UCD School of Medicine

UCD CLINICAL RESEARCH CENTRE

ANNUAL REPORT 2016/2017

MISSION

Our mission is to improve the health of the nation by ensuring that novel interventions are developed, evaluated and implemented in routine clinical practice.

VISION

Our vision is of an internationally recognised centre of clinical and translational research excellence which will develop the next generation of clinician scientists.

WELCOME

We are delighted to present the UCD Clinical Research Centre activity report for the 2016/17 academic year.

This report is the second update on our ambitious plans outlined in the UCD Clinical Research Centre - Strategic Priorities 2015-19 document. As you will see, we are making significant progress in realizing our ambition for the UCD CRC to be a leading internationally recognised centre for clinical and translational research. Across all our major strategic objectives significant progress has been made, ensuring the UCD CRC continues to be at the forefront of the national clinical research landscape.

We are delivering significant research activity, as detailed in this report. Across clinical research, scientific services and all other activity domains, UCD CRC staff are supporting major research programmes. This activity is vital to the UCD School of Medicine and the wider University, as the UCD CRC plays the major role in supporting hospital based research programmes. The importance of this activity is evidenced by the significant input and output metrics associated with this research activity. For example, funding awarded to hospital investigators represents almost half of the School of Medicine's total funding awards- funding that is mainly leveraged by CRC investigators.

The UCD CRC is committed to ensuring that all studies involving human subjects are carried out in a way which protects the interests of the subjects, whilst ensuring that healthcare is continuously improved. To enable this focus, we have developed a comprehensive quality and regulatory affairs system, available to investigators to support all stages of their projects

The UCD CRC is supported by the School of Medicine as a critical element of its research infrastructure. The growth of the education and research activities underpins the sustainability of the centre.

In line with our vision, the UCD CRC is impacting patient's lives, supporting our hospitals and delivering the School of Medicine, College of Health & Agricultural Sciences, and University Research strategies. Our continued success is underpinned by the expert team of CRC staff and associated researchers and investigators. On behalf of the CRC leadership team, we want to thank all the staff whose commitment, skill and hard work has driven the progress detailed in this report.

Peter Doran

Patrick Murray

Michael Keane

I am delighted to introduce the UCD Clinical Research Centre 2016-17 Annual Report.

The research ethos of the UCD College of Health & Agricultural Sciences is to foster curiosity-based and hypothesis-driven research to best international standards on areas of key strategic relevance to Ireland and to the global community. Under the One Health banner, we are uniting research expertise in human and animal health and disease with a view to enhancing lives. The UCD CRC is an important part of the CHAS research vision. The UCD CRC provides dedicated state-of-the-art infrastructure for translational medicine research at St Vincent's University Hospital and the Mater Misericordiae University Hospital and enables research activity at many other hospital sites. Since opening in 2006 the UCD CRC has emerged as a leading centre for patient focused research in Ireland. Through its dynamic bidirectional links to the other CHAS research institutes and centres,the UCD CRC contributes to improvements in healthcare and patient outcomes, by driving and facilitating bench-to-bedside research.

By providing leadership in patient focused research, the UCD CRC is enabling investigators to complete impactful studies, is a focus for the training of new research professionals and is enhancing our partnership with the Ireland East Hospital Group. The UCD CRC team led by Peter Doran has developed comprehensive research facilities and investigator supports to enable investigators within UCD and our partner hospitals to deliver important clinical research programmes that are impacting patients lives. This is reflected in the significant activity reported in this annual report.

I would like to congratulate all of the CRC team on their success to date and acknowledge their important role in supporting the CHAS research vision.

Professor Cecily Kelleher Dmed MD FRCPI MPH FFPHMI
Principal,
UCD College of Health and Agricultural Sciences

I am delighted to welcome the UCD CRC Annual Report. I would like to firstly recognise the quality and impact of the CRCs research and its importance to the Ireland East Hospital Group. The centre's work continues to enable us to address some of most serious and difficult challenges facing our healthcare system.

The importance of research and the role of the CRC can only increase in the coming years as the Ireland East Hospital Group (IEHG), in combination with our academic partner University College Dublin, evolves into an Academic Health Science Centre (AHSC). This strategic shift reflects international experience that shows that the integration of research and education in an Academic Health Science Centre model improves both patient care, research and drives the knowledge economy.

I believe that research is central to us delivering on our objective of becoming an AHSC and addressing the wider issues that face our health system and patients. While we will face some significant challenges in the coming decade, research in the medical sciences offer us an opportunity to address those challenges and deliver better patient care for the population we serve. I look forward to continuing to work with the UCD CRC to meet these challenges.

Professor Mary Day
Chief Executive Officer
Ireland East Hospital Group

UCD CLINICAL RESEARCH CENTRE

IN NUMBERS

CLINICAL RESEARCH

228	65	6813	133
STUDIES	NEW STUDIES	PATIENTS	CLINICAL TRIALS

SCIENTIFIC SERVICES

1600	127	105,000	25,000
PATIENT SAMPLES BIOBANKED	GOLIMUMAB ASSAYS	BIOMARKERS ON 50,000 PATIENT SAMPLES	BIOMARKERS ON 5,094 PATIENT SAMPLES

QUALITY & REGULATORY AFFAIRS

5	3	3	70	48	12
DSUR REPORTS	CSR REPORTS	HPRA APPROVALS	UCD CRC SOPS	STAFF COMPLETED NEW ICH GCP E6(R2)	CLINICAL TRIAL MONITORING VISITS COMPLETED

EDUCATION

6	10	105
EDUCATION PROGRAMMES	MODULES	STUDENTS

COMMUNICATIONS

19,400	2.04	862
CITATIONS	FIELD WEIGHTED CITATION IMPACT	TWEETS IN #IRISHMED DISCUSSION

CRC IMPACT

The current direction of the UCD CRC was envisaged in the Strategic Priorities 2015-19 document. It is useful to now reflect on the major objectives outlined in this document and review our progress in delivering these.

This document cast a vision for the UCD CRC as an internationally recognised centre of clinical and translational research excellence which will develop the next generation of clinician scientists. This vision would be underpinned by following major strategic objectives:

» **Build on the success to date of the UCD Clinical Research Centre at MMUH and SVUH. Expand the activity across the Ireland East Hospital Group**

- We have grown the research activity significantly. Across all activity domains there are more studies ongoing, having bigger impacts. For example- we are at the centre of many network studies being delivered through the IEHG network and beyond.

» **Become a leading centre for graduate education in clinical and translational research**

- We have developed a comprehensive graduate education programme in clinical and translational research. Through our multiple programme formats we are responding to the needs of both the academic and industry sectors.

» **Support UCD and IEHG ambition to be a leading European academic-led acute hospital network**

- Through the CRC we have developed significant high impact research activity. Our investigators have a combined field weighted citation impact of over 2. Furthermore, we are leading a number of large scale European clinical investigation networks including POPART and Convince, as detailed in this report.

» **Ensure that our patients have rapid access to the best available treatments and that novel interventions are developed and that these are successfully implemented in routine healthcare practice**

- Through our clinical trial activity, both industry and academic initiated, we are at the leading edge of testing new medicines. By establishing the CRC facilities and supports we are attracting these studies to our sites, benefiting our patients.

» **Maintain a diversified income stream for the UCD Clinical Research Centre through an appropriate level of clinical trial, investigator-led studies, laboratory services and educational activity**

- We have substantially grown the direct CRC income over the last two years. Income has grown in all areas of activity, from Clinical trials, to Education programmes, to Scientific Services. In addition, we have grown the research income to the university by providing supports to our investigators.

These major successes of the UCD CRC have been driven by creating an organisation which is fast to respond to new opportunities, whilst having all the required expertise within the centre.

DELIVERING THE UNIVERSITY STRATEGY

Through our activity to date we are supporting the achievement of a number of major objectives of the UCD Strategy Research Innovation and Impact 2015-2020. These objectives have been major influences of the CRC development to date.

Objective 1	Increase the quality, quantity and impact of our research, scholarship and innovation
Objective 2	Provide an educational experience that defines international best practice
Objective 3	Consolidate and strengthen our disciplines
Objective 4	Conduct strong interdisciplinary research and education in important areas of national and global need
Objective 5	Attract and retain an excellent and diverse cohort of students, faculty and staff
Objective 6	Build our engagement locally, nationally and internationally
Objective 7	Develop and strengthen our University community
Objective 8	Further develop world-class facilities to support the vision
Objective 9	Adopt governance, management and budgetary structures which enable the vision
Objective 10	Overcome financial, human resource management and other external constraints

The UCD Clinical Research Centre (CRC), directed by Dr. Peter Doran, provides comprehensive support for clinical research which includes clinical and laboratory infrastructure, IT, finance and quality & regulatory compliance. The key role that the CRC plays in facilitating national and international collaboration between UCD investigators, other academics and with industry is demonstrated by the number of publications by CRC investigators in high impact international peer reviewed journals and by their citation rate.

Professor Alistair Nichol, Consultant Anaesthetist at SVUH was a leading investigator on the Transfuse study, the results of which were published this year in the New England Journal of Medicine. This study involved 4,919 patients, at 59 centres in 5 countries, including Ireland and found that the age of transfused blood cells did not impact patient survival rates among critically ill adults. In addition, in the most severely ill patients the transfusion of older blood was associated with fewer deaths. The Transfuse study is a clear example of how collaboration in high quality clinical research can result in clear benefits for the patient and society as a whole.

The CRCs suite of educational programmes, which aim to ensure that research leaders are appropriately skilled to continue to advance human medicine, continues to grow. I am acutely aware of the value of the activity at the CRC and its role in enabling the delivery of the strategic objective of the School to advance high quality impactful investigator led translational and personalised medicine research. I would like to thank Peter and his team and indeed all CRC investigators for their dedication and hard work throughout the year and look forward to continue working with them and addressing the ever increasing challenges to ensure even greater output that will benefit our population.

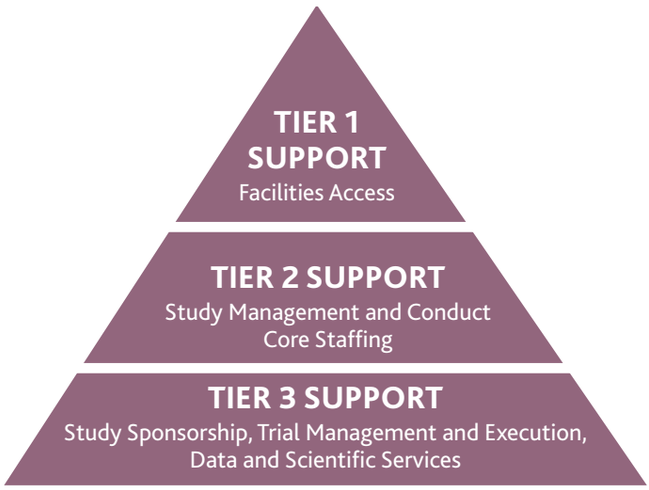
Associate Professor Marguerite Clyne
Associate Dean Research Innovation and Impact
UCD School of Medicine

CLINICAL RESEARCH

SUPPORTING CLINICAL INVESTIGATION

The UCD CRC has a significant track record of supporting both investigator and industry-initiated clinical research projects. These supports include:

- State-of-the-art facilities within major acute hospitals for high quality clinical research
- An environment which is:
  - Supportive to clinicians to undertake hypothesis-driven investigator-led clinical studies
  - Recognised by regulators, pharmaceutical companies and clinical research organisations as being professional, of the highest quality and suitable for the conduct of clinical trials
  - Attractive to patients and encourages participation in clinical research and trials by providing excellent clinical care and access to latest clinical interventions
  - Managed under a dedicated and approved quality policy
- A cohort of professional and experienced research scientists, data managers and clinical research nurses that can ensure studies are conducted and managed to the highest levels of quality
- Complete study management, oversight and sponsorship



RESEARCH EXPERTS:
CLINICAL RESEARCH NURSES

The Role of the Research Nurse is varied. Research Nurses are the primary point of contact for Subjects participating in a clinical trial and play a key role as the Subject's advocate. The Research Nurse can coordinate a clinical trial from proposal phase to reporting phase.

SERVICES AVAILABLE TO INVESTIGATORS

Proposal Phase	Pre-initiation Phase	Study Contact Phase	Reporting Phase
Grant Application	HPRA & Ethics submission	First Patient In	Last Patient Last Visit
Budget Review	Investigator Site File	ISF Maintenance	Study Close-out Visit
UCD Sponsorship	GCP Compliance & Training	Study Monitoring	End of Trial Notification
EudraCT Number	Trial Registration	Amendments	Archiving
Study Design Review	Monitoring Plan	Data Collection & Cleaning	Data Lock & Cleaning
Statistical Planning	Randomisation and Blinding Procedures	Pharmacovigilance	Data Transfer
Protocol Finalisation	Site Initiation	DSMB / Interim Analysis	Statistical Analysis
PIL & Consent Form		DSUR Submission	Budget Close Review
Insurance		Audits / Inspections	Clinical Study Report Submission
Contracts			

CLINICAL RESEARCH ACTIVITY

Across our research sites, 228 studies were ongoing over the past year, including 65 newly initiated studies.

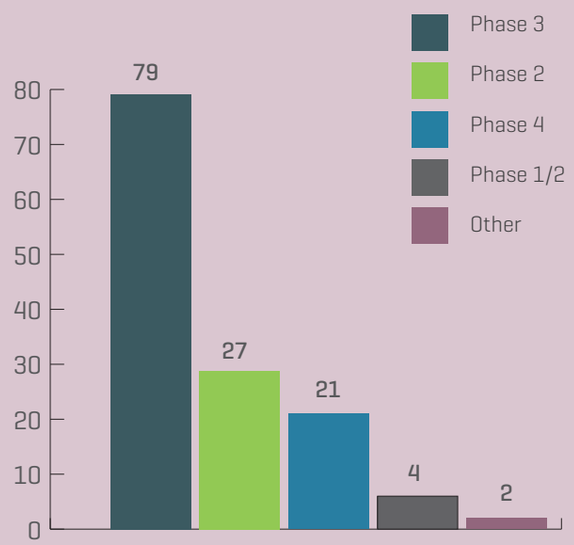
Of the active studies, 133 are clinical trials while 95 are observational, translational, biobanks, registries or device studies. It is important to note that a significant proportion of the studies are academic initiated: of the 228 active studies, 126 were academic-initiated and 102 industry-sponsored.

Within the clinical trials, the primary focus is on early to mid-phase trials:

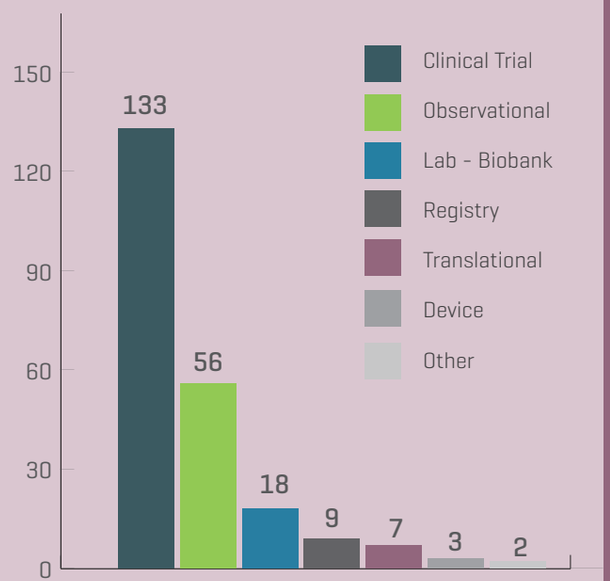
- 79 Phase 3 Studies
- 27 Phase 2 Studies
- 21 Phase 4 Studies

In aggregate, these studies accounted for over 6800 patient contacts [including 3550 contacts in clinical trials and 2500 in observational studies]. Studies active during 2016/17 were managed by 60 Investigators, with an average of 3.8 studies per Investigator.

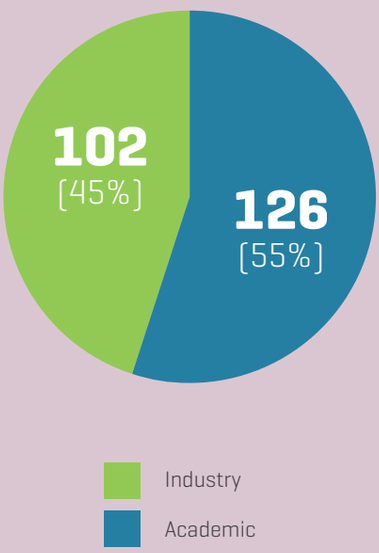
Number of Clinical Trials by Phase



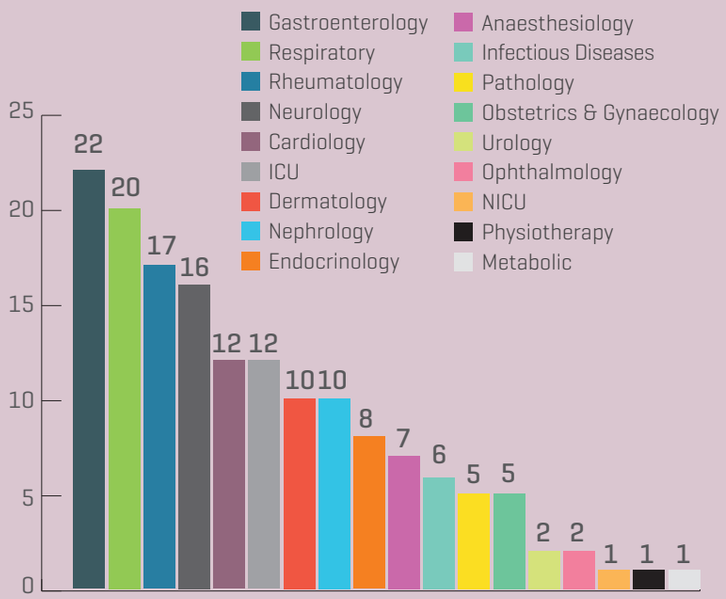
Number of Studies by Type



Number of Studies by Origin



Number of Studies by Therapeutic Area



CLINICAL RESEARCH

LEADING INVESTIGATOR INTITIATED TRIALS

The UCD CRC has a proven track record of supporting investigators to conduct investigator initiated clinical trials. Full study supports are available including UCD sponsorship. To date, UCD has sponsored 19 clinical trials with 4 new investigator initiated clinical trials in 2016/2017. Importantly, some of these clinical trials are multi–centre studies which enables us to link with centres throughout Ireland. Funding was provided via industry, public funding agencies and charities.

Sponsored studies include:

Study	Clinical Discipline	PI	Sites	Funding	Current Status
POPART	NICU	Colm O'Donnell	Holles Street	Industry	Start Up
GLOBE	Obstetrics & Gynaecology	Fionnuala McAuliffe	Holles Street	Funding Agency	Start Up
TEMPO-2	Neurology	Sean Murphy	MMUH	Industry	Start Up
GOAL-ARC	Gastroenterology	Glen Doherty	SVUH, MMUH, NUIG, SJH, Beaumont, Cork	Industry	Active
APART	Infectious Diseases	Paddy Mallon	MMUH	Funding Agency	Active
CONVINCE	Neurology	Peter Kelly	Multiple	Funding Agency	Active
DERMMARK	Dermatology	Brian Kirby	SVUH	Funding Agency	Active
NAPRESSIM	Anaesthesia	Alistair Nichol	SVUH	Charity	Active
TAISTR	Infectious Diseases	Paddy Mallon	MMUH	Industry	Active
DINUP	Dermatology	Brian Kirby	SVUH	Industry	Closed
DIP	Dermatology	Brian Kirby	SVUH	Industry	Closed
Fampyra	Neurology	Chris McGuigan	SVUH	Industry	Closed
GLP-1 Renal	Endocrinology	Carel le Roux	SVUH, Loughlinstown	Funding Agency	Closed
TEST	Obstetrics & Gynaecology	Fionnuala McAuliffe	Holles Street, Rotunda	Funding Agency	Closed
Vitamin D	Neurology	Michael Hutchinson	SVUH	Funding Agency	Closed
Letrozole	Endocrinology	Frances Hayes	SVUH, Loughlinstown	Funding Agency	Closed
Dexamethasone	Paediatrics	Ronan O'Sullivan	OLHSC, Crumlin	Charity	Closed
Sickle Cell	Paediatrics	Ronan O'Sullivan	OLHSC, Crumlin	Charity	Closed
SKA	Paediatrics	Colm O'Donnell	OLHSC, Crumlin	Charity	Closed

QUALITY & REGULATORY AFFAIRS

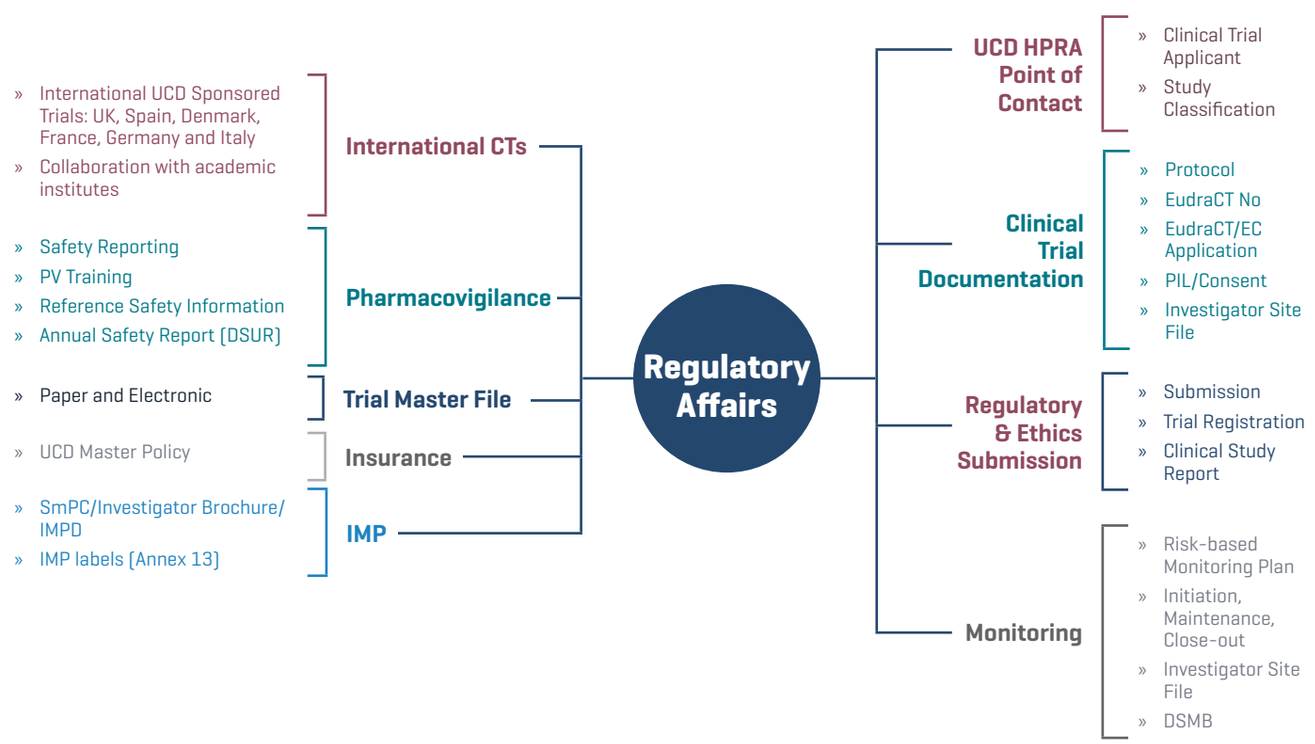
QUALITY

Throughout the life cycle of a research project, the CRC provides quality oversight from initiating all staff under the CRC's SOPs and quality management system, providing GCP training and risk assessment of our trials, through to monitoring and consultation through the maintenance of the study.

- 70 UCD CRC SOPs – Including areas: Clinical, Regulatory, Laboratory, Pharmacovigilance
- 48 Staff completed new ICH GCP E6(R2), rolled out in 2017
- Risk Assessments and Monitoring Plans established for 7 UCD sponsored clinical trials
- 12 Clinical Trial Monitoring Visits completed – 2 Site Initiation visits, 10 Routine visits
- External Systematic Audit conducted of partnering academic clinical research facility

REGULATORY AFFAIRS

UCD CRC provides extensive regulatory support for clinical trials:



QUALITY & REGULATORY AFFAIRS

SPONSORSHIP ACTIVITIES

The UCD CRC enables investigator led clinical trials by providing comprehensive regulatory support.

The study activity status as at the end of 2017:

POPART – International randomized clinical trial on prophylactic oropharyngeal surfactant for pre-term infants

GLOBE - A Randomized-Controlled Trial of Liraglutide treatment in obese, non-pregnant women with previous history of Gestational Diabetes Mellitus

NAPRESSIM
DERMMARK
GOAL-ARC
TAISTR
APART
CONVINCE

Actively Recruiting

TEST - CSR submitted

VITAMIN-D – CSR submitted

GLP-1 – CSR submitted

DIP – Study completed

DINUP – Study completed

MONITORING

The UCD CRC Regulatory Team ensure that clinical trials are conducted, recorded and reported in accordance with protocol, Good Clinical Practice (GCP) and UCD CRC standard operating procedures (SOPs).

Taking a Risk-Based approach, the CRA drives the finalization of the Monitoring plan for all UCD sponsored studies involving key stakeholders such as the Chief Investigator, Quality & Regulatory Affairs Manager and appropriate study staff.

Identify Risks ↓	» Systems Level » Trial Level
Evaluate Risks ↓	» Likelihood and detectability » Impact/Concerns (subject protection, reliability of results)
Risk Control ↓	» Mitigation Strategy » Additional Monitoring/Audit Methods Required
Communicate Risks ↓	» Document » Communicate to stakeholders
Review Risks ↓	» Regular Review
Report Risks	» Clinical Study Report » Summarise QMS and deviations

ACTIVITY DATA

- 2 International UCD Sponsored Clinical Trials approved by the HPRA currently active (CONVINCE & POPART)
- 5 Annual safety review with Development Safety Update Reports submitted to the HPRA for UCD Sponsored Clinical Trials for 2016/2017
- 3 Clinical Study Reports submitted to the HPRA (TEST, GLP-1, Vitamin D)
- 3 UCD Sponsored Clinical Trial Protocols received approval by the HPRA (including Protocol Amendments)
- 9 queries from UCD Investigators to the HPRA resolved centrally (including study classifications and general queries)
- Collaboration with UCD Research Office to provide oversight on UCD Risk Assessment for all Research involving Human Subjects.
- Active participation with the HRB-CRCI across 5 academic clinical research centres.

DATA & INFORMATION SYSTEMS

CLINICAL DATA MANAGEMENT

The CRC supports research staff with collection of high-quality, reliable data throughout their clinical research project. Assistance is provided with development of clinical trial protocols, advice on data protection issues, efficient data collection and CRF design, and establishment of electronic databases to ensure the right data is collected for each study protocol.

Case Report Forms have been designed across a number of new CRC studies this year:

- AbbVie/SFI-funded dermatology clinical trials on Hidradenitis Suppurativa, Psoriasis and Atopic Dermatitis (DERMMARK, PSO-AD)
- UCD investigator-initiated and academically funded clinical trial on patients with previous history of gestational diabetes (GLOBE)
- Investigator Initiated and Chiesi-funded clinical trial on prevention of endotracheal intubation for respiratory failure in neonatal infants (POPART)

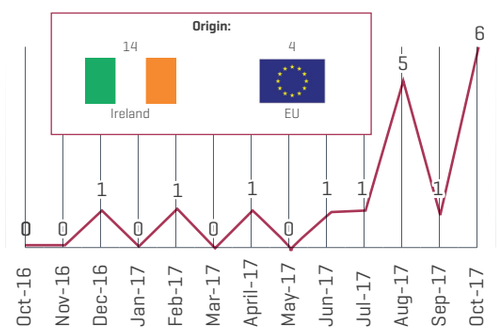
PHARMACOVIGILANCE

Our staff provide pharmacovigilance support for safety monitoring activities and processing of serious adverse events (SAEs) that occur in UCD-sponsored regulated clinical trials. Two staff members have completed the European Medicines Agency face-to-face Eudravigilance training.

Pharmacovigilance services include:

- Dedicated email address for reporting of SAEs on UCD-sponsored clinical trials
- Logging, processing and filing of all reported SAEs
- Submission of Suspected Unexpected Serious Adverse Reactions (SUSARs) to HPRA and/or EMA within regulatory timelines
- Assisting with development of Development Safety Update Report (DSUR) preparation and submission to HPRA

Number of SAEs processed per month



INFORMATION SYSTEMS

The appropriate use of intelligent and secure IT solutions is key to the translational research mission, permitting the generation and exchange of data and information between the 'bed' and the 'bench'. The UCD CRC is addressing these challenges by implementing cost-effective IT solutions which combine to create a sophisticated clinical research information infrastructure that supports all aspects of clinical research.

Our current electronic data capture system, Distiller, is available to all researchers for management of their clinical research data. Distiller is managed by UCD CRC on secure servers located in Ireland and is widely used by our investigators. Looking forward, a new data capture solution, REDCap, will be rolled out in the near future.

This is an up-to-date, secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support online or offline data capture for academic clinical research studies and operations. REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R) as well as a built-in project calendar, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

The REDCap system will support the following CRC functions:

- **Clinical Database Management System:** collection, management, verification, validation and simple analysis of clinical research study data
- **Pharmacovigilance Management System:** support assessment, reporting and review of serious adverse event data relating to clinical trials at UCD CRC
- **Clinical Trial Management System:** manage planning, performance and reporting functions, along with resource management, tracking deadlines and milestones

Clinical Trials Management System: Data Logged

273 STUDIES	**8181** PATIENT CONTACTS
53 INVESTIGATORS	**22** THERAPEUTIC AREAS

SCIENTIFIC SERVICES

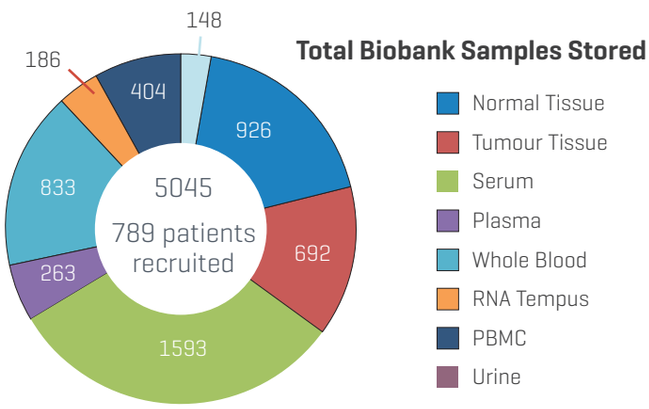
OVERVIEW

The UCD CRC provides a range of scientific services, which directly support its extensive portfolio of clinical research. Scientific services activities cover both the provision of state-of-the-art facilities, as well as technical support and translational research expertise.

CRC BIOBANK

Biobanks are systematic collections of biological samples such as blood, tissue or DNA taken from patients along with associated clinical and medical data made available for the purpose of clinical research. The UCD CRC has developed a network of biological resource centres for sample receipt, storage and processing across both the MMUH and SVUH sites.

There are over 40 biobank study collections currently ongoing in the CRC. Of this total, nearly 1600 samples were processed in 2016-2017. The CRC is responsible for generating over 3000 patient kits for its biobank projects.



In 2016-2017, the CRC introduced two new biobank registries; ENSAT (European Network for the Study of Adrenal Tumours) and PEG (Prostate Cancer Epigenetics Study). A total of 30 patients across both registries have been recruited with over 400 samples obtained. The CRC at SVUH is the first Irish healthcare institution to be registered on the ENSAT network.

CLINICAL RESEARCH STUDY/ INVESTIGATOR INITIATED TRIAL SUPPORT

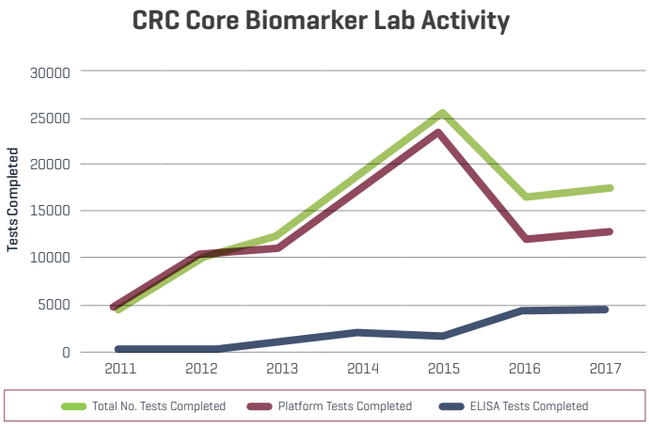
The provision of laboratory support for investigator led clinical trials is a major component of the UCD CRC. The investigator-initiated 'GOAL-ARC' study is a randomised, multi-centred 2-arm trial studying the effect of dose optimisation of Golimumab based on FCP and GLM drug levels versus standard treatment. The Scientific Services team has been actively involved in this trial since its inception. Our support has included:

- Providing patient kits to each of the six sites registered with this study (over 300 kits provided 2016/2017)
- Successful completion of a GLM stability study to elucidate optimum storage temperatures of patient samples
- Extraction of FCAL from patient stool samples for analysis in MMUH
- Analysis of serum GLM levels via the CRC Core Biomarker Lab

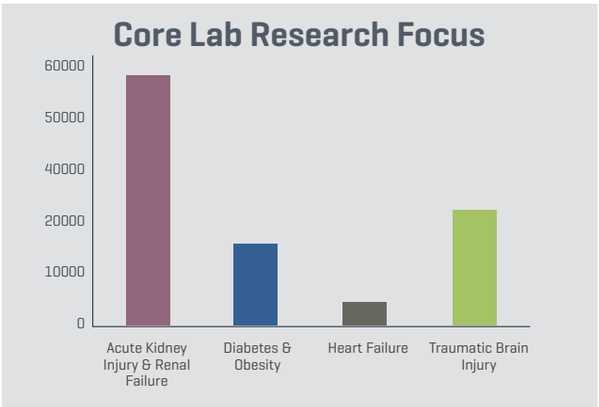
In 2016/2017 a total of 127 samples were analysed for serum GLM levels and 144 stool samples were extracted for FCAL. The CRC facilitated the registration of the FCAL assay for proficiency testing with the accreditation agency NEQAS. Proficiency testing has been successfully completed on a monthly basis since May 2017.

UCD CORE BIOMARKER LAB

The CRC Core lab facility is a biomarker testing laboratory located at the CRC in St Vincent's University Hospital. Founded through an extensive collaboration between UCD-CRC and Abbott Diagnostics, the CRC Biomarker lab has supported testing for a wide range of international and local studies since its inception. The lab houses Architect ci4100 integrated platform installed in 2011, an Architect i2000sr immunoassay analyser installed Q1 2016, and a Cobas e411 immunoassay analyser installed in Q1 2017, which affords the Core lab facility an expanded testing panel to accommodate the testing requirements of our collaborators and local investigators.



To date, nearly 105,000 tests have been completed on over 50,000 patient samples by the CRC Core lab. The majority of research projects undertaken by the core lab predominantly focus on four main disease areas; AKI, Diabetes, Heart Failure and TBI.



During Q3 2016, testing commenced on 2 main cohort studies comprising 4600 patient samples in order to assess known and experimental biomarkers of Traumatic Brain Injury (TBI). For each sample, the analysis of nine biomarkers is required. In Q3 2017, an additional cohort study was added to the existing TBI project consisting of an additional 5000 samples to be tested for three biomarkers. A total of 56400 tests are projected to have been completed by the end of this study. During the 2016/17 academic year, over 25000 tests were completed on 5094 patient samples, of which 7500 were ELISAs. The TBI study is scheduled to run until Q4 2018.

UCD-Abbott Core Biomarker Lab - studies undertaken during 2016/17:

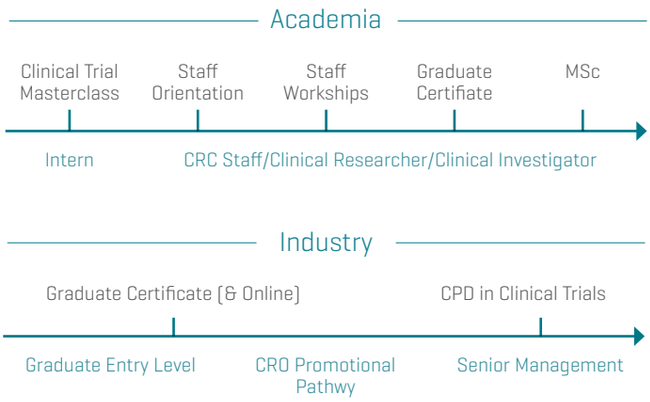
Study	Commencing	Samples	Analytes	Tests	Status
TBI Cohort 1	Q2 2016	3400	ApoA1, hsCRP, S100* NSE*, NFL**, Free BDNF**, Total BDNF**, Tau**, P-Tau**	30600	Ongoing
TBI Cohort 2	Q2 2016	1200	ApoA1, hsCRP, S100* NSE*, NFL**, Free BDNF**, Total BDNF**, Tau**, P-Tau**	10800	Ongoing
TBI Cohort 3	Q3 2017	5000	hsCRP, S100*, NSE*	15000	Ongoing
VINO	Q4 2017	3000	ST2**, GDF-15**	6000	Approved
GIFT	Q1 2018	1578	Gamma Prime Fibrinogen**	1578	Approved
Promise	Q1 2018	4100	hsTnI, Gal-3, NTpro BNP, Cystatin C, Creatinine, Homocysteine, Beta2, LipA, Glucose, Insulin, ALT, Free T3, Uric Acid	53300	Approved

*Roche **ELISA

Our study collaboration with Abbott has expanded further to include the addition of three new cardiology studies VINO, GIFT and Promise. In total, this will add an additional 61000 tests from 8700 patient samples to the CRC Core Biomarker Lab schedule for 2018/2019.

EDUCATION

Over the last 10 years, the UCD CRC has developed a comprehensive graduate programme in clinical and translational research. 2016/17 has yet again seen an expansion of our educational programme. The motivation for establishing this graduate programme was to train the next generation of investigators and research professionals, who would contribute to academic and industry led research. This is accomplished by means of a curriculum which strongly integrates research into teaching through a comprehensive programme of hands-on practical experience complementing classroom based learning as well as the skills and knowledge to appraise, evaluate and enhance clinical research.



PROGRAMMES

The CRC education programmes are specifically designed to address areas of need including:

Full time One Year MSc in Clinical and Translational Research (X789)
This programme is designed to train the prospective investigators of the future.

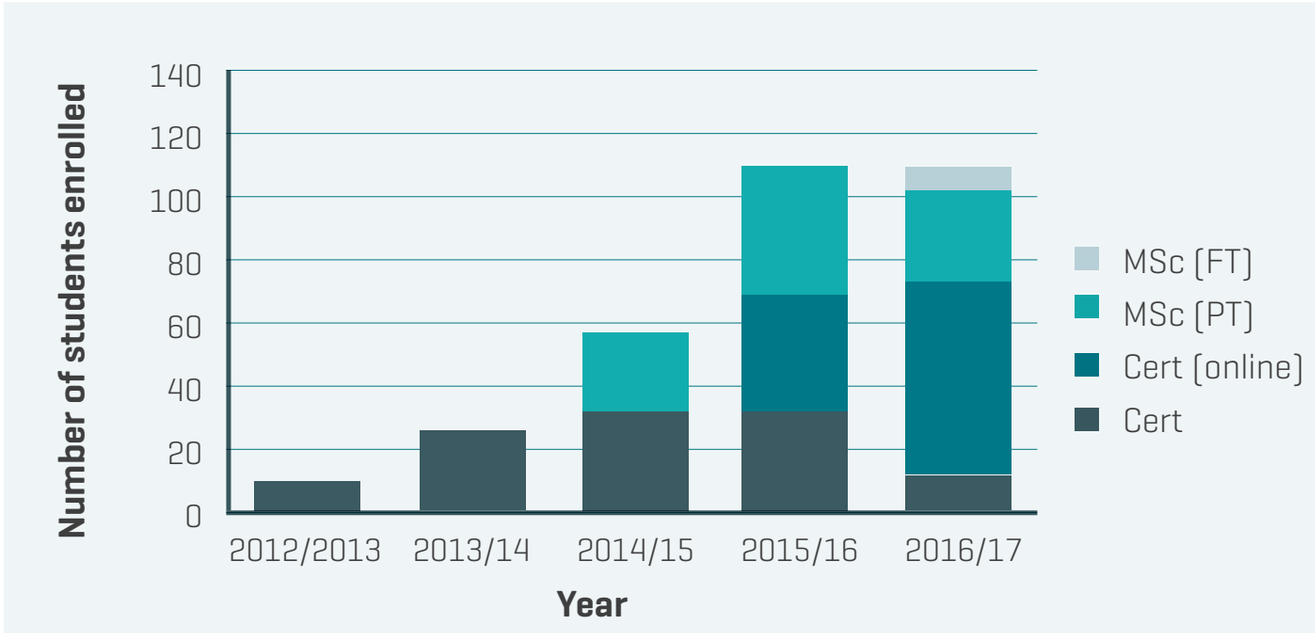
Part time Two Year MSc in Clinical and Translational Research (X427)
This programme is designed to train the prospective investigators of the future. Additionally, in September 2016, we welcomed our second class of the MSc programme with Shenzhen University to UCD.

Graduate Certificate in Clinical Research (X635/X649)
The certificate is intended to develop employment ready experts, who will implement clinical research programmes to the highest ethical, regulatory and scientific standards. Over 80% of graduates from the graduate certificate have found employment in the Clinical Research industry in Ireland and abroad.

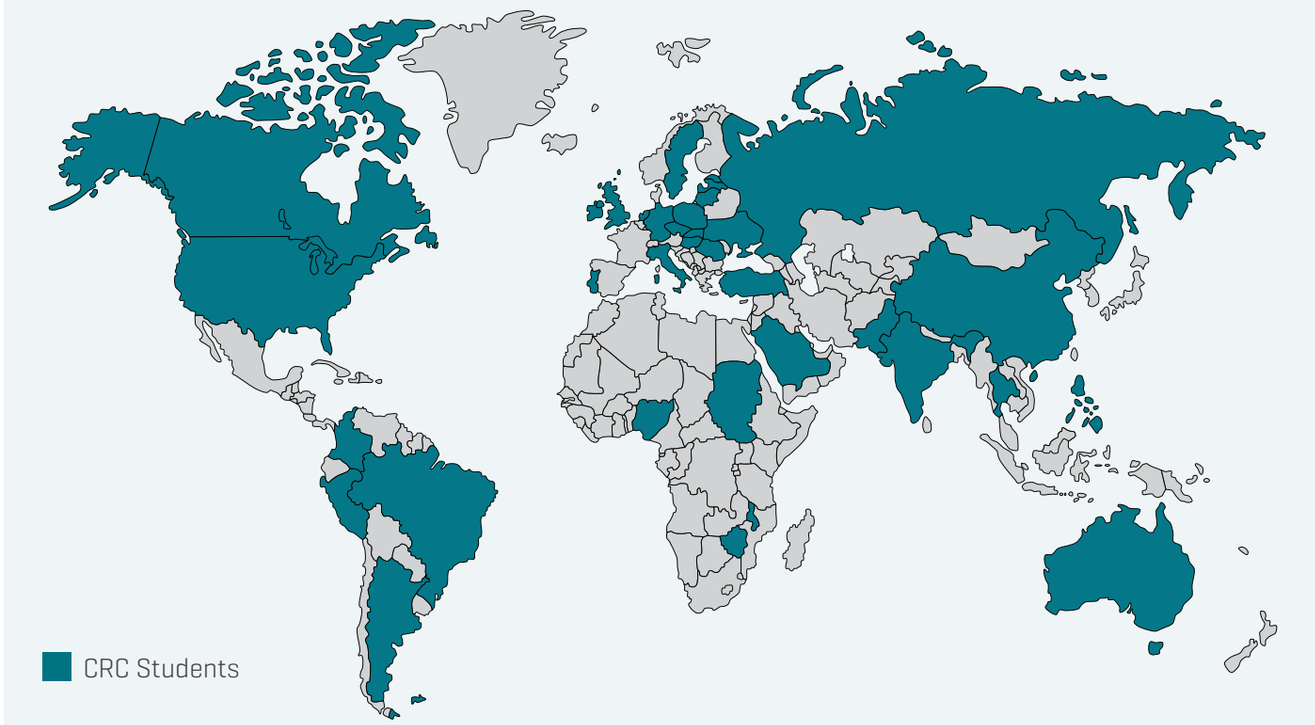
Online Graduate Certificate in Clinical Research (X787)
The strategy of the online graduate certificate course is to meet the staff development needs of the multinational CRO and pharmaceutical sectors. The second student cohort enrolled in October 2016 (65 students) and completed their studies in April 2017. Delivery of this programme utilises innovative Virtual Learning Environments such as recorded lectures, storyboards, videos, discussion boards, weekly quizzes and assignment based learning and assessment.

	MSc (PT) Yr 1	MSc (PT) Yr 2	Graduate Cert	MSc (FT)
Semester 1	Principles & Practices of Clinical & Translational Research Data Management & Biostatistics	Clinical Trials Clinical Trial Management	Clinical Trials Clinical Trial Management Data Management & Biostatistics	Clinical Trials Principles & Practices of Clinical & Translational Research Data Management & Biostatistics
Semester 2	Clinical Protocol Development Principles of Laboratory Medicine	Clinical Research Project	Clinical Trials Clinical Trial Management Data Management & Biostatistics	Clinical Protocol Development Clinical Trial Management Principles of Laboratory Medicine
Semester 3				Clinical Research Project

STUDENT ENROLMENT



Global student enrolment into our education programmes



NEW DEVELOPMENTS

Continuous Professional Development course in Clinical Trials

The CPD Course in Clinical Trials (OCHSS001) arose in response to needs of senior clinical research executives across many areas of the business. Key course content from the Clinical Trials and Clinical Trial Management modules was developed by the CRC education team for those from a non-science background and delivered via a virtual learning environment over seven weeks.

Clinical Trial Masterclass: National Academic Track for Internship

The academic track internship initiative provides an early and dedicated focus on research skills among doctors, and builds on research opportunities that are available from undergraduate training across the Irish medical schools. A UCD Masterclass Programme on Clinical Trials open to all Academic Track interns from around the country was held in September 2017. including 11 Academic Track interns from UCD, RCSI, NUIG, UL & UCC attended the event.

NETWORKS AND PARTNERSHIPS

2015/16 has seen a significant growth in student numbers and a year-on-year increase in total student numbers (see below). 110 students enrolled on our graduate programmes in the 2015/16 academic year, a doubling on the previous academic year.

This increase arises from demand and unmet needs from both students and industry, as is evident from the initiation of two new majors in the last year, a full time MSc (X789) and an online Graduate Certificate (X787). The online Graduate Certificate has been developed to meet the requirements of clinical research organisations to provide up to date training to staff, whilst earning a qualification from a leading university to enable staff up-skilling, retention and development. The e-learning delivery methodology used for this course reflects the global nature of the student body. The online Graduate Certificate is delivered over 22 weeks to classes which currently comprise of employees from ICON Plc. Delivery of this programme utilises innovative Virtual Learning Environment teaching modalities such as recorded lectures, storyboards, videos, online tutorials, weekly quizzes and assignment based learning and assessment.

The CRC's engagement with national and international networks has both broadened and deepened during 2016/17. The CRC's expertise is well-recognised as an indispensable resource by investigators at all affiliated clinical sites, industry and academic partners, funders and other collaborators throughout Ireland and internationally.

NETWORK SUPPORTS

The CRC offers a range of supports to clinical research networks and groups, with many based at the CRC facilities at the Mater Misericordiae and St Vincent's. The supports available include:

- Quality & Regulatory Affairs
- Data Management & Information Systems
- Office and meeting space
- Laboratory Services
- Clinical suites
- HR/recruitment, finance and project management

2016/17 ACTIVITY

Studies taking place at the CRC include a broad range of national, international and industry collaborations and speak clearly to the collaborative nature of high quality clinical research.

During the latest academic year the level of network activity hosted and facilitated by the CRC has grown considerably:

Building on the success of the previous year in supporting and enabling the development of networks in Critical Care, Stroke and Inflammatory Bowel Disease, we have enabled new clinical research partnerships including:

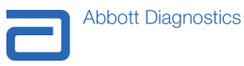
- **SFI-Abbvie dermatology studies – total funding €1.05m (clinical study = €328K)**
  Joint funded by SFI and Abbvie, the translational research programme between AbbVie, UCD Charles Institute of Dermatology, Systems Biology Ireland and UCD Clinical Research Centre aims to use a unique combination of clinical sampling techniques, high-throughput screening and systems approaches to facilitate discovery and development of new biomarkers and drugs for HS, AD and Psoriasis.
- **POPART study & PEDCRIN – total funding €550K**
  The study "Prophylactic Oropharyngeal surfactant for Preterm infants: A Randomised Trial", under Colm O'Donnell, initiated in 2017 and coordinated from the National Maternity Hospital at Holles Street with the support of the CRC, will enrol patients across sites in Ireland as well as Europe, facilitated through the PEDCRIN network.

CLINICAL RESEARCH COORDINATION IRELAND (CRCI)

CRCI became operational in May 2015 as a partnership of five university based Clinical Research Facilities/ Centres and their associated hospitals. It is supported by the Health Research Board, Enterprise Ireland and Molecular Medicine Ireland. The HRB CRCI central office provides overarching support and expertise, through a range of services and activities to academia and industry.

The CRCI coordinator at UCD CRC, Edel Meaney, has continued to spread awareness of the CRCI network throughout the UCD-affiliated clinical sites. In the last year, Edel Meaney has managed the submission of 52 study feasibilities, with 25 having been successful. 2 studies are active at St Vincent's and Mater Misericordiae.

COLLABORATORS AND SPONSORS OF CURRENT STUDIES INCLUDE:



COMMUNICATIONS

CRC communications activities have broadened throughout the year, with new materials and content produced, both in written media and online, as well as public events.

KEY COMMUNICATIONS ACTIVITY

CRC communications cover a broad range of channels and activities:

Defining our Services

In order to convey the services offered by the CRC the range of CRC information sheets was updated, together with improvements to the **www.ucd.ie/medicine/crc** website.

Informing our patients

A general information leaflet for patients is available for use at clinics and events, such as the International Clinical Trials Day.

Attracting our students

The information sheets and web pages detailing the CRC's suite of educational programmes, have been updated throughout the year.

Two open days were held during the academic year, one at St Vincent's and one at Mater Misericordiae. Over 20 potential students attended each event.

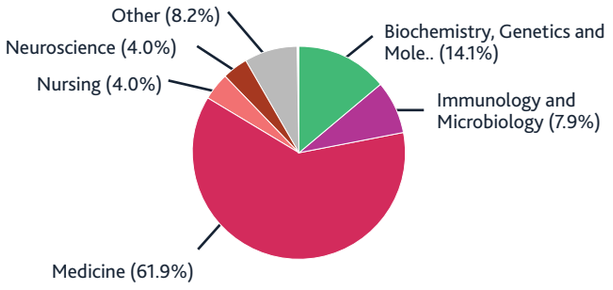
Engaging wider society

Multiple events and activities took place during the year which provided an opportunity to promote the CRC's activities to a wider audience. These included:

- **International Clinical Trials Day**
  Information stands were placed at key locations in St Vincent's, Mater Misericordiae and Holles Street hospitals on Friday the 19th of May. Nurse, lab and other CRC staff were on hand to speak to hospital staff, patients and the public about clinical research.
- **#IRISHMED Twitter discussion**
  Held during International Clinical Trials Week, a Twitter discussion was held on the subject of clinical research. The tweets created over 4 million impressions, and generated a discussion involving 862 tweets and 114 participants from across the world.
- **Print and radio coverage**
  CRC investigators, including Fionnuala McAuliffe, Peter Kelly, Alistair Nichol and Glen Doherty have been the subject of press and radio coverage throughout the year.

Publishing our outputs

Publications	Citations	Researchers	Field-Weighted Citation Impact	Citations per Publication
1,542	19,479	48	2.04	12.6



A bibliometric analysis of CRC Investigators output from 2012-17 shows a cumulative field-weighted citation impact score of 2.04, and over 19,400 citations.

CRC GOVERNANCE

The UCD CRC is led by Peter Doran and reports to the Head of UCD School of Medicine. A number of groups contribute to the oversight and management of the Centre:

CRC STRATEGIC ADVISORY BOARD

The UCD CRC Strategic Advisory Board, chaired by Prof Ravindra Mehta, University California San Diego, UCSD, plays a major role in advising the CRC strategy by completing annual reviews of the centre's activities and finances. The committee includes representatives of external clinical research facilities, industry and patient organisations.

CRC EXECUTIVE COMMITTEE

The UCD CRC Executive Committee is chaired by the Head of Clinical Pharmacology, Patrick Murray, and includes UCD CRC directors and research leaders. The CRC Executive Committee advises the Head of School on governance and leadership of the Centre and meets quarterly.

CRC OPERATIONS COMMITTEE

The UCD CRC Operations Committee oversees the general management of the centre and is chaired by the CRC Director, Peter Doran. The Committee deals with all operational activities of the Centre and reviews and approves all items relating to the ongoing functions of the CRC, including the review of access requests, SOPs, work instructions and strategic projects. The committee meets monthly and is the primary operational and management group of the Centre.

CRC FACILITIES GROUPS

The management and development of the CRC's facilities and physical infrastructure are coordinated through Facilities Management Groups at St Vincent's University Hospital and Mater Misericordiae University Hospital. The groups, chaired by Gareth Shaw, report to the UCD CRC Operations Committee.

CRC NURSE MANAGEMENT GROUP

The management of nurse workload assignments, training and recruitment are coordinated through the Nurse Management Group. Chaired by Terri Martin, the group reports to the UCD CRC Operations Committee.

AN INTER-DISCIPLINARY TEAM PROVIDING FULL SERVICE TO INVESTIGATORS

The core UCD CRC team members have a broad range of knowledge and expertise in the fields of clinical research and research management. The inter-disciplinary team work together to provide bespoke guidance and support to clinical investigators. With backgrounds in academic research, academic leadership, healthcare and industry, in-house fields of expertise include:

- Research Leadership
- Research Planning
- Quality & Regulatory Affairs
- Data Management
- Scientific Services & Lab Management
- Biostatistics
- Research Nursing
- Finance & Budgeting
- Business Development
- Teaching & Learning
- Project management & planning

FACILITIES AND INFRASTRUCTURE

CLINICAL INFRASTRUCTURE

Core research infrastructure has been created to support clinical investigations at the Mater Misericordiae and St Vincent's University Hospitals. The clinical research infrastructure includes:

1. Eight out-patient interview rooms for patient examination and tissue collection
2. Four procedure rooms for more complex patient studies
3. An endoscopy suite for internal medical examination, including arthroscopy and bronchoscopy
4. Recovery room facilities for patients post-procedure
5. Dual Energy X-ray Absorptiometry (DEXA) Scanner with full body composition analysis capabilities which support osteoarthritis/osteoporosis studies
6. Climate-controlled storage facilities for Investigational Medicinal Product materials

INFORMATION SYSTEMS

The appropriate use of intelligent and secure IT solutions is key to the translational research mission, permitting the generation and exchange of data and information between the 'bed' and the 'bench'. The UCD CRC is addressing these challenges by implementing cost-effective IT solutions which combine to create a sophisticated clinical research information infrastructure that supports all aspects of clinical research.

LABORATORY INFRASTRUCTURE

UCD CRC on-site laboratory facilities support the immediate processing of biological samples collected during research studies. The laboratory infrastructure complements biomedical research facilities on the University campus and includes:

1. Cell and tissue culture suites for primary cultures, equipped with sterile cell culture hoods & incubators
2. A molecular biology laboratory with standard equipment and facilities for molecular analysis
3. Imaging Laboratory (with contrast and fluorescence microscopy)
4. UCD-Abbott Core Biomarker Laboratory including Architect i2000 and Ci1200 high throughput analysers

Recognising the importance of access to appropriately consented, well phenotyped quality controlled biological samples to translational research, the UCD CRC has developed a network of biological resource centres for sample receipt, storage and processing across the hospital campuses. These include:

- Dedicated biobank rooms with temperature monitoring and control
- Twelve -80°C and four -20°C sample freezers
- Large Liquid Nitrogen storage capacity
- 24/7 monitoring of freezer and temperature controlled storage
- Comprehensive security and emergency response plans

LIST OF CRC PEOPLE

CRC CORE TEAM

Anna Malara
Aoife Kelly
Brenda Molloy
Carita Bramhill
Colm O'Brien
Debbie Wallace
Denise Gosling
Doireann Dickinson
Douglas Veale
Edel Meaney
Elaine Cawley
Elaine Gilroy
Gareth Shaw
Helen Campion
Karl McAuley
Kate Lynam-Loane
Laura Feeney
Laura Helbert
Loai Shakerdi
Marie Galligan
Michael Keane
Michelle Groarke
Niamh Redmond
Patrick Murray
Peter Doran
Rabia Hussain
Rosanna Inzitari
Sarah Griffin
Sean Kearns
Sebastian Vencken
Siobhan Smith
Terri Martin

CRC EXECUTIVE COMMITTEE

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Colm O'Brien
Doug Veale
Fionnuala McAuliffe
Marguerite Clyne
Michael Keane
Michaela Higgins
Paddy Mallon
Patrick Murray
Paul Harkin
Peter Doran
Peter Kelly
Rachel Crowley

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Fiona Rawat
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Gillian Horgan
Giulio Calzaferri
Hazel Bergin
Helen Keane
Jane O'Halloran
Jillian McCue-Musarra
Jo Ballott
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Joe Duffy
John Paul Byrne
Jun Zhao
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Mustapha Irnaten
Myra Walsh
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Susan Cairney
Tara O'Connor
Werd Al-Najim
Willard Tinago

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Carel le Roux
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Tim Lynch
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