forum to be established with representation from across the health, health research and innovation system.

Moreover, we are pleased that the Health Service Executive’s National Service Plan 2019 also advocates for a strong evidence-based research culture and that it has declared its commitment and support to the implementation of the Slaintecare Implementation Plan. The development of a national framework for research governance and the roll-out of digital health technologies and notably electronic patient records are particularly welcome HSE priorities, and as a stakeholder, CRDI looks forward to working with both the Department of Health and HSE on the implementation of all the actions relating to health research in both plans.

Whilst acknowledging the significant investment already made by Government and industry in the clinical research system in Ireland, CRDI believes that there is much more to be done to scale it up to the level found in comparable countries. In light of this, CRDI is leading an initiative known as Future Investment in Clinical Research which seeks to strategically examine and define the optimal future clinical research infrastructure, support, capacity and capability for the benefit of the population and the economy of Ireland. Underpinning this initiative is the consensus among stakeholders that a real opportunity now exists to enhance Ireland’s level of clinical research to its fullest potential and that Government needs to prioritise the policy changes and investment required. A Steering Group was convened in March 2018 and chaired by CRDI Chief Executive, Prof Pat O’Mahony. It comprises representatives from patient bodies, healthcare delivery, academia and industry and is tasked to develop a national response to significantly increase the clinical research footprint, with the ultimate goal of integrating it into the Irish health service delivery system.

Challenges that will be addressed by the group go beyond the aspirations of Slaintecare and include bottlenecks that inhibit the conduct of clinical trials in Ireland by both the pharmaceutical industry and clinicians. Chief among these are the lack of a national ethics committee, electronic patient records and a national clinical trial agreement, the impact of which has led to long delays at the start-up phase for clinical trials.

CRDI believes that strategies that promote Irish R&D across the economy
are necessary to help mitigate against any prospective negative effects of Brexit and we therefore call on Government to work with the health service, industry and academia to help make Ireland a location of choice for innovative, value-adding clinical research.

In parallel, CRDI continued its involvement in a separate but related body of work entitled the Corporate Enabling of Clinical Research. Building on the excellent work conducted over a number of years by the partner institutions under the auspices of CRDI’s predecessor Molecular Medicine Ireland, this initiative brings together the complementary expertise and experience of stakeholders including the HSE, State Claims Agency, Cancer Trials Ireland and funding bodies in addition to the academic institutions with the aim of identifying and addressing the challenges of sponsoring clinical research. This initiative which commenced in its current form in early 2017 is co-chaired by Nora Geary of UCC, Dr Paola Della Porta of RCSI and Prof O’Mahony and the final report to be published in 2019, will provide, inter alia, a cooperation framework in which academic institutions and the health sector can work covering the areas of governance, sponsorship, contracts, insurance, resourcing of sponsorship and engagement with clinicians.

I would like to extend my appreciation to my colleagues on the Board of CRDI for their ongoing support and commitment to the development of a sophisticated, coordinated clinical and translational research partnership.

I would also like to acknowledge with gratitude the persistent dedication and expertise of the staff of CRDI, under the superior leadership of Prof O’Mahony, who have worked diligently, in the spirit of collaboration, to achieve CRDI’s strategic goals.

Thomas Lynch
Chairman,
Clinical Research Development Ireland
By mobilising the combined strength of the partner academic institutions, their associated hospitals and clinical research facilities, the organisation continued to make progress on its strategy to develop and support Ireland’s clinical and translational research infrastructure and delivery system.

A key highlight of the year was the expansion of the partnership to include the University of Limerick. This new membership has strengthened the partnership, positioning it as a collaboration of all the Irish medical schools, their parent institutions and clinical research facilities and centres, thus collectively enhancing the capabilities of the clinical research sector to make the breakthrough advances that better serve patient needs.

During 2018, CRDI succeeded in building new alliances as well as strengthening existing ones. This was particularly evident with the **Future Investment in Clinical Research (FICR)**, an initiative introduced in the first quarter of the year which aims to enhance the level of clinical research in Ireland through increased investment in infrastructure, support, capacity and capability. It has involved the formation of a Steering Committee comprising stakeholders in clinical research, including patient representative groups, the Health Service Executive, Health Research Board, Enterprise Ireland, Science Foundation Ireland, IDA Ireland, Cancer Trials Ireland, Biopharmaceutical Healthcare Association, MedTech Ireland and IMSTA, along with the partner academic institutions and their associated clinical research facilities/centres. The accumulated expert opinions of all stakeholders will feed into a significant report on the future resourcing requirements and a road-map will be drafted on how best to achieve this.

CRDI and the Health Service Executive identified areas of common ground in which to engage during 2018. Key among these was the recruitment in August 2018 of a shared legal adviser, whose remit includes the development of a structured legal and contractual framework, suitable for the requirements of both the university sector and the health service to govern clinical research in Ireland. Reporting to the Assistant National Director of Research and Development as well as to the Chief Operations Officer of HRB CRCI, this role provides a vital link between the CRDI academic partners and the health service.

CRDI’s relationship with the HSE was furthered strengthened through the provision of project management and administrative support for the Hospital Group Association of CEO’s and Chairs. The activities at present include supporting the establishment of the HGA, coordinating and managing all 2019 monthly meetings and a work plan, and developing branding for the association.

In an effort to develop capacity and capability across the clinical research network, CRDI together with its partner CRF/Cs, has been a strong advocate for Irish representation in the European Clinical Research Infrastructure Network (ECRIN ERIC). I am pleased that Ministerial and Cabinet approval was granted in October and Ireland is now a full member of ECRIN, with the designation of the HRB Clinical Research Coordination Ireland (HRB CRCI) as the Irish Scientific Partner. Funding for the
The role of the ECRIN European Correspondent (EUCO) is available as part of this new membership and the appointee will sit in CRDI.

As a result of the very significant advances in genomics research made in recent years, CRDI has been co-ordinating a series of engagements with colleagues from across the partnership and other external experts and interested parties to help resolve some of the complexities experienced by the institutional partners in this growing area of research, in part through the development of guidance for interactions with commercial third parties.

In August 2018, funding was renewed by Enterprise Ireland for the role of Clinical Industry Liaison Officer (CILO) and recruitment began to fill this post which had become vacant in the previous financial year. The role was established in 2009 to support indigenous researchers, medical device and biotechnology companies, including start-ups, SMEs and multinationals, in the development of new medical devices and diagnostics. A key aspect of the CILO role is the provision of clinical research advice and guidance to assist clients in the development, commercialisation and post-marketing activities of their product.

Building on the success of the Irish Clinical Academic Training (ICAT) Programme and previous structured PhD programmes co-ordinated by CRDI, CRDI is a core partner in Neonatal Brain Consortium Ireland which succeeded earlier this year in its application to the HRB Collaborative Doctoral Awards for the collaborative Neonatal Encephalopathy PhD Training Network (HRB NEPTuNE). Launched in September, this programme aims to produce a cohort of experts who will advance patient-focused research in neonatal encephalopathy. CRDI co-ordinates the NEPTuNE programme, providing resources and the framework for training.

I would like to take this opportunity to thank the CRDI Board for their continued support for the mission of CRDI and the staff for their hard work and commitment to patient-focused research.

Dr Pat O’Mahony
Chief Executive,
Clinical Research Development Ireland
CRDI Structure & Governance

CRDI was formed in response to the need to create a critical mass of excellence in molecular medicine research and education in Ireland and to deploy a clinical research infrastructure to facilitate medicine into better healthcare provision.

CRDI was known as Molecular Medicine Ireland when it was formally incorporated as a not-for-profit company by the aforementioned partner institutions in April 2008. MMI was preceded by the Dublin Molecular Medicine Centre, created in 2002 by Trinity College Dublin and University College Dublin, and joined in 2005 by the Royal College of Surgeons in Ireland. The University of Limerick became the sixth member of the partnership in June 2018.

CRDI is funded by the five academic institutions along with programme funding from a number of sources including the Health Research Board, Enterprise Ireland, Wellcome Trust, Science Foundation Ireland, Irish Cancer Society and the Health Service Executive.

CRDI is governed by a Board of Directors (see Page 12), comprising two representatives from each partner institution and external appointees from the public and industry sectors. Queen’s University Belfast is represented at CRDI Board meetings in an observer capacity. At the end of 2017, the core business of CRDI was supported by a staff of 21 people.
CRDI Strategy

CRDI STRATEGIC VISION:
To be an effective and innovative force for the development of clinical and translational research in Ireland, and to be recognised, both nationally and internationally, as a model of organisational excellence focused on advancing evidence-based patient care and network coordination.

CRDI MISSION STATEMENT:
To advance patient care and health service delivery by supporting the development of clinical and translational research across our partner academic institutions, their medical schools and associated hospitals.

CRDI VALUES:
• Acting in the best interests of patients.
• Operating to the highest standards of scientific rigour and quality.
• Behaving with integrity and impartiality.
• Promoting research, innovation, openness to change and continual learning.
• Treating stakeholders and each other with dignity and respect at all times.

Strategic Goals

+ Advance the development of a sophisticated, coordinated clinical and translational research partnership across our partner academic institutions, their medical schools and associated hospitals.
+ Develop and support clinical trials delivery.
+ Develop capability across network partners and CRDI.
+ Advocate for adequate funding for the development of clinical and translational research.
+ Develop and support education and training.
CRDI Board

Thomas Lynch  
**Chair**

Professor Calvin Coffey  
Professor of Surgery & Foundation Chair of Surgery, University of Limerick

Professor Willard Dere  
Professor of Internal Medicine, University of Utah

Professor Joe Eustace  
Professor of Medicine at University College Cork, Consultant Nephrologist, Cork University Hospital and Director of HRB Clinical Research Facility, Cork

Professor Orla Feely  
Vice-President for Research, Innovation & Impact, University College Dublin

Professor Michael Gill  
Head of School of Medicine & Professor of Psychiatry, Trinity College Dublin

Professor Orla Hardiman  
Professor of Neurology and Consultant Neurologist at the National Neuroscience Centre, Trinity College Dublin

Professor Lokesh Joshi  
Vice-President for Research, NUI Galway
Professor Dermot Kenny
Professor of Cardiovascular Biology and Director of Clinical Research Centre, Royal College of Surgeons in Ireland

Professor Anita Maguire
Vice-President for Research & Innovation, University College Cork

Professor Rachel Msetfi
Director of the Health Research Institute & Executive Dean of Faculty of Education and Health Sciences, University of Limerick

Professor Ray Stallings
Director of Research and Professor of Cancer Genetics, Royal College of Surgeons in Ireland

Professor Patrick Murray
Professor of Clinical Pharmacology, University College Dublin & Clinical Director of UCD Clinical Research Centre

Professor Martin O’ Donnell
Professor of Translational Medicine, NUI Galway and Associate Director of HRB Clinical Research Facility Galway

Professor Mike Clarke
Observer for Queen’s University, Belfast Chair of Research Methodology and Director of All-Ireland Hub for Trials Methodology Research, Queen’s University Belfast
Pictured from left to right are: Prof Joe Eustace of UCC, Prof Michael Gill of TCD, Prof Calvin Coffey & Prof Rachel Msfti of UL, Prof Des Fitzgerald, President, of UL, Dr Michelle Kelly of RCSI, Prof Pat O’Mahony, Chief Executive & Thomas Lynch, Chair, of CRDI.
In June 2018, the University of Limerick joined Clinical Research Development Ireland, becoming the sixth partner of this leading academic research partnership.

This new collaboration was marked with a gathering hosted by Professor Des Fitzgerald, President of the University of Limerick, and attended by representatives of all six members including the newly appointed directors from UL, Professor Rachel Msetfi, Director of the Health Research Institute & Executive Dean of the Faculty of Education and Health Sciences, and Professor Calvin Coffey, Professor of Surgery & Foundation Chair of Surgery.

UL boasts some of the most innovative and successful research centres in Ireland including the Health Research Institute and the Centre for Interventions in Infection, Inflammation & Immunity (4i). The addition of this expertise and experience to the CRDI partnership will further enhance its capacity to become an effective and innovative force for the development of clinical and translational research in Ireland.

“I am delighted to welcome the University of Limerick to the CRDI partnership. I also welcome the Health Research Institute Clinical Research Support Unit at University Hospital Limerick, which simultaneously, has become a new member of HRB Clinical Research Coordination Ireland. UL’s accession to CRDI has strengthened the partnership, positioning it as a collaboration of all the Irish medical schools, their parent institutions and clinical research facilities, thus collectively enhancing CRDI’s capabilities in clinical and translational research”, said CRDI Chair, Thomas Lynch.

“I welcome the accession of the University of Limerick to the CRDI partnership. We are stronger together and cooperation across all aspects of clinical and translational research provides for the best achievement for the sector. We now have all the university medical schools in the country, their parent institutions and clinical research facilities, cooperating in CRDI which augers well for the ability of the clinical research sector to make the breakthrough advances we all wish for to better serve patient needs. We look forward to the support of all stakeholders and funders in advancing clinical research across Ireland and with our collaborative international partners”, added Professor Pat O’Mahony, Chief Executive of CRDI.

“UL’s accession to CRDI has strengthened the partnership, positioning it as a collaboration of all the Irish medical schools, their parent institutions and clinical research facilities, thus collectively enhancing CRDI’s capabilities in clinical and translational research”
NEW PROGRAMMES

FUTURE INVESTMENT IN CLINICAL RESEARCH

In March 2018, Clinical Research Development Ireland brought together senior executives from stakeholder organisations in clinical research in Ireland for an exciting new initiative entitled the Future Investment in Clinical Research (FICR) that aims to enhance the level of clinical research in Ireland for the benefit of the patient and the wider economy.

The initiative is led by a Steering Committee, comprising experts representative of the stakeholder organisations which include patient representative bodies, clinical research facilities/centres, academia, the Health Service Executive, Cancer Trials Ireland, state funding and enterprise agencies, namely, the Health Research Board, Enterprise Ireland, Science Foundation Ireland and IDA Ireland, industry representative bodies including the Irish Pharmaceutical Healthcare Association, Irish Medical and Surgical Trade Association, BioPharmaChem Ireland and the Irish MedTech Association.

Whilst recognising the valuable efforts and investments made in recent years, the FICR Steering Committee agreed a mandate to strategically examine and define the optimal future clinical research infrastructure, support, capacity and capability for the population and economy of Ireland.

During the latter half of 2018, the FICR Steering Committee conducted a consultation process, seeking written submissions from all those with an interest in clinical research in Ireland. These insights, expert knowledge and recommendations will form the basis of a report that will outline the evidence to support the need identified and will provide a high-level coordination roadmap on how best to achieve the desired outcome. This is expected to be launched in Spring 2019.

Further details at https://ec.europa.eu/programmes/erasmus-plus/

ERASMUS+ CONSCIOUS

In December, CRDI became part of a new Erasmus+ funded programme with European partners known as the Curriculum Development of Human Clinical Trials for the Next Generation of Biomedical Students (CONSCIOUS). CONSCIOUS will address the skills gaps and mismatches relating to European-level clinical trial professionals through curriculum development and the preparation of e-learning material for the career development of Master’s degree students in the areas medicine, pharmacy and clinical research.

The European partners comprise the University of Pécs, Hungary as Coordination Lead, Masaryk University, Czech Republic, University of Nova De Usboa, Portugal, University of Paris-Diderot, France, CRDI and ECRIN acting as Associate Partner.

CRDI will contribute its broad experience in developing and delivering innovative collaborative education programmes, including PhD programmes for scientists and clinicians, as well as its expertise in developing and delivering e-Learning materials.

Erasmus+ is the EU’s programme to support education, training, youth and sport in Europe.

Further details at: https://ec.europa.eu/programmes/erasmus-plus/
https://www.crdi.ie/resources/elearning/
https://www.crdi.ie/phd-programmes/
The Neonatal Brain Consortium Ireland (NBCI) launched its collaborative Neonatal Encephalopathy PhD Training Network (HRB NEPTuNE) in Trinity’s Biomedical Science Institute in September 2018. The training programme will improve understanding of the occurrence and long-term impacts of encephalopathy in newborns.

The multidisciplinary nature of this research training programme aims to produce a cohort of experts who will advance patient-focused research in neonatal encephalopathy. CRDI is a core partner in this HRB Collaborative Doctoral Award Training Programme and will provide the framework for the programme’s training and induction.

Five PhD scholars were recruited to the HRB NEPTuNE programme in 2018 and are conducting their research in centres of excellence (Trinity College Dublin, UCC’s Infant Centre and NUI Galway), thus advancing their knowledge with integrated support for professional development. A dedicated public patient involvement (PPI) representative was assigned to each of the five scholar projects, acknowledging the importance of patient focused research. The programme’s outcomes will result in improved synthesis between research and healthcare and will have positive impacts on patient care and health.

CRDI coordinated the formal launch of the HRB NEPTuNE Programme in September 2018. This event included the launch of a dedicated curriculum for scholars, the NCBI website, along with a Moodle platform and Skillslog resource for scholars. CRDI also facilitated a successful Study Day on 6 December which gave scholars the opportunity to participate in core skills workshops and to discuss their research challenges with each other. Further quarterly Study Days will be arranged throughout the course of this 4-year programme.

The Principal Investigators in this consortium, Professor Eleanor Molloy (TCD), Professor Geraldine Boylan (UCC Infant Centre), Professor Arun Bokde (TCD), Professor Declan Devane (NUI Galway) and Professor Elizabeth Nixon (TCD), have internationally recognised expertise in neonatology, paediatrics, neurodevelopment, family-centred care, clinical trials and methodology, pharmacology, epidemiology, biostatistics, translational research and neuroimaging in neonatal brain injury. While focusing on their five individual projects, the Scholars will also collaborate with each other to ensure that their results will contribute to evidence-based improvement in healthcare.

Further information can be viewed at: www.nbci.ie & www.crdi.ie/neptune

in4kids is a new national paediatric clinical research network whose aim is to build a strong network within Ireland to enhance collaboration amongst the paediatric research community and to develop national capacity for high-quality, ethical paediatric clinical research. The network will have a broad membership from across the Irish paediatric research community and its initial services will include signposting, a feasibility service for paediatric studies and a membership programme for the Irish network.

In 2018, the Terms of Reference for the Steering Committee were developed, Proof of Viability Requests were processed and contributions related to c4c work packages were made by the in4kids network.

c4c (conect4children) is a large collaborative European network that aims to facilitate the development of new drugs and other therapies for the entire paediatric population and it endeavours to provide a sustainable, integrated platform for the efficient and swift delivery of high-quality clinical trials in children and young people across all conditions and phases of the drug development process. It provides the funding for in4kids to coordinate the c4c hub for Ireland.
The Health Research Board Clinical Research Coordination Ireland (HRB CRCI) is a collaborative partnership of the university-based clinical research facilities/centres (CRF/Cs) and their associated hospitals.

It was established in 2015 as an independent, integrated national clinical research network, to provide centralised support in the conduct of multicentre clinical trials for both academia and industry across Ireland. It is funded by extramural grants from the HRB and Enterprise Ireland (EI), supported by the five largest universities in Ireland and it is hosted by CRDI.

There are eight partners in the HRB CRCI network with over forty years of combined research experience. They are: HRB CRF Cork at University College Cork and Mercy University Hospital; HRB CRF Galway at University Hospital Galway, Royal College of Surgeons Ireland CRC at Beaumont Hospital, University College Dublin CRCs at Mater Misericordiae University Hospital and St. Vincent’s University Hospital; Wellcome Trust – HRB CRF at St. James’s Hospital; Health Research Institute Clinical Research Support Unit (HRI-CRSU): at University Hospital Limerick; and the National Children’s Research Centre (NCRC) at Our Lady’s Children’s Hospital, Crumlin. Both the HRI-CRSU and NCRC joined in 2018.

HRB CRCI is funded by the HRB for an initial six-year period from May 2015 to April 2021, with an interim review after 3 years. The interim review was completed in 2017 and funding was renewed for the second phase which runs from May 2018 to April 2021.
AIMS OF HRB CRCI

Providing infrastructure for multicentre clinical trials

Central point of contact for academia and industry

Delivering high quality clinical research

Advancing the care of patients through a coordinated Clinical Trial Network

HIGHLIGHT:

IN 2018, TWO NEW PARTNER CENTRES JOINED THE HRB CRCI NETWORK: THE HEALTH RESEARCH INSTITUTE CLINICAL RESEARCH SUPPORT UNIT AT UNIVERSITY HOSPITAL LIMERICK AND THE NATIONAL CHILDREN’S RESEARCH CENTRE AT OUR LADY’S CHILDREN’S HOSPITAL, CRUMLIN.
The HRB CRCI central office provides overarching support and expertise to academia and industry, through a range of services and activities that have been developed to help address the unmet needs in clinical research in Ireland. CRDI provides corporate support services to the central office and the partner CRF/Cs provide the infrastructure, physical space and facilities, experienced research and specialist support staff and the necessary quality and oversight of programmes that are critical for the successful conduct of world-class patient-focused research.

HRB CRCI SERVICES

1. Signposting:
   Primary point of contact for clinical innovation and research, facilitating industry and academia.

2. Study feasibility:
   Streamlined process with coordination and oversight through the central office and dedicated resource in the CRF/Cs to navigate local systems and engage with investigators, ultimately leading to efficient and timely identification of sites.

3. Regulatory and Ethics:
   Management of the application process, including preparation and submission of study documents when feasible. This service can be delivered locally or by the CRF/Cs and/or the central office.

4. Study start-up:
   Range of supports available to optimise start-up activities, including central coordination and dedicated resource in CRF/Cs accelerating all aspects of the process at the site level.

5. Recruitment:
   Tracking/monitoring of recruitment targets. Collation of metrics from across CRF/Cs and provision of advisory support.

6. Audit and Monitoring:
   Oversight of study conduct through risk-based plans and activities, with reporting to sponsor. This service can be delivered locally by the CRF/Cs or centrally.

7. Quality:
   Ensured through a team of quality managers located across the central office and CRF/Cs, facilitating best practice and harmonisation across the network.

8. On-line services:
   Provision of resources, including templates, guidance and signposting to training and education programmes, as appropriate.

9. Consultancy & Advisory:
   Consultation on regulatory pathways and provision of advice on conduct of clinical research in all fields.

10. Promotion:
    Ambassadors for Irish clinical innovation and research, nationally and internationally.
HRB CRCI STRUCTURE
HRB CRCI WORKING GROUP ACTIVITIES

1. The Quality Working Group (QWG) consists of the Quality and Regulatory Affairs Managers (QRAMs) from across the centres and is chaired by the HRB CRCI QRAM. In 2018, the first cycle of the HRB CRCI Mutual Recognition Scheme was completed. The Scheme defines a set of minimum expectations for the CRF/Cs Quality Management Systems which the CRF/Cs are peer reviewed against. Five of the CRF/Cs participated in the first cycle. The Mutual Recognition Scheme is repeated every three years with an annual self-assessment carried out during the interim years. The QWG expanded in 2018 to include the new members of the HRB CRCI Network, the HRI CRSU and NCRC CCRU. The group also opened its membership to organisations from outside the Network with representatives from Cancer Trials Ireland and the Infant Centre in Cork joining as non-core members at the December meeting. The QWG continued to operate its Horizon Scanning Programme in 2018 to monitor upcoming changes to legislation and regulations which impact clinical research.

2. The Study Feasibility and Study Start-up Working Group (SFSWG) consists of the HRB CRCI Feasibility and Study Start-up Facilitators based at each of the centres and it is chaired by the HRB CRCI Clinical Trial Liaison Manager (CTLM). The mission of the SFSWG is to facilitate cooperation and sharing within the HRB CRCI partnerships with respect to efficient delivery of investigator and site selection and study start-up and first patient-first visit timelines. In 2018, this group together with the core office staff delivered on the HRB CRCI Feasibility Programme, tracking all metrics using the HRB CRCI adapted CRF Manager System to enable HRB CRCI track study progress and support study start-up and recruitment across the centres.

3. The Budget Working Group (BWG) consists of personnel from HRB CRCI and the CRF/Cs who work together to streamline and standardise the process for clinical trial costings and budget development nationally. In 2018, the group started the development of a clinical study budget template.

4. The Clinical Research Patient Public Involvement Working Group (CR-PPI-WG) consists of representatives from the CRF/Cs, clinical trial networks (CTNs), PPI interested organisations, the Irish Platform for Patient Organisations, Science and Industry (IPPOSI) and the HRB CRCI. The mission of the working group is to facilitate cooperation and sharing within the member organisations with respect to PPI knowledge, resources, training and innovation. In 2018, there were two meetings of the group.

5. The Legal Working Group (LWG) consists of representatives from the legal offices of the university partners. The primary mission of the group is to develop a two-tier Confidential Disclosure Agreement (CDA) process for clinical research in Ireland. Progress was made on a number of CDAs during 2018.

6. The Pharmacovigilance Working Group (PWG) comprises the Pharmacovigilance officers from each of the CRF/Cs. The purpose of the group is to facilitate cooperation and sharing within the HRB CRCI partnerships with respect to pharmacovigilance. The group meets twice a year to discuss best practice in pharmacovigilance, provide Eudravigilance training advice and to monitor any changes to regulations which may affect pharmacovigilance. The PWG expanded in 2018 to include the new members of the HRB CRCI network, the HRI CRSU and NCRC Children’s Clinical Research Unit (CCRU).

7. The Health Research – Data Protection Network (HRDPN) consists of Data Protection Officers and other legal representatives involved in data protection from the university partners and their associated hospitals as well as from other health research organisations and networks. The mission of the HRDPN is to facilitate a coordinated and collaborative approach to data protection for health research in Ireland, such that, harmonisation is promoted, duplication is avoided and available resource is maximised. The work of the network is applicable to all aspects of data protection relating to health research, excluding clinical audit and service evaluation. The network aims to provide a forum for sharing and the peer-review of templates, processes and documents; to make representations as a collective voice on behalf of the health research community for data protection issues to the appropriate organisations; to support the provision of training in data protection for health research; and to provide considered opinion on the approach to implementation of legislation and standards relating to data protection for health research. The HRDPN was established and held first meeting in December 2018.
The National Study Feasibility Programme operated by HRB CRCI was established in August 2015. The programme connects academic and industry sponsors with potential investigators in Ireland. HRB CRCI acts as the central channel through which study feasibility assessments can be distributed and completed efficiently.

The HRB CRCI Investigator Membership Database, CRF/C network and clinical research networks are utilised to significantly reduce the time taken to identify investigator sites and to assess study feasibility. The programme is actively managed to ensure that feedback to the applicant is made within two weeks of the initial receipt of the feasibility request. Dedicated HRB CRCI staff, based in each CRF/C, work to identify local investigators and to support these investigators with the completion of their feasibility assessment.

Types of assessments undertaken include Key Opinion Leader assessments, Investigator Identifications, with and without completion of Feasibility Questionnaires. The initial programme target to process 20 feasibility requests over a duration of 24 months (i.e. to August 2017) was dramatically surpassed. By the end of 2018, 41 months following project commencement, 197 feasibility assessments were processed, 47 in 2018, with interest expressed by investigators in 151 of these studies (77%) and 46 studies classified as proceeding at Irish sites (22%).

For further details on how to place a feasibility request with HRB CRCI please see: https://www.hrb-crci.ie/services/study-feasibility/

In 2018, the HRB CRCI processed 47 studies for feasibility with eight new studies proceeding to the next stage across the centres.

The graphic below summarises the Feasibility Programme Metrics for the Year 2018:
HRB CRCI MEMBERSHIP

HRB CRCI offers two types of memberships: one for Investigators (Investigator Membership) and one for all clinical research personnel working in hospitals, practices and academic organisations (Standard Membership).

By end of 2018, 119 Investigators and 52 clinical personnel were registered as HRB CRCI members.

Through this system, members are kept informed of HRB CRCI activities and clinical research opportunities within their clinical interest area.

Further details on how to become a member of HRB CRCI can be found at: https://www.hrb-crci.ie/about/membership/

CRF MANAGER

RESEARCH STUDY MANAGEMENT SYSTEM

In 2018, HRB CRCI continued to support the implementation of the CRF Manager system in Ireland. This system is used at CRF/Cs across the country to:

- Manage research study setup and approval
- Plan and record patient recruitment and visit scheduling
- Resource allocation, costing and invoicing
- Report metrics on studies, patients and costs

The CRF Manager system was developed at the University of Edinburgh and is used at more than 50 clinical research sites across the UK. In Ireland, the system operates on a single cloud-based installation, with 140 active users in nine CRF/Cs.

The IT Manager at HRB CRCI provides first line support to all sites that use the CRF Manager system, with second line support being provided by the development team at Edinburgh.

In 2018, the IT Manager attended two meetings of the UK user group on behalf of HRB CRCI. These provide a forum for making decisions on further enhancements and the development of the system. Changes to the Irish implementation were made as a result of these decisions in order to facilitate the gathering and reporting of metrics specific to the Irish system.
During 2018, HRB CRCI continued to provide support for existing data collection and eCRF facilities for academic studies which had previously been part of the Dublin Centre for Clinical Research, a former CRDI programme.

There were eight such studies actively involved in recruiting patients across several disease areas including ophthalmology, prostate cancer, infectious disease, cardiovascular disease, auto-immune disease and renal disease.

HRB CRCI supported facilities for the collection, verification, query and reporting of patient study data.
INTERNATIONAL NETWORK ACTIVITIES

EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK (ECRIN)

Ireland officially joined the European Clinical Research Infrastructure Network (ECRIN) as a member in December 2018, with HRB CRCI as the national partner. ECRIN is a not-for-profit, intergovernmental organisation that supports the conduct of multinational clinical trials across Europe. Since 2013, ECRIN has had the legal status of a European Research Infrastructure Consortium (ERIC).

ECRIN is a distributed organisation with a central office in Paris and a network of European Correspondents located in national partners across the European member countries. The national partners work with clinical trial units (CTUs) within their country to provide services to ECRIN. As full members, Ireland is represented by a fully funded European Correspondent, based in HRB CRCI.

There are currently two Irish coordinated Horizon 2020 projects that ECRIN is supporting. These include the POPART (Prophylactic Oropharyngeal Surfactant for Preterm Infants: A Randomised Trial) Study coordinated by Prof Colm O’Donnell in UCD and the CONVINCE (Colchicine for Prevention of Vascular Inflammation in Non-cardio Embolic Stroke) Study coordinated by Prof Peter Kelly of UCD. In addition, the Irish CRF/Cs have been providing monitoring, project management and regulatory supports to a number of UK study sites throughout 2018.

The Central Pharmacovigilance Centres Qualification Project was initiated by ECRIN in 2018 and is represented in Ireland by the senior pharmacovigilance officer at HRB CRF-Cork.

ECRIN established a quality group in 2018 and the HRB CRCI QRAM attended the first meeting of the group in November 2018, presenting on the HRB CRCI Mutual Recognition Scheme. The aim of the group is to share best practice and prepare for upcoming regulatory changes.

During 2018, the HRB CRCI QRAM represented HRB CRCI through attendance at European Correspondent teleconferences, scientific meetings and face-to-face meetings in an observer capacity. The QRAM also attended the ECRIN Summer School in Toulouse, France in September, while the HRB CRCI COO and QRAM attended the ECRIN International Clinical Trials Day event in Budapest in May 2018. The HRB CRCI COO attended the network committee meeting in Paris in November 2018 and the assembly of members meeting in Paris in December 2018 which was also attended by Oonagh Ward from the HRB.

Ireland became a member of ECRIN in December 2018 with HRB CRCI appointed as the national partner.
INTERNATIONAL NETWORK ACTIVITIES

UK CLINICAL RESEARCH FACILITY NETWORK

The UK Clinical Research Facility Network (UKCRFN) was restructured in 2018 and the previous workstreams were organised into four themes. The Quality Assurance (QA) Theme Group was assigned to Theme 3 Workforce Development. The HRB CRCI QRAM is a member of the QA Theme Group. This group aims to foster and facilitate collaborative working and sharing of good practice to develop common QA systems in clinical research facilities across its network.

HRB CRCI hosted the QA Theme Group meeting on 26 February at the HRB CRCI offices in Dublin. The 2018, the UKCRFN Conference was held in Leeds on 12-13 July and a representative from HRB CRCI was in attendance.

During 2018, the HRB CRCI CTLM was invited to join the Theme 2 Steering Group, ‘Accelerating Clinical Trials’. The Network collates CRF capacity and capability information and works with stakeholders to promote CRFs as an integrated national platform for the delivery of high intensity experimental medicine studies to research funders. CRF/Cs from Ireland are included as CRF locations within their network.

CLINICAL RESEARCH INITIATIVE FOR GLOBAL HEALTH (CRIGH)

HRB CRCI is Ireland’s representative of the Clinical Research Initiative for Global Health (CRIGH), enabled by funding from the HRB.

CRIGH aims to improve international collaboration, coordination, and efficiency in clinical trials.

This initiative is coordinated internationally through ECRIN with collaborators from across the globe.

The CRIGH General Assembly was held in Japan in March 2018.

SOCIAL MEDIA AND COMMUNICATION HIGHLIGHTS

14.6k+ WEBSITE VISITORS IN 2018

1,502 FOLLOWERS BY END OF 2018 (+480)

40.9% AVERAGE OPEN RATE FOR EMAIL UPDATES (INDUSTRY AVERAGE IS 19.2%)
HRB CRCI leads ICTD celebrations in Ireland

The second national seminar to celebrate International Clinical Trials Day was hosted by HRB CRCI on 10 May 2018 in the historical Round Room at the Mansion House in Dublin. With the theme, “Growing Clinical Research in Ireland Together”, the seminar highlighted how improved access to clinical trials can increase health benefits for patients and showcased some of the clinical research being conducted in Ireland.

Almost 170 delegates heard from Ireland’s leading experts about their involvement in clinical research in hospitals and in the clinical research facilities and centres around the country. Funding bodies and patients also spoke at the event, the latter relating their positive experiences as participants of clinical trials.

A key feature of the event was the launch of a calendar, outlining the events taking place across the country to mark International Clinical Trials Day, celebrated on or around 20 May. A number of posters were exhibited, highlighting a cross-section of the research activities undertaken by individual researchers.

Statistics released on the day showed that the Irish clinical trials infrastructure is growing at a steady pace, with 237 trial sites open across the network. This has surged from 134 in 2015 when HRB CRCI was first established to enable and support more clinical trials in Ireland.

The seminar featured a panel of national and international expert speakers who highlighted the importance of international collaboration. This was followed by the announcement that Ireland would soon become a member of the European Clinical Research Infrastructure Network (ECRIN), and that Government approval was imminent.

ECRIN membership will provide Ireland with direct access into this important European public, non-profit network, linking scientific partners and clinical research networks across the continent to facilitate multi-national, multicentred research.

Prof. Jacques Demotes, Director General of ECRIN and Keynote Speaker at the event, stated that, “Over the next few years, we can expect major changes in the way data is collected and analysed in clinical trials, with a better reuse of digital data collected in the context of healthcare. However, this will raise questions regarding data standards, data security and personal data protection; a major challenge for the clinical research community.”

Prof. Joe Eustace, Director HRB CRF Cork & Chair of HRB CRCI Senior Management Team, chaired the event and commented that, “The conduct of clinical trials is highly regulated and requires stringent quality control structures. The growth in clinical trial activity in Ireland not only serves to identify new medical interventions and care pathways but also to promote quality and conformance with international best practice within the Irish health system.”
Corporate Enabling of Clinical Research Initiative

In 2017, Irish academic institutions and research funders came together to identify and address the challenges of sponsoring clinical research in the areas of governance, contracts, insurance, operations, financial resources, engagement with the health sector, training and support. This initiative became known as Corporate Enabling of Clinical Research (CECR).

KEY CHALLENGES

A review and assessment of the challenges relating to the sponsorship and support of clinical research helped identify the following gaps and areas for improvement:

- A need for engagement and cooperation between the academic institutions and the health sector in relation to the planning, governance and management of clinical research.
- The need for transparency and clarity on the roles and responsibilities of academic institutions and hospitals in the governance and conduct of clinical research.
- The requirement to develop a plan for assessing and managing sponsorship risk and fulfilling sponsorship responsibilities.
- The requirement for the academic and health sectors to develop and agree a national contractual framework for the governance and management of clinical research.
- The requirement to achieve consistency of contractual approaches across the academic and health sectors.
- The need to agree a more timely and efficient inter-institutional approval pathway which would enable smoother contracting processes and ensure that clinical studies begin within a reasonable time frame.
- The need to clarify the scope and requirements of the Clinical Indemnity Scheme (CIS) cover and clarify the gaps that need to be filled via commercial insurances.
- The need to adequately fund the resource intensive sponsorship role of academic institutions.
- The need to provide support and training for clinicians engaged in clinical research and to recognise the importance of the role played by hospitals in clinical research.

CECR ACTION PLAN

To address the key challenges identified above, an Action Plan was developed by an overarching Steering Group and delivered by six Working Groups, namely: Governance and Leadership, Sponsorship and Quality, Insurance, Contracts and Legal, Resourcing of Sponsorship and Clinician Engagement and Support.

The Action Plan was delivered in the time frame of one year (2018) using a project management approach. The final report is due to be drafted and published in 2019. The final report will include the outputs of the six working groups, their recommendations and next steps.

CECR CONTRIBUTORS

The CECR initiative is hosted by Clinical Research Development Ireland. The CECR founding members include TCD, UCC, UCD, HRB, RCSI, NUIG, UL, CRDI and HRB CRCI. Representatives from Maynooth University, EI, Cancer Trials Ireland, Mercy University and Beaumont Hospitals, State Claims Agency (SCA) and HSE joined at a later date.

The initiative was co-chaired by Dr Paola Della Porta of RCSI, Ms Nora Geary of UCC and Prof Pat O’Mahony of CRDI.
WORKING GROUP ACHIEVEMENTS

Governance and Leadership WG
• Brought together all stakeholders in clinical research to share challenges, propose solutions and seek engagement in the delivery of the CECR Action Plan.
• Achieved a consistent approach on the terminology for clinical research used across academic institutions, in particular, on classifications and types of trials.
• Produced a discussion document on the need for collaboration between the academic and health sectors to enable safe clinical research. This document identifies the governance, legal and insurance challenges of enabling academic clinical research and proposes principles of good practice, governance and management arrangements that are required to deliver safe, high-quality clinical research within the academic and health sectors.

Sponsorship and Quality WG
• Recommendations, samples tools and methodologies were developed to help academic sponsors deliver and manage sponsorship responsibilities.

Insurance WG
• As a result of the engagement of SCA representatives in the WG activities, the SCA developed a State Indemnity Guidelines (SIG) document which clarifies the indemnities provided by the Clinical Indemnity Scheme for national clinical trials.
• Provided clarity on the difference between “trial by trial” versus “whole of trials” commercial insurance policies and benefits of the latter.

Contracts and Legal WG
• Identification of the contractual challenges of clinical research and recommendations to funders, academic institutions and the health sector on how to address them.
• Development of template Clinical Trial Agreements and Clinical Trial Network Agreements.
• Development of a contractual framework for data protection.
• Identification of the contractual challenges of clinical trial networks and recommendations to funders, academic institutions and the health sector on how to address them.

Resourcing of Sponsorship WG
• In the absence of an indirect cost rate that covers institutional costs for the sponsorship of clinical research, the Resourcing of Sponsorship WG has proposed the introduction of a new cost category called Enabling Costs.

Clinician Engagement and Support WG
• A number of recommendations were made for the delivery of support in the areas of project management, pre and post award activities, administration, ethics and the coordination and liaison of research support services with clinical research support activities.
Corporate Enabling of Clinical Research Conference

The Corporate Enabling of Clinical Research initiative held a full-day conference on Wednesday 30 May 2018 in the Liffey Suite at the Ashling Hotel in Dublin. The purpose of the conference was to bring together stakeholders in clinical research to:

- Update them on the progress made by the working groups in their efforts to address the challenges identified
- Provide a platform to share expertise and experience and to facilitate discussion on themes and topics that reflect emerging needs, and
- Inform them of clinical research currently being conducted in Ireland and future developments.

An audience of 120 delegates from senior management, legal and contract offices, research support services, clinical research facilities and centres, insurance, quality and regulatory affairs, human resources and funding bodies heard from leading experts from the Health Products Regulatory Authority, State Claims Agency, Health Research Board, Health Service Executive, St James Clinical Research Facility, Ireland East Hospital Group, UCC Research and Innovation Office and the CECR Working Group Chairs.

The morning session focused on the topics of Enabling Academic Sponsored Clinical Trials, Institutional Challenges and Corporate Enabling of Clinical Research Solutions, The Perspective of Academic Sponsors and The Regulator and the Funder. Two key messages emerging from this session were firstly, the need to ensure that all clinical research is carried out to the correct standard; and secondly, the clear acknowledgement by the HSE and others that collaboration and the active involvement of the health sector are essential to success.

The afternoon session looked at the CECR plan to address the needs and challenges of clinicians, clinical sites and the health sector. This session opened with a panel of clinicians, addressing the ongoing challenges that they face in delivering clinical research. The clinicians expressed concern for the need for more protected time for research-active clinicians.

The audience left with the clear message that we need to conduct good clinical research in order to improve patient outcomes.

The Feedback from the event was very positive, with delegates highlighting that the topics covered were relevant and it was a good opportunity for networking and learning.
Irish Prostate Cancer Outcomes Research (IPCOR) is a clinically-led quality improvement initiative which has established a national prostate cancer registry to follow men diagnosed with prostate cancer through their cancer journey.

IPCOR is carried out by a research consortium comprising CRDI, the National Cancer Registry Ireland (NCRI) and the Clinical Research Facility in Galway (HRB CRFG) and has been funded since 2014 by the Movember Foundation, in partnership with the Irish Cancer Society.

IPCOR systematically tracks the clinical and patient reported outcomes of men diagnosed with prostate cancer in Ireland and makes recommendations to health care providers aimed at improving the quality of care of men with prostate cancer.

**IPCOR SUMMIT**

IPCOR had a successful inaugural IPCOR Summit on 15 May 2018. The meeting, held in the NUI offices, brought together the IPCOR team and key stakeholders including patients, investigators, clinicians, project manager, statistician, research officers, data manager and database officer to discuss the current status of the project and future plans.

**IPCOR SITE REVIEW**

An external review of the IPCOR study took place in the Irish Cancer Society offices on 6 July 2018. The Irish Cancer Society invited a panel of international prostate cancer experts to review the IPCOR study and to provide feedback on its strategic direction.

IPCOR team members presented on the progress of the study, plans for research using IPCOR data and sustaining the registry into the future.

The feedback from the external review has led to new initiatives within the study including establishing a patient panel and increasing engagement with clinical teams.

**PATIENT PANEL**

IPCOR selected a panel of 10 men to form a patient panel, through engagement with cancer support groups, daffodil centres and prostate cancer nurses throughout the country.

The panel will meet in January 2019 to provide feedback to the investigators on many aspects of the project and will augment the patient voice already present on the Steering Committee.

The panel members are from different regions around the country and are undergoing various treatment modalities, and as such, are an accurate representation of the population of men with prostate cancer in Ireland.

You can visit the IPCOR website at: www.ipcor.ie

Or follow us on Twitter: @IPCOR_Ireland


Examples of the published data are depicted below:

The average age at diagnosis was 66 years (Figure 1), one-fifth of men diagnosed were less than 60 years of age and two-thirds of men diagnosed were less than 70 years of age.

Figure 2 shows that a typical man had a diagnostic biopsy 49 days after an elevated prostate specific antigen (PSA) blood test and was informed of his prostate cancer diagnosis at 79 days following the PSA test.
BIOBANKING

GDPR & HEALTH RESEARCH REGULATIONS

On 11 January 2018, the Translational Research Manager at CRDI presented an overview of Biobanking in Ireland at the UCD Biobanking Seminar and Debate held in the Catherine McCauley Centre at the Mater Misericordiae University Hospital.

Following discussions at this seminar, it was agreed that CRDI would coordinate and draft a submission, in consultation with the Irish biobanking community, to voice concerns and pose questions about the General Data Protection Regulation (GDPR) (EU) 2016/679 in relation to biobanking and research sample collections.

The submission and a list of stakeholders endorsing it were sent by CRDI to the Data Protection Commission and the Department of Health on 4 May with a follow-up meeting in the Department of Health and a further submission on 3 August. These exchanges served to highlight the importance of collecting patient samples and data for scientific research and the need for clarity, particularly in relation to existing collections and research studies approved under the previous data protection directive.

The Department of Health published the Data Protection Act 2018 (Section 36(2)) (Health Research Regulations 2018) on 8 August 2018. To view these regulations please see https://www.hrb.ie/funding/gdpr-guidance-for-researchers/health-research-regulations-2018/

CRDI FACILITATES NEW DATA PROTECTION OFFICER NETWORK

On 14 November, the Translational Research Manager presented on GDPR and the Health Research Regulations: setting the scene at the Irish Health Research Forum’s GDPR and Health Research: Stakeholder Voices event in the Hilton Hotel. This forum meeting examined the impact of the new Health Research Regulations on the use of patient data and samples for health research and featured the views of both patients and researchers. The Forum Report and Recommendations are available at https://www.ihrf.ie/gdpr-health-research-stakeholder-vo

ISO STANDARD DEVELOPMENT

CRDI’s Translational Research Manager chairs the National Standards Authority of Ireland (NSAI) Biotechnology Standards Consultative Committee. This committee was established in 2014 to facilitate Irish involvement in the development of international standards in the field of biotechnology. The committee mirrors the work of International Organisation for Standardisation Technical Committee (TC) 276 – Biotechnology and represents Irish interests in the standards being developed by ISO. There are five working groups in ISO TC/276, of which working group (WG) 2 is Biobanks and Bioresources.

With the active involvement of the NSAI Biotechnology Standards Consultative Committee over five years, the ISO 20387 – Biotechnology – Biobanking – General requirements for biobanking was published in August 2018. A special mention should be given to committee member, Emma Snapes of the INFANT Centre in UCC, who contributed hugely to the development of this new standard, representing Ireland at international meetings of ISO TC/276 WG2.

A technical report document is under development which will support the biobanking standard and act as a guide for implementation. Other biotechnology standards published by ISO TC/276 in 2018 were in the areas of cell counting and ancillary materials present during the production of cellular therapeutic products.

BBMRI/ESBB CONFERENCE

The Translational Research Manager at CRDI attended the Europe Biobank Week Conference, co-organised by Biobanking and BioMolecular resources Research Infrastructure (BBMRI) and the European, Middle Eastern &
African Society for Biopreservation and Biobanking (ESBB) and held in the Antwerp Zoo Conference Centre, Belgium on 4-7 September 2018.

BBMRI is a European Research Infrastructure which aims to facilitate the use of samples and data collected in Europe for the benefit of human health.

The theme of the conference was Biosharing for Scientific Discovery. Many of the scientific sessions had relevance for Ireland and Irish biobanks including sessions on the Impact of Policies and GDPR on Biosharing; achieving long-term sustainability in biobanking; Biosharing for scientific progress: ethics and stakeholder engagement and Artificial intelligence & big data in biobanking.

The Translational Research Manager met with Erik Steinfelder, Director of BBMRI, to express CRDI’s support for Irish membership. Erik Steinfelder is keen for Ireland to collaborate with BBMRI, for example, as a partner on EU grant proposals.

Ireland is one of the leading countries in the EU in the field of diagnostics and medical device development. We have a culture of innovation and a highly trained workforce in the areas of biological sciences, healthcare and computing. There are numerous world-class genomics facilities located in universities and research institutes around Ireland. However, unlike most other European and developed countries, there is no public population-scale genomic sequencing initiative in Ireland, nor national policy nor recommendations for setting up genomics projects.

GeneLibrary Ireland, an MMI coordinated initiative, was proposed in 2009 as an all-Ireland resource of 10,000 volunteer DNA samples to allow genomic studies of diseases impacting Ireland. Unfortunately, following the design phase of the project, national funding was not made available to set up the project. A lack of a public genomics resource means Ireland is missing out on opportunities to participate in international initiatives, such as, the ‘Declaration on linking databases across borders: Towards access to 1 million genomes in the EU by 2020’.

In June 2018, CRDI prepared a briefing document on genomics research which gave an overview of the broad-ranging issues relating to genomics research in order to provide an informed position on the social, ethical and legal matters of large-scale genomics studies, relevant to Ireland. Key international population-scale studies were reviewed and recommendations were made for new genomics studies being set up. This paper was presented to the Board of CRDI as well as at an informal meeting of relevant stakeholders held in CRDI and at a meeting with the Department of Health in July.

In the ensuing discussions, the CRDI Board requested the preparation of a guidance document for engagement with commercial companies in the area of genomics. As a result, a series of consultative meetings were convened with colleagues from across the partnership, other external experts and interested parties, as well as a number of direct meetings with one of the main Irish commercial companies engaged in the area of genomics. These engagements have proven to be useful and CRDI is grateful for the expert collaboration and information sharing experienced.

The guidance paper was presented to the CRDI Board in October 2018 and included a suggestion that a multi-stakeholder working group in the area of genomics should be established. The aim of the working group would be to provide a forum to gather, review, discuss and disseminate information on emerging topics regarding genomics research to all relevant stakeholders as well as develop best practice recommendations which are in the public interest.
CRDI/ CÚRAM Partnership
DEVELOPING KEY STRUCTURES AND RESOURCES TO SUPPORT MEDICAL DEVICE CLINICAL RESEARCH IN IRELAND

CRDI is a funded partner in CÚRAM, the Centre for Research in Medical Devices. The CRDI/ CÚRAM partnership focuses on the development and provision of resources addressing the need for:

- A greater awareness amongst academic, clinical, early-stage innovation and SME audiences of the potential for regulation to impact medical device innovation and ambition for market, and
- Improved access to clinical advisory support for device development and clinical trials.

We have produced an interactive European Credit Transfer and Accumulation System (ECTS) and Open Badge accredited eLearning course Fundamentals in Medical Device Design and Regulation, which speaks to the central tenets of device design and regulation.

In parallel, we are developing an interactive web portal, MedTechTranslate, which will be launched in 2019 to deliver important regulatory concepts and clinical advisory support to early stage device developers. This is being undertaken in close collaboration with academic researchers, regulatory agencies and industry. Project stakeholders include the Health Products Regulatory Authority, the National Standards Authority of Ireland, Aerogen Ltd and HRB CRCI.

E-LEARNING

Fundamentals in Medical Device Design and Regulation comprises two modules, Principles of Medical Device Design and EU Regulation of Medical Devices. The course, now in its second year of delivery, has seen a three-fold increase in expressions of interest, a significant rise in enrolment numbers as well as wider participation (See Figure 1).

Course content presents important design and regulatory concepts relevant to the entire life cycle of medical devices. The material was produced in collaboration with national and international biomedical/ bioengineering research experts, national regulatory agencies and with the involvement of pharmaceutical and medical device companies. Successful course completion involves online MCQ examination and participation in interactive problem solving workshops that analyse real world examples (See Figure 2).

MEDTECHTRANSLATE & CLINICAL ADVISORY SUPPORT

The interactive MedTechTranslate web portal, currently in development, will centralise expertise on medical device translation, focusing first on pathways to EU regulatory approval for medical devices. MedTechTranslate will map EU regulatory requirements to key stages of a medical device product’s life cycle whilst signposting device innovators towards relevant practice and expertise information (See Figure 3).

In addition, MedTechTranslate will serve as a conduit to increased numbers of clinical trials by supporting greater linkages between the fields of biomedical research, clinical science and early stage innovation.

The development process for MedTechTranslate benefits from significant advisory input from industry, regulatory experts and representatives of the clinical research infrastructure.

The CRDI / CÚRAM Partnership Project is supported by Science Foundation Ireland SFI and is co-funded under the European Regional Development Fund under Grant Number 13/RC/2073

The CRDI / CÚRAM Partnership project stakeholders. Continuous engagement with the relevant national regulatory agencies, industry, and the national clinical research infrastructure has been central to meeting project objectives.
Figure 1 – Course participation breakdown by institution (a and b) and by occupation (c) for the module, Fundamentals in Medical Device Design and Regulation, since its inception in 2017.

Figure 2 – Principles of Medical Device Design Workshop delivered on 18 January 2019 in CÚRAM as part of the CRDI/CÚRAM Partnership Fundamentals in Medical Device Design and Regulation e-Learning course. Dr. Manus Biggs (standing), CÚRAM funded Investigator and Lecturer, Dept. of Biomedical Engineering, NUI Galway, presented concepts on medical device design and development from the perspective of the innovation led researcher.

Figure 3 – MedTechTranslate stage of development focused model for imparting regulatory guidance and information resources to include clinical advisory support relevant to all stages of the device development process.
Figure 1. ICAT is an all-Ireland collaboration between six academic institutions (Trinity College Dublin, University College Dublin, Royal College of Surgeons in Ireland, Queen’s University Belfast, NUI Galway and University College Cork), two health services (HSE National Doctors Training and Planning, and Health and Social Care R&D Division), two funding agencies (Wellcome and Health Research Board), the Forum of Postgraduate Medical Training Bodies, the Northern Ireland Medical and Dental Training Agency and CRDI.
Wellcome-HRB Irish Clinical Academic Training (ICAT) Programme

The ICAT Programme is an integrated national training programme for clinician scientists that was established in 2016. ICAT is a collaborative network, with funding from Wellcome and the Health Research Board and co-funding from the six partner academic institutions, the HSE National Doctor’s Training and Planning, and the Health and Social Care R&D Division in Northern Ireland. It is coordinated by CRDI (Figure 1).

The ICAT Programme aims to identify exceptional clinical trainees with ambitions to pursue careers in academic medical research and to provide academic training in conjunction with specialist clinical training, generating clinician scientists of the highest calibre. On an individual level, ICAT will support each Fellow’s career development by mentoring them throughout their PhDs and beyond as they navigate the pathway to research independence.

ICAT will appoint five cohorts of Fellows over five consecutive years between 2017-2021 inclusive.

Figure 2. The ICAT Executive Team

Top row (l-r) Professor Michael Gill (TCD), Dr Patrick Mallon (UCD), Dr Michael Conall Dennedy (NUI Galway). Middle row (l-r) Professor Peter Maxwell (Queen’s University), Dr Deirdre Murray (UCC), Professor David Williams (RCSI). Bottom row (l-r) Dr Mark Watson (CRDI), Professor Martina Hennessy (TCD), Dr Karen Misstear (Programme Manager, CRDI).
STRUCTURE OF THE ICAT PROGRAMME

Following a competitive application process, ICAT Fellows are appointed to one of the partner universities for Year 1 during which 30% of their time is protected for academic activities. The protected time enables the new Fellows to identify a PhD supervisory team, to conduct a mini-project, hone their research skills and develop a PhD proposal. Other academic activities in Year 1 include designing and undertaking a mini-project and exploring the large multi-institutional curriculum of educational modules offered via the CRDI Curriculum Portal.

ICAT Fellows defend their PhD project proposals at the annual ICAT Retreat (see Page 45) and at interview during Year 1, before proceeding to register as PhD students in their chosen universities in Year 2. ICAT Fellows can undertake a PhD in any field of interest, including blue skies research, clinical research or big data analysis.

Cross-institutional collaborations and multi-sectorial projects with an innovative nature are encouraged.

Following approval of their PhD proposal, ICAT Fellows register for a PhD in their chosen institution in Year 2. ICAT Fellows do not exit clinical training during their PhD but maintain a minimal clinical training component, thus enabling them to continue to accrue clinical skills and interact with their peers who are continuing in full-time training.

On completion of a three-year PhD, ICAT Fellows will continue to receive support from the ICAT Programme as they submit and defend their theses and explore postdoctoral funding opportunities, whilst completing their clinical training. Figure 3 illustrates the structure of the ICAT Fellowships and the funding provided by the collaboration for each stage of training.

Collegiality, collaboration and peer support are values emphasised by ICAT and events for the Fellows include the annual ICAT Retreat, an annual induction event to introduce new Fellows and regular study days.

ICAT Fellows embark on Year 1 which is split 70/30 for clinical/academic activities, including development of a PhD proposal; this year is funded by the six universities and the two health services. PhD years 2-4 are funded by Wellcome and the HRB as well as by the two health services and encompass full-time research with minimal clinical training (dependent on the specialty). Following their PhDs, trainees return to clinical training for a further 1-3 years. A key component of ICAT is continuous support from mentors and peers.*

*CSCST – Certificate of Satisfactory Completion of Specialist Training (RoI); CCT – Certificate of Completion of Training (UK).

Figure 3. ICAT Training Structure

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<tr>
<th>Universities (x30)</th>
<th>Welcome/HRB (x30)</th>
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<tr>
<td><strong>Year 1</strong></td>
<td><strong>Year 2</strong></td>
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<tr>
<td>Health Services in NI and RoI (x10)</td>
<td>Health Services in NI and RoI (x40): trainees return to existing posts</td>
</tr>
<tr>
<td><strong>Year 5</strong></td>
<td><strong>Year 6</strong></td>
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<tr>
<td>Clinical &amp; research skills</td>
<td>PhD</td>
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<tr>
<td>Complete PhD and CSCST/CCT*</td>
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Mentoring & career development
In keeping with the Wellcome ethos, ICAT aims to attract the brightest clinicians who strive to become academic leaders.

ICAT FELLOWSHIPS

In keeping with the Wellcome ethos, the ICAT Programme aims to attract the brightest clinicians who strive to become academic leaders. The two cohorts of ICAT Fellows appointed to date include psychiatry, dermatology, radiology, nephrology, oncology, endocrinology, paediatric and infectious diseases trainees. Across the three recruitment drives to date, there has been a steady increase in the number of clinical specialties represented by trainees. Thirty clinical specialties have now been represented by applicants (Figure 4A) and eleven clinical specialties are represented by ICAT Fellows appointed to the first two cohorts in 2017 and 2018 (Figure 4B).

The second intake of ICAT Fellows are embarking upon a wide variety of PhD projects in July 2019, including an investigation into the impact of intensive lifestyle, medical and surgical control of diabetes, understanding how radiotherapy for lung cancer can affect your heart, a big data approach to study how environmental influences can impact autoimmune disease flares and elucidating the mechanism behind medical crises in children with sickle cell disease. More information about the ICAT Fellows and their research can be found on the ICAT website.

WEBSITE: www.icatprogramme.org
EMAIL: info@icatprogramme.org
TWITTER: @ICATProgramme

Figure 4. Diverse Clinical Specialties

(A) The number of clinical specialties represented by applicants has increased with each consecutive application call (each colour represents one clinical specialty).
(B) Eleven clinical specialties are represented by ICAT Fellows appointed to the first two cohorts in 2017 and 2018.
The second annual ICAT Retreat took place in Malahide on 15 and 16 November 2018. The ICAT Retreat gathers together the ICAT Fellows, Directors, PhD supervisors, members of the ICAT Steering Committee and Independent Advisory Board, as well as aspiring clinician scientists.

The packed two-day schedule included presentations from the ICAT Fellows, personal career development stories from invited guests and talks on funding opportunities and public and patient interaction in clinical research. Amongst the invited guests were Dr John Williams, CEO of Birmingham Health Partners, Professor Sarah Fidler, Professor of HIV Medicine at Imperial College London, and Professor Sir Michael Owen, Director of MRC Centre for Neuropsychiatric Genetics and Genomics at Cardiff University, who critiqued new intake PhD research proposals and appraised preliminary data presented by established Fellows. The focus of the ICAT Retreat is the evaluation of the proposed PhD projects and it is an opportunity for ICAT Fellows to present their ideas and receive valuable feedback from the audience of established researchers.

The Retreat closed with a very valuable discussion on the Future of Academic Medicine, with panel members Professor Michael Keane (Head of UCD Medical School), Professor Frank Murray (Director of HSE National Doctors Training and Planning), Professor Sarah Fidler, Professor Michael Gill (Head of TCD Medical School) and two ICAT Fellows, Dr Sarah Cormican (NUI Galway) and Dr Gerard Walls (QUB). A long-term goal of ICAT is to promote the development of a structured career pathway for clinical academics in Ireland and this will be an ongoing theme throughout the programme.

“Wellcome-HRB ICAT Programme
Second Annual Scientific Retreat

“The focus of the ICAT Retreat is the evaluation of the proposed PhD projects and for ICAT Fellows to receive valuable feedback from the audience of established researchers”
CRDI Short Courses
CRDI is coordinating expertise across its partner academic institutions and beyond to develop and deliver resources for research training. Development of one such resource, e-Learning, is a priority area for CRDI.

The module entitled *Case Studies in Drug Discovery & Development*, coordinated by Prof David Brayden (UCD), introduces the concepts involved in the drug discovery and development process in the pharmaceutical industry and provides case studies of both small molecule and biotech molecule development from discovery to market.

40 applicants from the CRDI partner institutions registered for the module in 2018 and a cohort of 18 students took the online MCQ. This module is accredited for 2.5 ECTS in UCD and in TCD and a CRDI Open Badge is also awarded to those who successfully complete the online MCQ.

At the end of 2018, over 50 applicants had registered for the 2019 delivery.

---

**e-LEARNING**

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---

**OPEN BADGES**

Open Badges are connected, verifiable credentials represented in portable image files, with embedded metadata about skills and achievements. They comply with the Open Badges Specification and are shareable across the web (Social Media, e-Portfolio, Blogs or Online CVs).

CRDI uses Open Badges to reward attendees who successfully complete the assessments of the widely-available CRDI continuing professional development opportunities. CRDI also acknowledges the training contributed by instructors for the CRDI courses, workshops and e-learning contributions via the award of Open Badges.

See: https://www.crdi.ie/open-badges/
Comms Update for 2018

WEBSITE STATISTICS 2018

18,354
New Users
31.18% up on 2017 figures
(18,354 v 13,730)

28,421
Sessions
32.51% up on 2017 figures
(28,421 v 21,449)

02:17
Avg. Session Duration
Similar to previous period
(02:11)

MAILCHIMP

6 Updates sent
48.85% Avg. Open Rate
Industry Avg. 16.4%

TWITTER

867 followers
179 new followers
Top tweet: 309 impressions

LINKEDIN

744 followers
Top post: 806 impressions
(ICAT Fellowship call)
Financial Statement

INCOME & EXPENDITURE
ACCOUNT YEAR ENDED
30 SEPTEMBER 2018
Unaudited

<table>
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<th>INCOME</th>
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<td>Grants</td>
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<tr>
<th>EXPENDITURE</th>
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<td>Professional and consultancy fees</td>
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<td>Communications: telephone, fax and postage</td>
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<td>Office rebrand</td>
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<td>Bank interest and charges</td>
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<tr>
<td>Depreciation</td>
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<td>- Fixtures and fittings</td>
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<td>- Computer equipment</td>
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<td>- Office equipment</td>
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<td>Auditors remuneration</td>
<td>24,908</td>
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<td></td>
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</table>

Result for the year -
CRDI Team

Dr Suzanne Bracken
European Correspondent, ECRIN – Ireland

Fiona Campbell
Clinical Industry Liaison Officer

Fiona Cregg
Quality and Regulatory Affairs Manager

Beth Corcoran
NEPTuNE Programme Manager

Michèle Cunnane
Clinical Trial Liaison Manager, HRB CRCI

Sarah Dever
Legal Advisor

Cara Dooley
IPCOR Researcher

Dr Fionnuala Keane
Head of Clinical Research, Chief Operations Officer, HRB CRCI

Gemma Leacy
Project Manager, CECR

John Mc Court
IT Manager, HRB CRCI
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BBMRI</td>
<td>Biobanking and BioMolecular Resources Research Infrastructure</td>
</tr>
<tr>
<td>BWG</td>
<td>Budget Working Group</td>
</tr>
<tr>
<td>CDA</td>
<td>Confidential Disclosure Agreement</td>
</tr>
<tr>
<td>CECR</td>
<td>Corporate Enabling of Clinical Research</td>
</tr>
<tr>
<td>CILO</td>
<td>Clinical Industry Liaison Officer</td>
</tr>
<tr>
<td>CRF/C</td>
<td>Clinical Research Facility/ Centre</td>
</tr>
<tr>
<td>CRIGH</td>
<td>Clinical Research Initiative for Global Health</td>
</tr>
<tr>
<td>CRDI</td>
<td>Clinical Research Development Ireland</td>
</tr>
<tr>
<td>CR PPI WG</td>
<td>Clinical Research Public Patient Involvement Working</td>
</tr>
<tr>
<td>CSFP</td>
<td>Clinician Scientist Fellowship Programme</td>
</tr>
<tr>
<td>CTRSP</td>
<td>Clinical &amp; Translational Research Scholars Programme</td>
</tr>
<tr>
<td>CURAM</td>
<td>Centre for Research in Medical Devices</td>
</tr>
<tr>
<td>C4C(Connect4Children)</td>
<td>Collaborative Network for EU Clinical Trials for Children</td>
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<tr>
<td>DCU</td>
<td>Dublin City University</td>
</tr>
<tr>
<td>ECRIN</td>
<td>European Clinical Research Infrastructures Network</td>
</tr>
<tr>
<td>ECTS</td>
<td>European Credit Transfer and Accumulation System</td>
</tr>
<tr>
<td>EI</td>
<td>Enterprise Ireland</td>
</tr>
<tr>
<td>CONSCIOUS</td>
<td>Development of Human Curriculum Clinical Trials for the Next Generation of Biomedical Students</td>
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<tr>
<td>ERIC</td>
<td>European Research Infrastructure Consortium</td>
</tr>
<tr>
<td>FICR</td>
<td>Future Investment in Clinical Research</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>GDPR</td>
<td>General Data Protection Regulation</td>
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<tr>
<td>HPRA</td>
<td>Health Products Regulatory Authority</td>
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<tr>
<td>HRB</td>
<td>Health Research Board</td>
</tr>
<tr>
<td>HRB CRCI</td>
<td>Health Research Board Clinical Research Coordination Ireland</td>
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<tr>
<td>HRB CRFC</td>
<td>Health Research Board Clinical Research Facility Cork</td>
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<tr>
<td>HRB CRFG</td>
<td>Health Research Board Clinical Research Facility Galway</td>
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<tr>
<td>HRB NEPTuNE</td>
<td>Neonatal Encephalopathy PhD Training Network</td>
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<td>HRI CRSU</td>
<td>Health Research Institute Clinical Research Support Unit</td>
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<tr>
<td>HSE</td>
<td>Health Service Executive</td>
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<tr>
<td>ICAT</td>
<td>Irish Clinical Academic Training</td>
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<tr>
<td>INFANT Centre</td>
<td>Irish Centre for Fetal and Neonatal Translational Research</td>
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<tr>
<td>in4kids</td>
<td>Irish Network for Children’s Clinical Research</td>
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<tr>
<td>IPCOR</td>
<td>Irish Prostate Cancer Outcomes Research</td>
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<tr>
<td>IPHA</td>
<td>Irish Pharmaceutical Healthcare Association</td>
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<tr>
<td>IPPOSI</td>
<td>Irish Platform for Patient Organisations, Science and Industry</td>
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<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<td>Legal Working Group</td>
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<td>MRCG</td>
<td>Medical Research Charities Group</td>
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<td>NCRC CCRU</td>
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<td>National Cancer Registry Ireland</td>
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<td>NSAI</td>
<td>National Standards Authority of Ireland</td>
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<tr>
<td>NUI Galway</td>
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<tr>
<td>PhD</td>
<td>Doctor of Philosophy</td>
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<tr>
<td>PSA</td>
<td>Prostate Specific Antigen</td>
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<td>PWG</td>
<td>Pharmacovigilance Working Group</td>
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<td>Quality Assurance</td>
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<td>QRAM</td>
<td>Quality &amp; Regulatory Affairs Manager</td>
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<td>QUB</td>
<td>Queen’s University Belfast</td>
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<tr>
<td>QWG</td>
<td>Quality Working Group</td>
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<td>RCSI</td>
<td>Royal College of Surgeons in Ireland</td>
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<td>SCA</td>
<td>State Claims Agency</td>
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<td>Science Foundation Ireland</td>
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<td>Small to Medium Sized Enterprises</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>University College Dublin</td>
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<td>WT HRB CRF- SJH</td>
<td>Welcome Trust Health Research Board Clinical Research Facility, St James’s Hospital</td>
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