UCD Clinical Research Centre
UCD School of Medicine

UCD CLINICAL RESEARCH CENTRE

ANNUAL REPORT 2018/19

CONTENTS

WELCOME

I am delighted to present the 2018-2019 Clinical Research Centre's (CRC) Annual Report. The UCD Clinical Research Centre has demonstrated the benefits of the university-hospital research model and has established a significant track record in supporting high impact research at the Mater Misericordiae University Hospital, St Vincent's University Hospital and the National Maternity Hospital, Holles Street.

The CRC is supported by the School of Medicine and the College of Health and Agricultural Sciences as a critical element of their research infrastructure. With the development of CRC's education programme and the growth in research activities underpinning the continued sustainability of the centre.

The ambitious plans outlined in the CRC's 2015-2019 Strategic Priorities were delivered through a constant focus on advancing high quality, impactful investigator-led translational and personalised medicine research. The delivery of the 2015-2019 Strategic Priorities has created a good platform for the mapping out of the next phase of the CRC's development through to 2024. Of which you will hear more in next year's report.

One area that I would like to mention is the Clinical Research Centre's commitment to ensuring that as many people as possible, irrespective of their geographical location, have access to cutting edge research and care. That is why, in 2019, the CRC initiated a site expansion project that includes Wexford General Hospital and St Luke's General Hospital, Carlow/Kilkenny as CRC research sites. These new research sites will deliver the benefits of participation in clinical and translation research to a much wider cohort of patients.

The last few years have demonstrated that research in medical sciences is central to addressing the major health challenges that we face as a society. The Clinical Research Centre will continue to support a wide range of research and our flexible model of delivery will enable that support to be sustained in the long term.

Prof Peter Doran

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.

UCD CLINICAL RESEARCH CENTRE

IN NUMBERS

CLINICAL RESEARCH

284	74	6283	149
STUDIES	NEW STUDIES	PATIENTS	CLINICAL TRIALS

SCIENTIFIC SERVICES

2420	231	65,000	30,700
PATIENT SAMPLES BIOBANKED	GOAL ARC SAMPLES ASSAYS	BIOMARKERS ON 25,000 PATIENT SAMPLES	ELISA MARKERS ON 13,000 PATIENT SAMPLES

QUALITY & REGULATORY AFFAIRS

6	5	>30	58
DSUR REPORTS	CSR REPORTS	HPRA APPROVALS	UCD CRC SOPS

15	8
STAFF COMPLETED TRIANING REPORTS	INVESTIGATOR INITIATED TRIALS

EDUCATION

5	10	66
EDUCATION PROGRAMMES	MODULES	STUDENTS

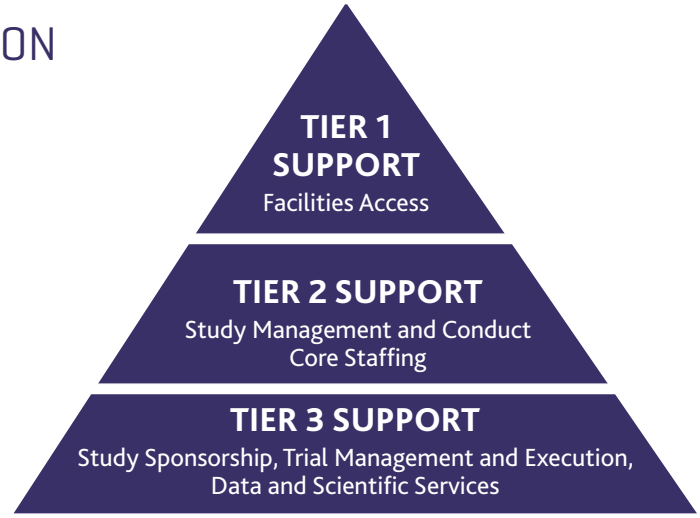
CLINICAL RESEARCH

Clinical Trials Day 2019

SUPPORTING CLINICAL INVESTIGATION

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



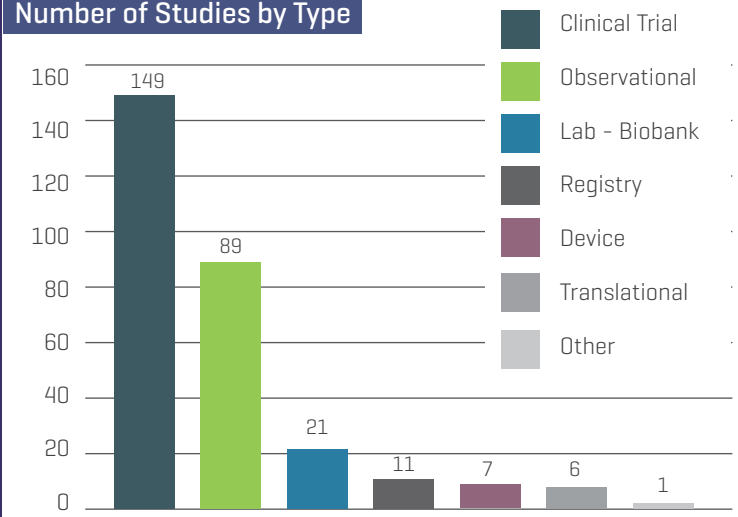
- A cohort of professional and experienced research scientists, data managers and clinical research nurses that can ensure studies are conducted and managed to the highest levels of quality
- Complete study management, oversight and sponsorship

SERVICES AVAILABLE TO INVESTIGATORS

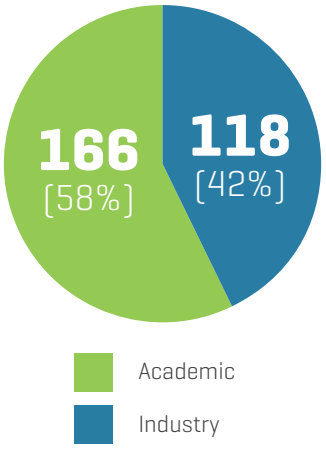
Proposal Phase	Pre-initiation Phase	Study Contact Phase	Reporting Phase
Grant Application	HPRA & Ethics submission	First Patient In	Last Patient Last Visit
Budget Review	Investigator Site File	ISF Maintenance	Study Close-out Visit
UCD Sponsorship	GCP Compliance & Training	Study Monitoring	End of Trial 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

Number of Studies by Type



Number of Studies by Origin



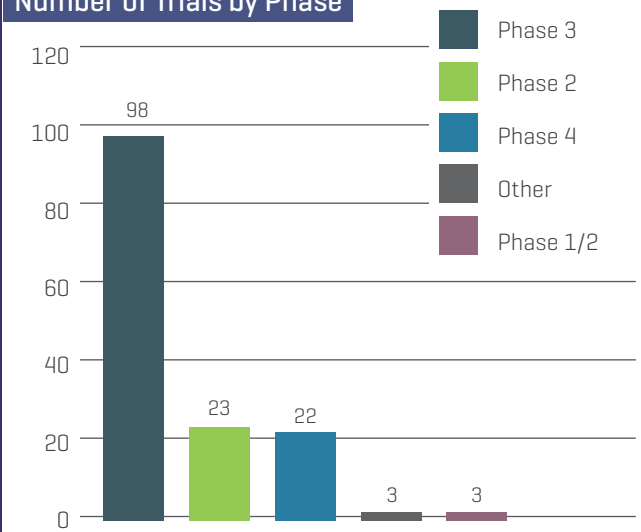
6,283

PATIENT CONTACTS ACADEMIC YEAR 2018/19

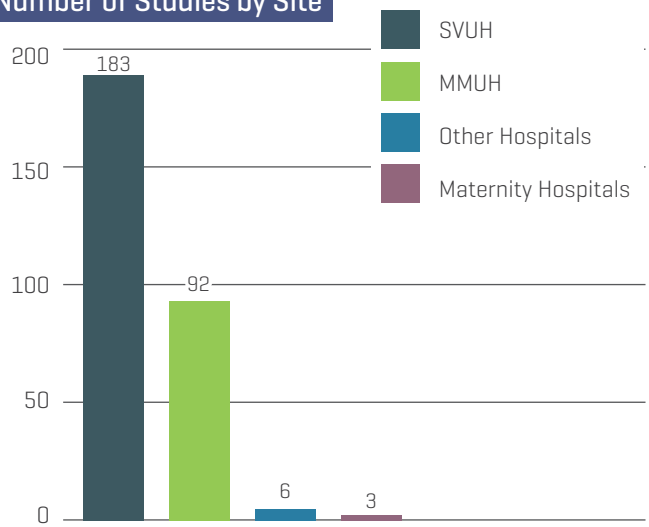
74

NEW CRC STUDIES 2018/19

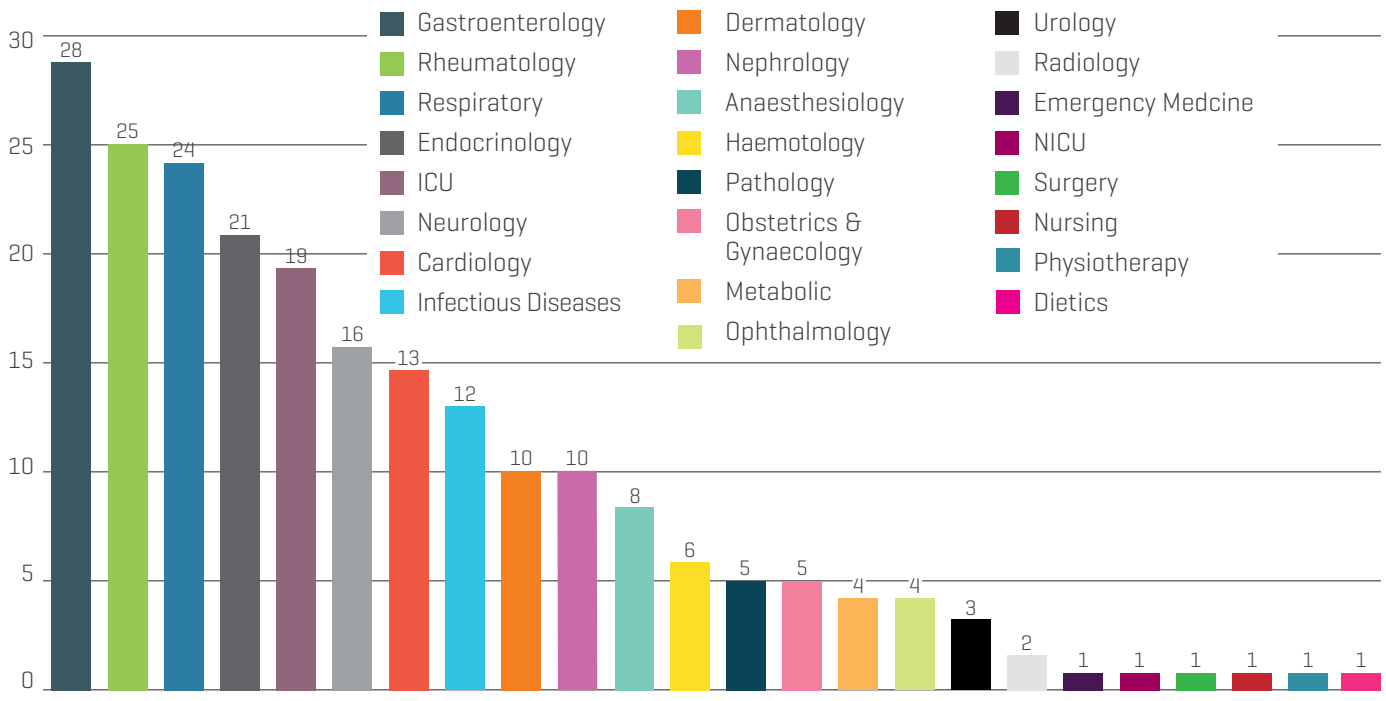
Number of Trials by Phase



Number of Studies by Site



Number of Studies by Therapeutic Area



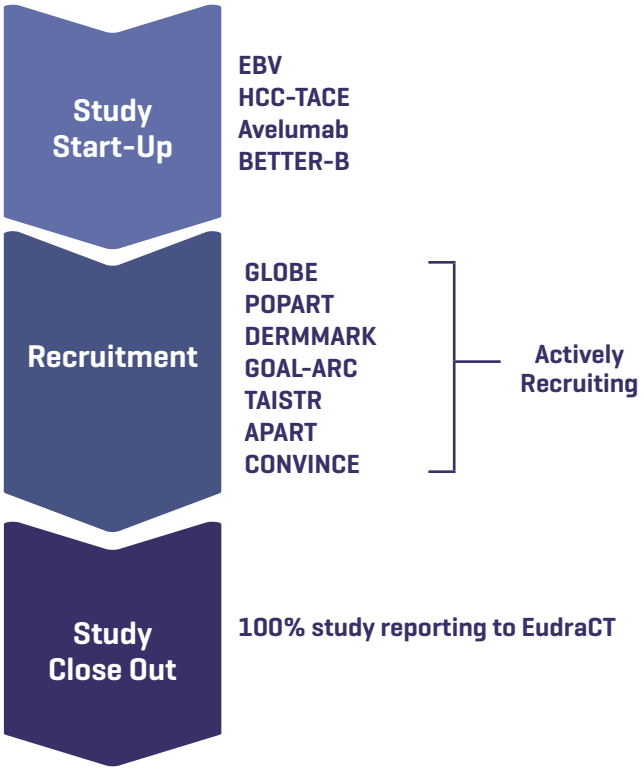
LEADING INVESTIGATOR INTITIATED TRIALS

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 19 clinical trials. 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.

ACTIVITY DATA

- 58 UCD CRC SOPs – including areas: Clinical, Regulatory, Laboratory, Pharmacovigilance
- 5 International UCD Sponsored Clinical Trials approved by the HPRA currently active (CONVINCE, POPART, TAISTER, APART, BETTER-B)
- Active participation with the HRB-CRCI across eight academic clinical research facilities in Ireland
- 15 new CRC staff completed staff induction and orientation

UCD SPONSORED STUDIES ACTIVITIES:



UCD has extended sponsorship activities to 4 further regulated clinical trials with 3 more clinical trials in the pipeline for the upcoming academic year.

Study	Chief Investigator	Study Start	Number of patients in Ireland Recruited	2018-2019 Activities
GOAL-ARC	Prof. Glen Doherty	Dec-2015	77	6 hospital sites recruiting in Ireland
POPART	Prof. Colm O'Donnell	Jan-2017	124	Study actively recruiting in Ireland as well as Czech Republic, Norway, Sweden, Belgium and Portugal.
GLOBE	Prof. Fionnuala McAuliffe	Mar-2017	2	Active recruitment
DERMMARK	Prof. Brian Kirby	Aug-2016	20	Active recruitment
CONVINCE	Prof. Peter Kelly	Jun-2016	308	Study expanded internationally – conducted in Belgium Spain, Germany, Czech Republic, Canada, Estonia, Denmark, Poland, Lithuania and Switzerland
TAISTR	Prof. Patrick Mallon	Feb-2017	33	Actively recruiting
APART	Prof. Patrick Mallon	Jun-2016	47	Actively recruiting – expanding to UK sites

QUALITY & REGULATORY AFFAIRS

UCD SVHG Translational Medicine Symposium 2019

QUALITY & REGULATORY AFFAIRS ACTIVITY DATA

- UCD CRC providing active role and support as EU Legal Representative to academic sponsors in Edinburgh, Leicester and King's College London.
- UCD undertaking active role as Co-Sponsor with King's College London on the Horizon-2020 funded EU-wide clinical trial – BETTER-B
- Regulatory Affairs function within UCD responsible for submission of over 3 Protocol amendments, 2 Clinical Trial Authorisations, 6 development safety update reports and co-ordination and oversight of regulatory support for these submission in Ireland as well as internationally in countries including Czech Republic, Norway, Belgium and Portugal.
- International ECRIN support provided for 2 of UCD sponsored clinical trials.
- UCD staff training record reviews completed for CRC staff.
- Interactive GCP training sessions provided across 4 hospital sites providing training for over 100 investigators and supporting research staff.
- All UCD regulated clinical trials results posted to EudraCT including trials NAPRESSIM, DIP and DINUP.

TRIAL MONITORING

UCD CRC Clinical Research Associates (CRA) provide close support to ensure that clinical trials implemented at hospital sites are conducted, recorded and reported in accordance with protocol, Good Clinical Practice (GCP) and UCD CRC standard operating procedures (SOPs) undertaking both external and internal clinical trials, adopting a risk-based approach.

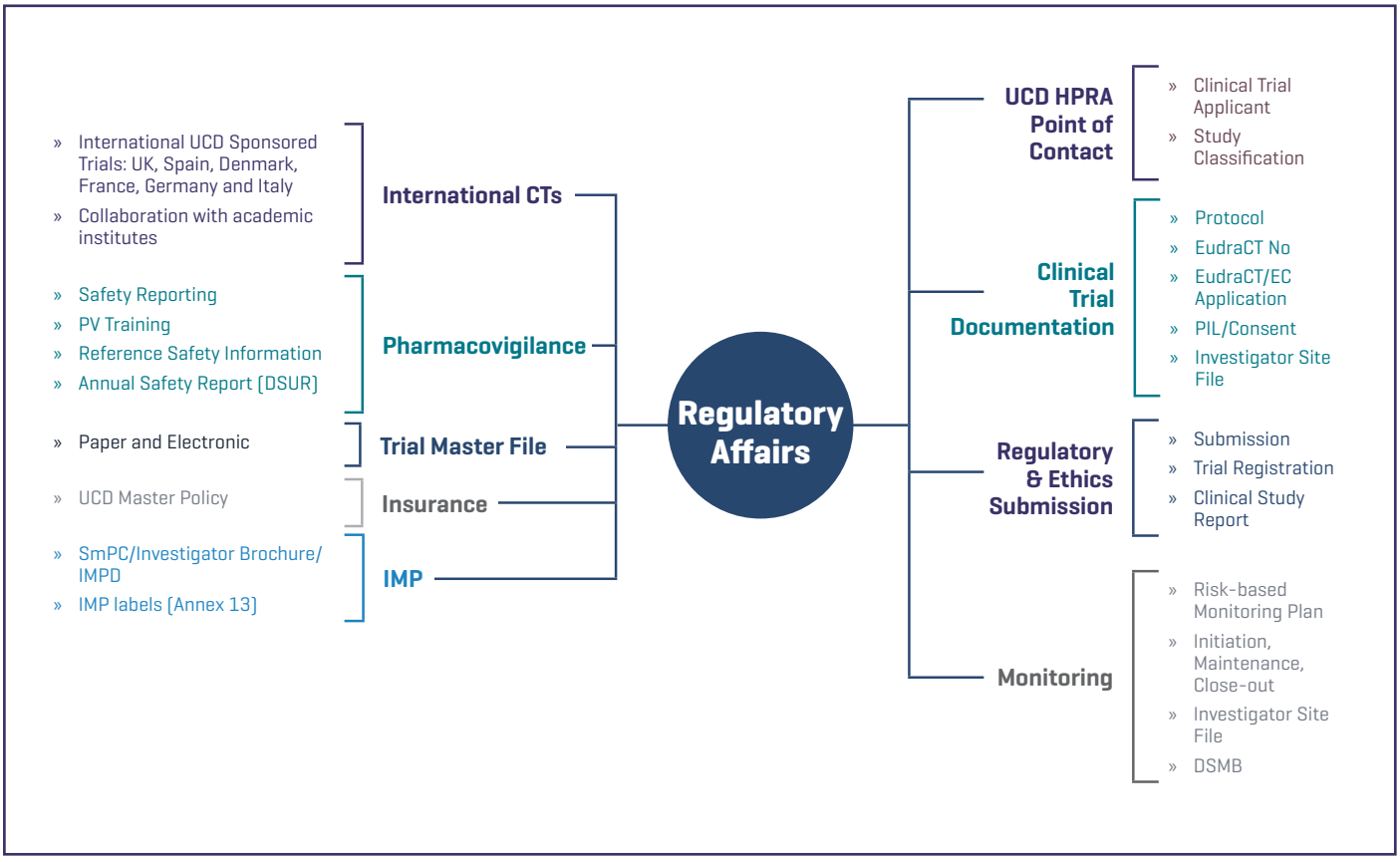
3 UCD CRC Clinical Research Associates actively working over UCD sponsored clinical trials monitoring within Ireland and internationally at affiliated research sites. Site Feasibility assessment support has also been conducted prior to study start in investigational sites internationally with CRA training provided to CRAs working locally for UCD-sponsored studies.

REGULATORY AFFAIRS

UCD CRC provides extensive regulatory support for all clinical trials conducted at the research facilities with the goal to provide staff with the tools, training and support needed to navigate the complex regulatory pathways that come with undertaking clinical research.

All clinical trial functional obligations are achieved through providing services to investigators which combines the quality and regulatory requirements for the conduct of robust and successful clinical trials, compliant and to high standard with the oversight.

UCD CRC has been actively working to adapt research activities to be compliant with GDPR. Advice and checklist provided to research staff at the research facilities to review their consent documents to be in compliance with GDPR expectations.



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:

Obesity and Uterine Cancer: Molecular Interactions and Surgical Interventions

REACCT Collaborative Study - Establishment of a data registry for early age onset colorectal cancer

TiLLIRI study - A prospective observational multicentre study to assess the risk factors that contribute to thrombosis in patients with lower limb injuries requiring immobilization to identify a group of patients with a high predicted venous thrombo-embolism risk (VTE) risk.

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

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 legacy electronic data capture system, Distiller, is now being phased out of general use with the launch of our new data capture solution, REDCap.

REDCap is managed by UCD CRC on secure servers located in Ireland and is widely used by our investigators and research teams, with approximately 200 active users across Ireland and around the world. REDCap 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 supports the following CRC functions:

- **Clinical Database Management System:** collection, management, verification, validation and simple analysis of clinical research study data
  - 20 studies currently collecting data in REDCap: 4 Clinical Trials, 10 Observational Studies
- **Pharmacovigilance Management System:** support assessment, reporting and review of serious adverse event data relating to clinical trials at UCD CRC

Over the coming year, REDCap will also support:

» **Clinical Trial Management System:** manage planning, performance and reporting functions, along with resource management, tracking deadlines and milestones

Clinical Trials Management System: Data Logged

284 STUDIES	**6,283** PATIENT CONTACTS
78 INVESTIGATORS	**24** THERAPEUTIC AREAS

EU GENERAL DATA PROCTECTION REGULATION

The EU General Data Protection Regulation (GDPR) came into force across all of Europe on 25-May-2018, replacing the previous EU Data Protection Directive (95/46/EC) and Ireland's Data Protection Acts 1988 and 2003. GDPR aims to balance citizen's rights, society's needs and the legitimate needs of business and organizations to process personal information – it builds on existing data protection rules and principles, with extensive updates.

Alongside GDPR, the Irish government has also updated the Irish Data Protection Acts, now known as Data Protection Acts 1988 to 2018, and released new Health Research Regulations 2018. The Health Research Regulations provide a clear regulatory framework in which health research must now be conducted in Ireland alongside creating a new governmental committee, the Health Research Consent Declaration Committee. The CRC is continuing to provid researchers with practical advice and support to comply with these new regulations.

BIOSTATISTICS

The UCD CRC has two in-house medical statisticians who provide statistical support to projects affiliated with the centre. Statistical support is available to investigators throughout the investigational process, from composing Health Products Regulatory Authority (HPRA) and funding applications through to reporting and publication. The centre supports open science principles, and in the 2018/2019 period has implemented an analysis pipeline that includes methods to enhance transparency and reproducibility.

This pipeline includes:

» the use of freely available, open source analysis software, such as R (R Core Team)

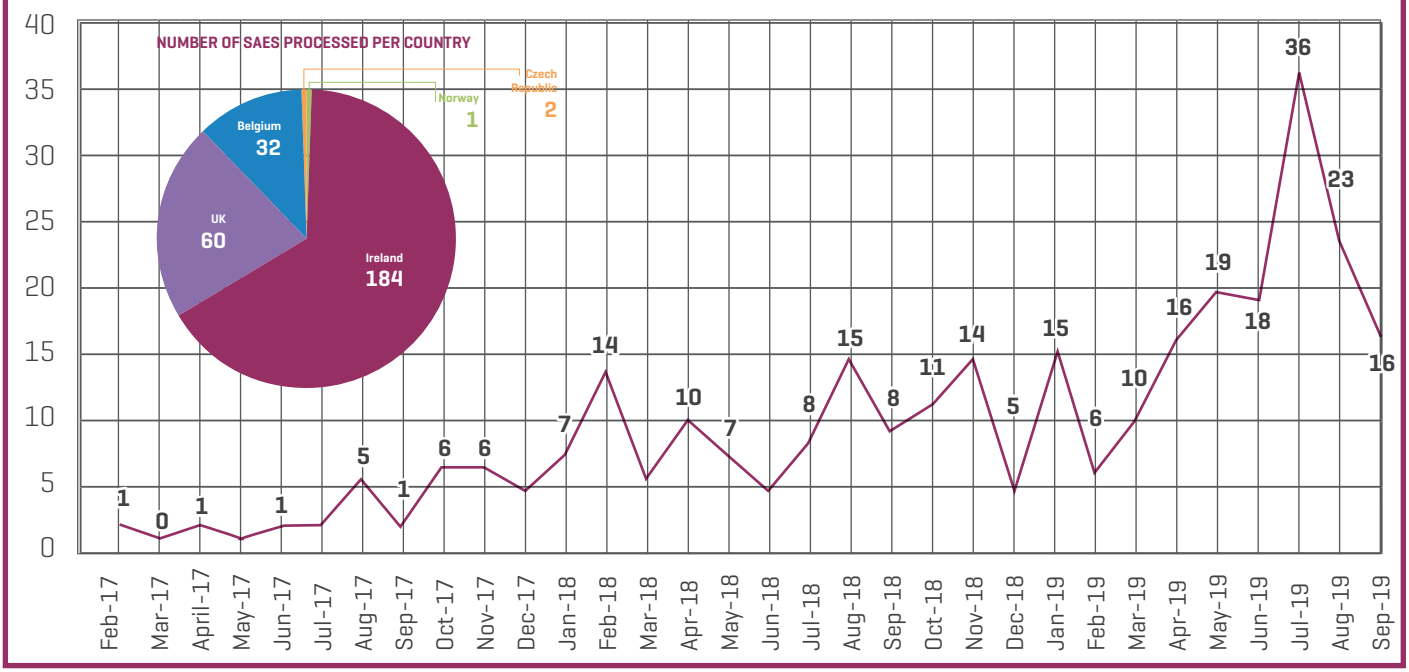
» publication of analysis code and scripts

» documentation of any correspondence between PIs and statisticians.

TRIAL REPORTING

As of 2019, the UCD CRC has a 100% compliance record of results from its completed trials reported on the EU Clinical Trials Registry.

Number of SAEs processed per month



SCIENTIFIC SERVICES

The UCD CRC provides a range of core 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.

SCIENTIFIC SERVICES

- Laboratory support & Training
- Biobank
- Clinical Research SME
- Core Biomarker Facility

LABORATORY SUPPORT AND 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 which includes:

- Cell and tissue culture suites for primary cultures, equipped with sterile cell culture hoods & incubators
- Biomedical laboratories with standard equipment and facilities for sample processing and analysis
- Imaging Laboratory (with contrast and fluorescence microscopy)
- Molecular biology laboratory
- UCD-Abbott Core Biomarker Laboratory which houses an Abbott Architect I2000sr, Abbott Architect CI4100, Alinity CI and a Roche Cobas e411 for high throughput analysis. OPENTRONS O-2 robot and Quanterix SR-X multiplexing ELISA.

The CRC's laboratory instrumentation is calibrated on a routine basis to satisfy regulatory requirements for clinical studies. Laboratory inductions are provided to all personal availing of the facility. The Core Biomarker Laboratory is uniquely set up to cater for academic students enrolled in the CRC's educational programs, so that they may receive practical training in clinical laboratory diagnostics. In 2019, twenty-six new user received training to access the CRC Laboratories that brought up the total number of current users to 59 users between the two sites.

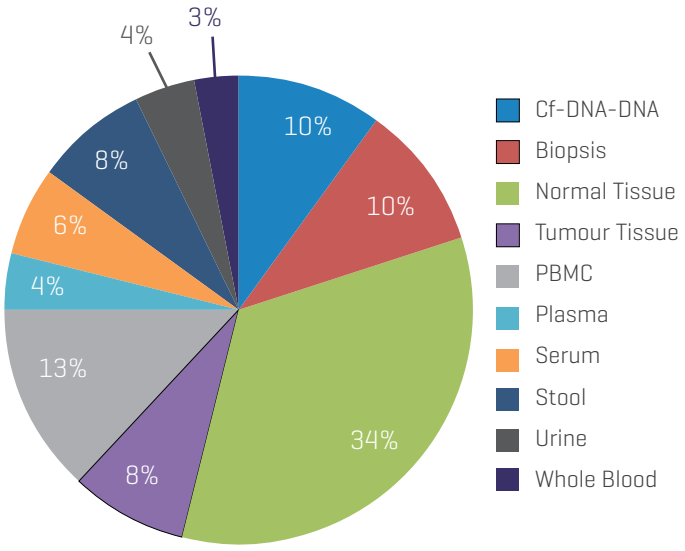
CRC BIOBANK

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. Recognising the importance of access to appropriately consented, well phenotyped and quality controlled biological samples for translational 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. Each site provides:

- Dedicated biobank rooms with temperature monitoring and control
- Multiple freezer units with temperatures ranging from -20 to-80oC (11 -20oC; 4 -40oC and 34 -80oC freezer)
- Large Liquid Nitrogen storage capacity
- 24/7 temperature monitoring of freezers and temperature controlled storage
- Comprehensive security and emergency response plans in the event of temperature excursions or unit failure

To date, there are over 40 biobank study collections currently ongoing in the CRC comprising a total of around 6000 patients recruited since the CRC Biobank was established. Of this total, nearly 350 Patients were recruited in 2018-2019 and a total of almost 2000 samples were processed. The CRC is responsible for generating patient kits for its biobank schemes. The Scientific Services team is also at hand to offer SME in relation to biobank setup and coordination.

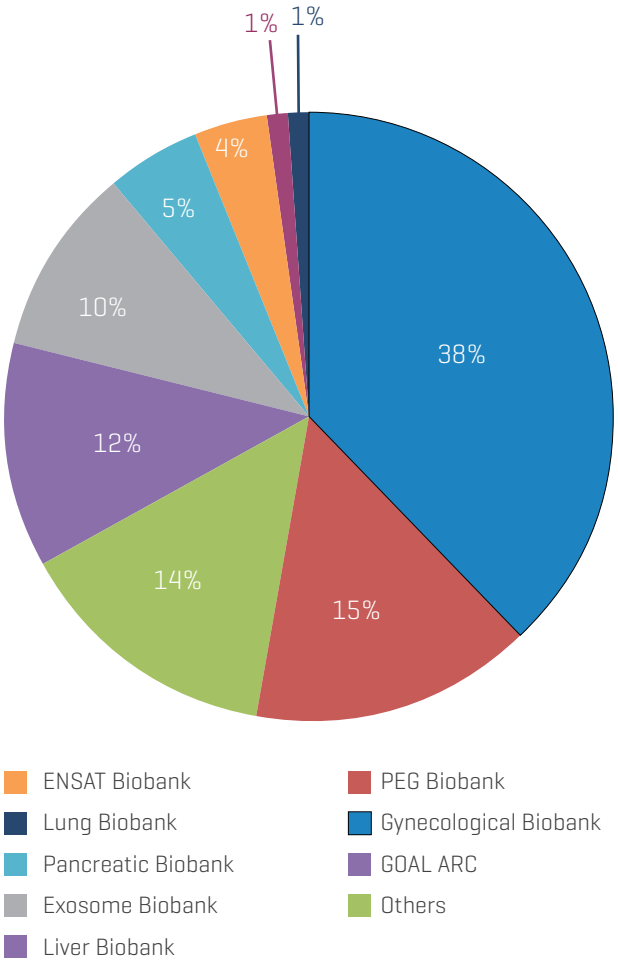
Total Biobank stored samples 2018-2019



Since 2017, the CRC continue to collect for 2 new biobank registries; ENSAT (European Network for the Study of Adrenal Tumours) and PEG (Prostate Cancer Epigenetics Study). Patients collected in 2018-2019 were of 35 across both registries have been recruited providing over 600 samples. The CRC at SVUH is the first Irish based healthcare institution to be registered on the ENSAT network.

In 2018 the CRC also started the collection for gynecological cancer and since the start of the biobank collection in March 2018 the patients recruited have been 170, in 2018-2019: 31 were recruited for uterine cancer and 70 for ovarian cancer. The collection of samples for this biobank is in line with the standard of European Biobank Collection and it is also the most complete collection of samples up to date, including biological fluids, DNA and tissue from up to 30 different sites from cancer and normal tissues.

Total Biobank samples 2018-2019



In 2019, we also consolidate our existing collaboration with Abbott and CRC biobank is now storing over 5000 samples in our 'Bioresource Centre'. The construction of this biobank designated facility facilitates access of local PI to samples collection. The addition of new freezer units, accompanied by the acquisition of a laboratory information system (LIMS), helped further enhance the biobank's efficiency, sophistication and standing within the research community.

CLINICAL RESEARCH STUDY/ INVESTIGATOR INITIATED TRIAL SUPPORT

The Scientific Services division provides support to both clinical research studies and investigator initiated trials sponsored by the CRC. Support comes in the form of patient kit provision, sample logistics, sample processing and sample analysis. SME is offered to collaborators with respect to each component of the study lifecycle. There are currently over 3400 study samples stored in the CRC stemming from around 600 enrolled patients.

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 2018-2019)
- 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 2018-2019 a total of 117 samples were analysed for serum GLM levels and 1114 stool samples were extracted for FCAL. The CRC facilitated the registration of the FCAL assay for proficiency testing with the accreditation agency NEQAS and since 2018 we joined an Alternative Assessment for GLM Assay. Proficiency testing has been successfully completed on a monthly basis since May 2017 for FCP and from January 2018 for GLM.

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 four state-of-the-art high-throughput analysers including an Architect CI4100 integrated platform, which offers a wide test menu covering both clinical chemistry and immunoassay testing. An Architect I2000SR immunoassay analyser installed Q1 2016, offering an increased throughput of assays per hour and a Cobas e411 immunoassay analyser installed Q1 2017, which affords the Core lab facility an expanded testing panel to accommodate the testing requirements of our collaborators and local investigators. A new Alinity CI from Abbot was installed in early 2019. The Scientific Services team has implemented ELISA based testing for a number of research projects, acquiring the necessary automated apparatus for plate washing and reading. In 2018 an automated platform for plating ELISA samples has also been installed and in 2019 a new Multiplex automated ELISA's platform Quanterix SR-X has been installed in summer 2019.

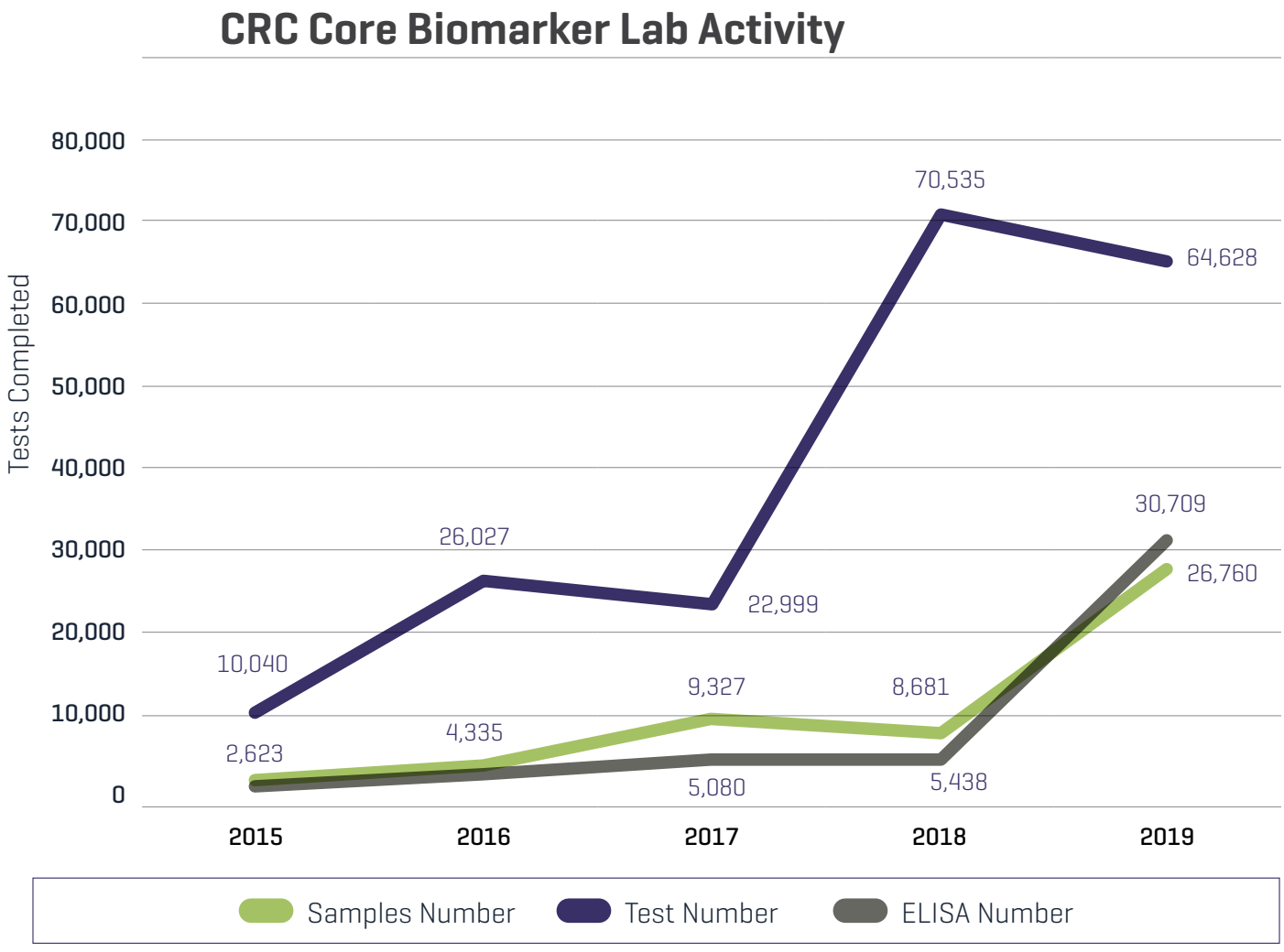
In the last year, nearly 80,000 tests have been completed on over 10,000 patient samples by the CRC Core lab. The majority of research projects undertaken by the core lab in the last year predominantly focus on three main disease areas: Cardiology, TBI and Diabetes.

Moreover an additional collaboration with an industrial partner started in early 2019 that involved method comparison and validation of new formulation's markers.

A total of almost 65000 tests have been completed by the CRC Core Lab on over 25000 samples. For the 65000 test, 30000 were on ELISA's platform.

Since 2016 testing commenced on 2 main cohort studies in order to assess known and experimental biomarkers of Traumatic Brain Injury (TBI). In 2018 TBI study added a new TBI Cohort A and Adaptive for which a schedule to run until the end of 2022. On this new Cohort, 23 markers will be tested on each samples including 11 ELISA, 3 markers on Roche and 9 markers on Architect platform. A new study involving the Quanterix platform started in July 2019 and it will run until the end of 2020. In 2018 our study collaboration has expanded further to include cardiology studies.

In 2019 we started a collaboration for method comparison that has been brought 4 new project since the beginning of the year.

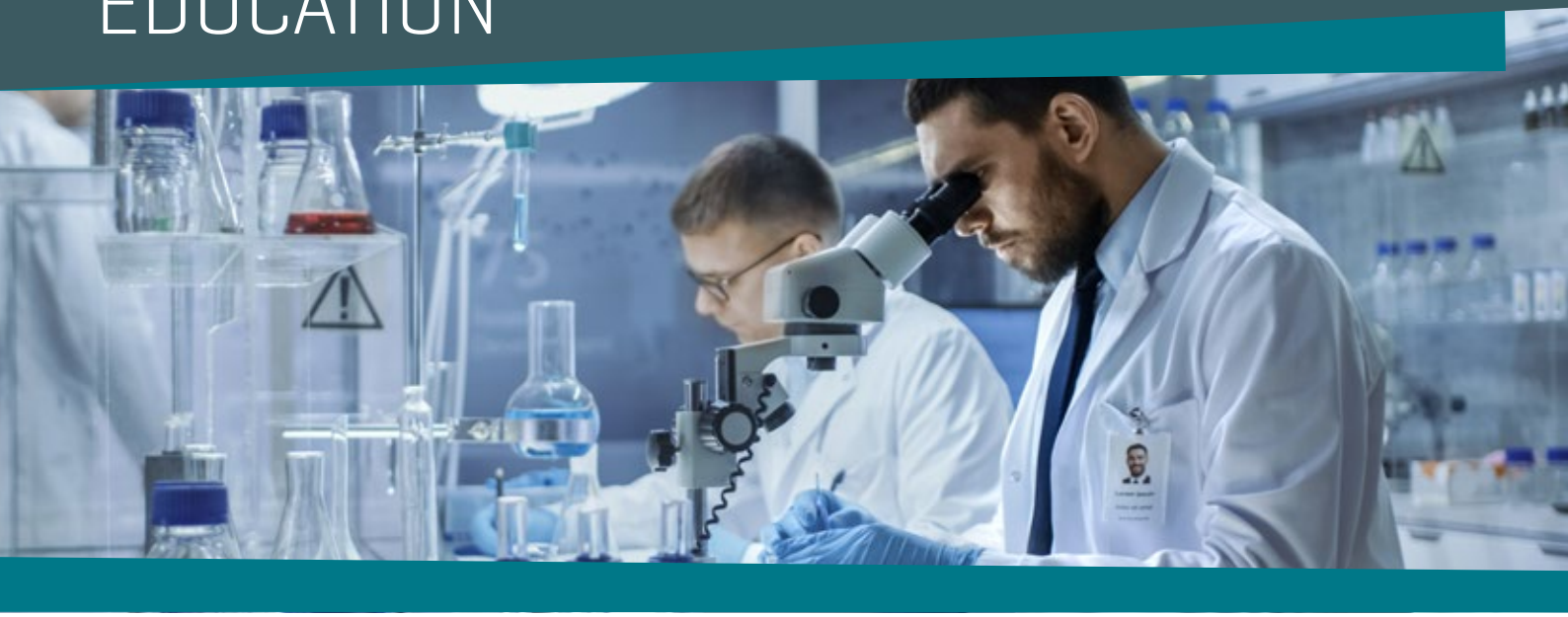


Title	Cohort	Markers	Elisa	Test Number	Elisa Tests	Test Done/Comments
Biomarkers for prediction of cardiac events and mortality after non-cardio surgery (VINO)				0	0	Ongoing
TBI (2017)	TBD			8505	2720	Ongoing
Cohort 3	2600	hsCRP, S100*, NSE*		7800		Samples Received
Testing of Subjects with Head Injury (TBI)	TBD			10487	5710	Ongoing
AROMI (Accelerated Rule Out of Myocardial Infraction)	10000	1	0	10000	0	End: September 2019
Testing of Subjects with Head Injury (TBI)	3000	0	5	15000	15000	Ongoing First Batch Of 3000- Finish Testing June 2020
Testing of Alinity hsTnI 99%ile Evaluation on Healthy Normals	1000	2	0	2000	0	Ongoing-Finish November 2019
Thyroid Biomarker performance characterization testing ARCHITECT and Alinity				1100	0	Received All Samples
Abbott Stress Delta Biomarkers for ACS Risk Stratification	500	2		1000	0	End: October 2019

NOTABLE ACTIVITY 2018-2019

- **Core Lab:** Expanded our collaboration with Abbott from 11 studies in 2018 to 15 ongoing studies in 2019, a total of 65000 tests have been completed on over 25000 samples. For the 65000 test, 30000 were on ELISA's platform. Upon completion of the 15 studies a test completion of nearly 165,000 tests by the end of all the studies of which almost 50,000 on ELISAs platform.
- **Biobank:** CRC Bioresource Centre has been created and continue to grow, 3 new freezers were added to the previous resources, new Biobank collaboration started with Industrial partners.
- **GOAL-ARC:** 117 samples analysed for the bioavailability of Golimumab (GLM) in patient serum by ELISA. Extraction of Calprotectin from 114 stool samples for analysis at the MMUH immunology department. Accreditation for both markers.

EDUCATION

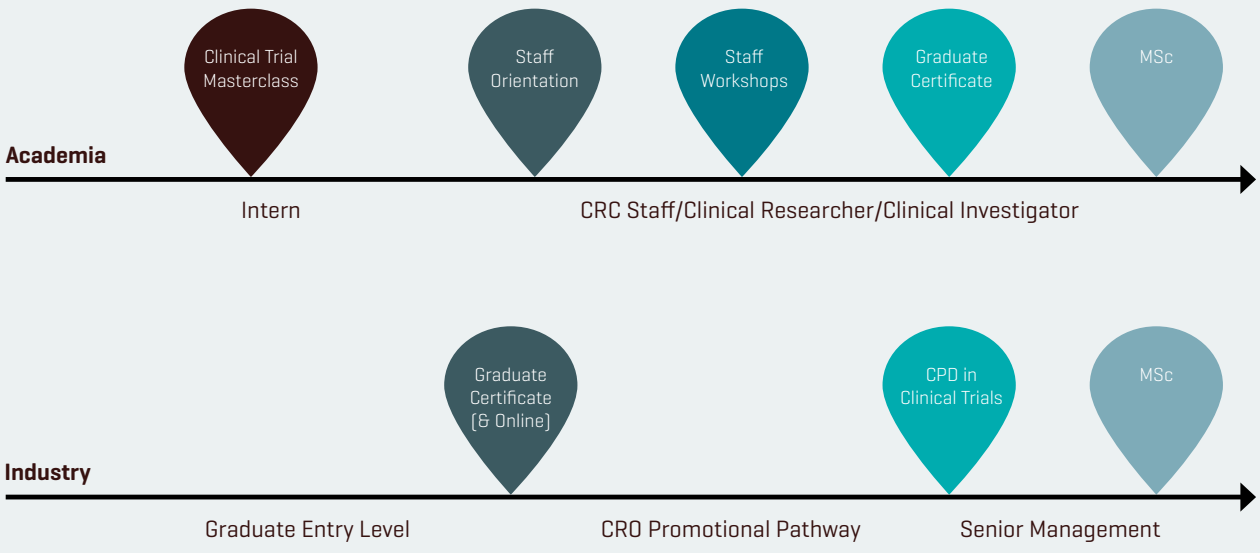


PROGRAMME OVERVIEW

The capability of the Clinical Research Centre to deliver career-spanning relevant and innovative educational programmes is evident through facilitation of education and training opportunities for both students and staff. The academic year 2018/19 has seen the continued success of our educational programme in clinical and translational research. Our industry focused Graduate Certificate in Clinical Research was delivered in-class and online and the MSc in Clinical and Translational Research saw a growth in popularity. Additionally, in 2018/19 we facilitated an online course in Biostatistics for hospital-based researchers, a Clinical Trials Masterclass for Interns and a Patient Education Programme in partnership with IPPOSI.

The motivation for establishing our graduate programmes is to train the next generation of investigators and research professionals who will lead cutting edge clinical research into the future. We value high quality clinical research as the means to ensure novel interventions are developed to improve patients' lives. Our programmes are delivered in an active Clinical Research Centre, thereby ensuring students are taught by and gain experience alongside expert staff and internationally renowned investigators. This unique learning environment exposes students to high quality clinical research. A comprehensive programme of hands on practical experience is a core element of the course, complementing classroom based learning as well as the skills and knowledge to appraise, evaluate and enhance clinical research. Student assessment is focused on evaluating practical as well as theoretical skills and knowledge.

NEEDS-BASED EDUCATION AND TRAINING



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. The option of two year version is very popular for those in full time employment.

Graduate Certificate in Clinical Research (X635)

The certificate is intended to develop employment ready experts, who will implement clinical research programmes to the highest ethical, regulatory and scientific standards. Our graduates are industry ready, internationally mobile and adequately skilled to pursue successful clinical research careers.

Online Graduate Certificate in Clinical Research (X787)

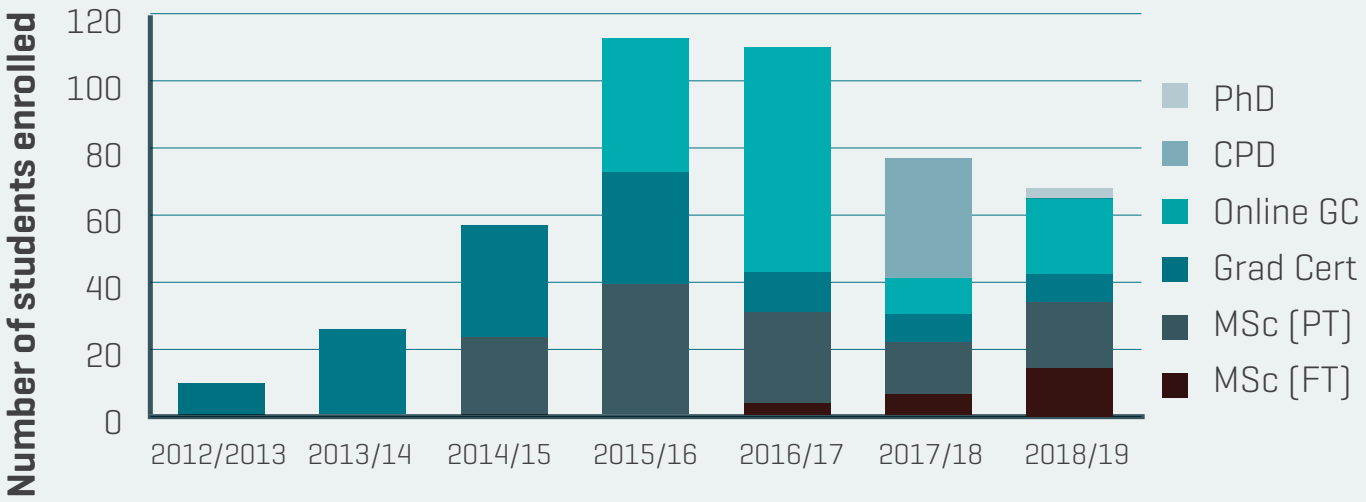
The strategy of the online graduate certificate course is to meet the staff development needs of the multinational Clinical Research Organisation and pharmaceutical sectors. Delivery of this programme utilises innovative Virtual Learning Environments such as recorded lectures, storyboards, videos, discussion boards, weekly quizzes and assignment based learning and assessment. The e-learning delivery methodology used for this course reflects the global nature of the student body and exemplifies UCD's strategic ambitions around both external partnerships and internationalisation. This is a truly international programme with the current class including students from over 20 countries demonstrating how an Irish based postgraduate programme is having a global impact.

PROGRAMME STRUCTURE AND MODULES

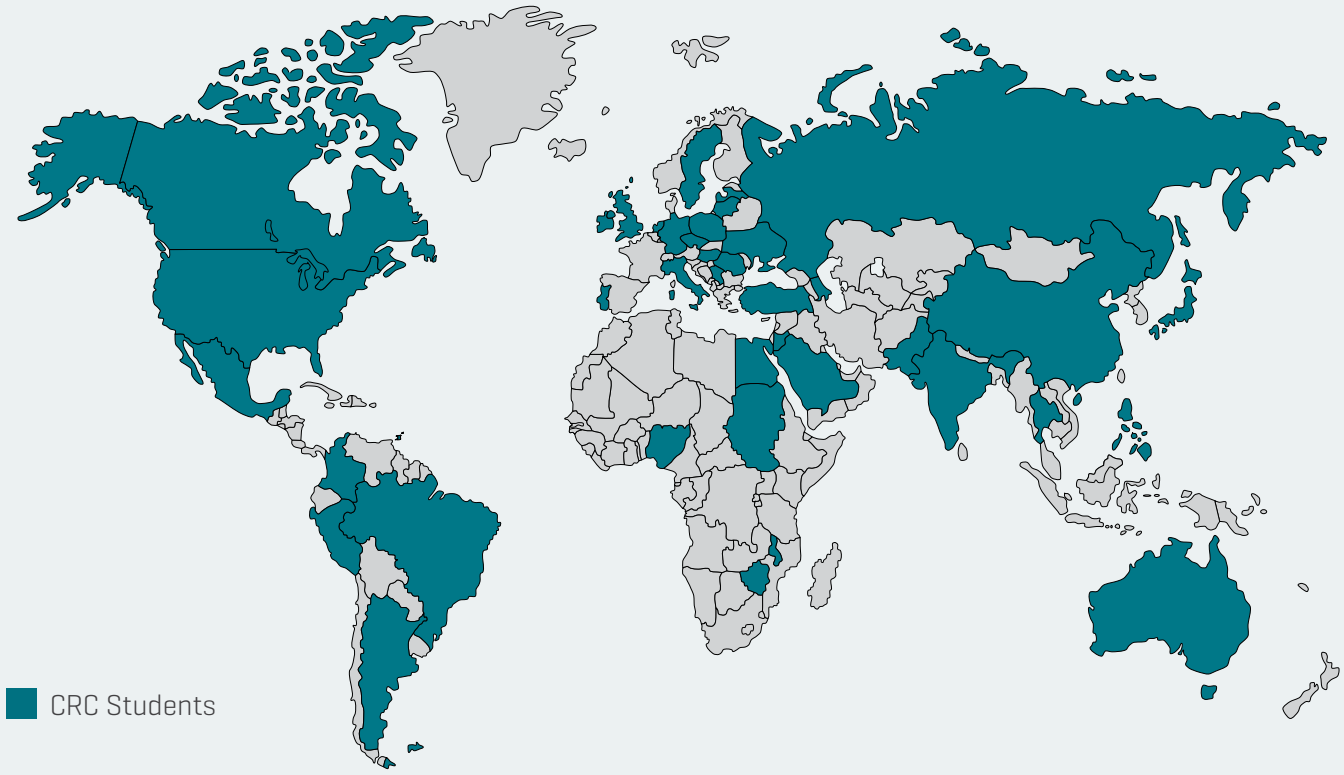
Module/Major	**MSc FT** (X789)	**MSc PT Yr 1** (X427)	**MSc PT Yr 2** (X427)	**Grad Cert** (X635)	**Online Grad Cert.** (X787)
MDCS41630 Principles and Practice in Clinical and Translational Research	S1	S1			
MDCS41950 Biostatistics and Data Management	S1	S1		S1	
MDCS41640 Clinical Trials	S1		S1	S1	
MDCS41900 Clinical Protocol Development	S2	S2			
MDCS41890 Principles of Laboratory Medicine	S2	S2			
MDCS41940 Clinical Trial Management	S2		S1	S1	
MDCS41880 Research Project	ST		S2		
MDCS41970 Clinical Trial Management (online)					S1 S2
MDCS41890 Clinical Trials (online)					S1 S2
MDCS41990 Biostatistics and Data Management (online)					S1 S2

S1 Semester 1 S2 Semester 2 ST Summer Term

STUDENT ENROLMENT



GLOBAL STUDENT ENROLMENT INTO OUR EDUCATION PROGRAMMES



Dr. Deborah Wallace, Dr Sebastian Vencken (UCD CRC), Dr. Derick Mitchell (IPPOSI) and participants of the "Understanding Clinical Trials" module delivered as part of the patient education programme 2019

Introduction to Biostatistics

This course was designed to provide introductory-level statistical training to staff at St Vincent's University Hospital Dublin and Midland Regional Hospital Mullingar. Content covered included basic statistical theory and introductory training in the statistical software, IBM SPSS with the live and online lectures delivered over 6 weeks in early 2019. Eventually, this course will be available to all staff in the Ireland East Hospital Group and will focus on clinical research, study design and biostatistics.

INTERN NETWORK EXECUTIVE

Clinical Trial Masterclass: National Academic Track for Internship

The Intern Network Executive oversees intern training in collaboration with medical schools. 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 on September 8th 2018 at the UCD Catherine McAuley Centre. 24 UCD Interns and 11 Academic Track interns from UCD, UCC & UL attended the event. This Masterclass is a formal teaching event facilitated by the UCD Intern Network and the UCD Clinical Research Centre supporting the Academic Track Intern Programme with the aim of fostering participants' curiosity in pursuing a career as an academic clinician. The Masterclass covered topics such as Drug Discovery and Development, Preclinical Trials, Knowledge Generation, Trial Principles & Design, Statistical Considerations- Hypothesis Testing, Power, Sample Size & Randomisation/ Blinding, and Study Endpoints.

"We got loads of great hands-on experience. I went in not knowing about clinical trials, e.g. the regulatory and ethics side, and I really learned a lot. Learning about the project management of trials was great – learning about monitoring, site visits etc. The guest lecturers were excellent. It was great to hear from PIs, and also from all the different roles at the CRC. Everyone was interested in helping us. One of the best decisions I ever made was to do the Graduate Certificate. There are no other similar courses going in Europe that are of the same calibre".

Graduate

Patient Education Programme

The CRC Education team successfully delivered the Clinical Trials module as part of the pilot Irish Platform for Patient Organisations, Science and Industry (IPPOSI)-led Education Programme by means of approximately 40 purposely-designed online lectures, weekly discussion forums and three face-to-face workshops. 24 students were enrolled by IPPOSI and commenced the module in January 2019 with a face-to-face session at UCD. This was followed by ten weeks of online lecture content. In total, three CRC-facilitated face-to-face workshops took place; at the start, mid-point and the end of the ten week period and included training in Good Clinical Practice for the participants. Subsequently, the students completed modules delivered by the Health Products Regulatory Authority and Trinity College Dublin. The envisaged output of this programme is to create a research-informed patient group / patient advocates as part of the wider research-driven Patient and Public Involvement (PPI) initiative.

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 on hospital sites 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 i2000SR, ARCHITECT ci4100, the new Alinity ci and the Roche Cobas411 high throughput analysers. Also a Quanterix multiplex Elisa machine was added to the portfolio in 2019.

Recognising the importance of access to appropriately consented, well pheno-typed 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 monitoring and control
- Multiple freezer units with temperatures ranging from -20 to-80oC (11 -20°C; 4 -40°C and 34 -80°C freezer)
- Large Liquid Nitrogen storage capacity
- 24/7 monitoring of freezer and temperature controlled storage
- Comprehensive security and emergency response plans

NETWORKS AND PARTNERSHIPS

HRB-TMRN

The UCD CRC is an active member of the HRB Trials Methodology Research Network. It has promoted 25 HRB-TMRN workshops, funding calls and activities to UCD researchers, students, alumni and IEHG hospital staff. It has organised its own HRB-TMRN-funded workshop on "Correctly reporting your clinical trial" and has actively contributed to the annual HRB-TMRN Symposium.

CLINICAL RESEARCH CENTRE AT WEXFORD AND KILKENNY

Through our partnership with the Ireland East Hospital Group (IEHG) the UCD Clinical Research Centre (CRC) has expanded its research programme to St Luke's and Wexford General Hospitals. This is part of the IEHG and UCD's joint commitment to ensure patients in the hospital group, regardless of geography, are provided access to cutting edge research and care.

Research Oversight Committees have been formed in both hospital and are operating on both sites. Two potential studies, and one study amendment, have been filed with the South-East Ethics Committee with a view to launching early in the first quarter of 2020, in both hospitals. A positive site assessment was held in Wexford General Hospital with a view to the hospital being part of a teenage obesity study. he team continuously assess the potential for the other studies to be run at Wexford and Kilkenny.

COLLABORATORS AND SPONSORS OF CURRENT STUDIES INCLUDE:

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 meetsquarterly.

CRC MANAGEMENT COMMITTEE

The UCD CRC Management 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, report to the UCD CRC Operations Committee.

CRC NURSE MANAGEMENT GROUP

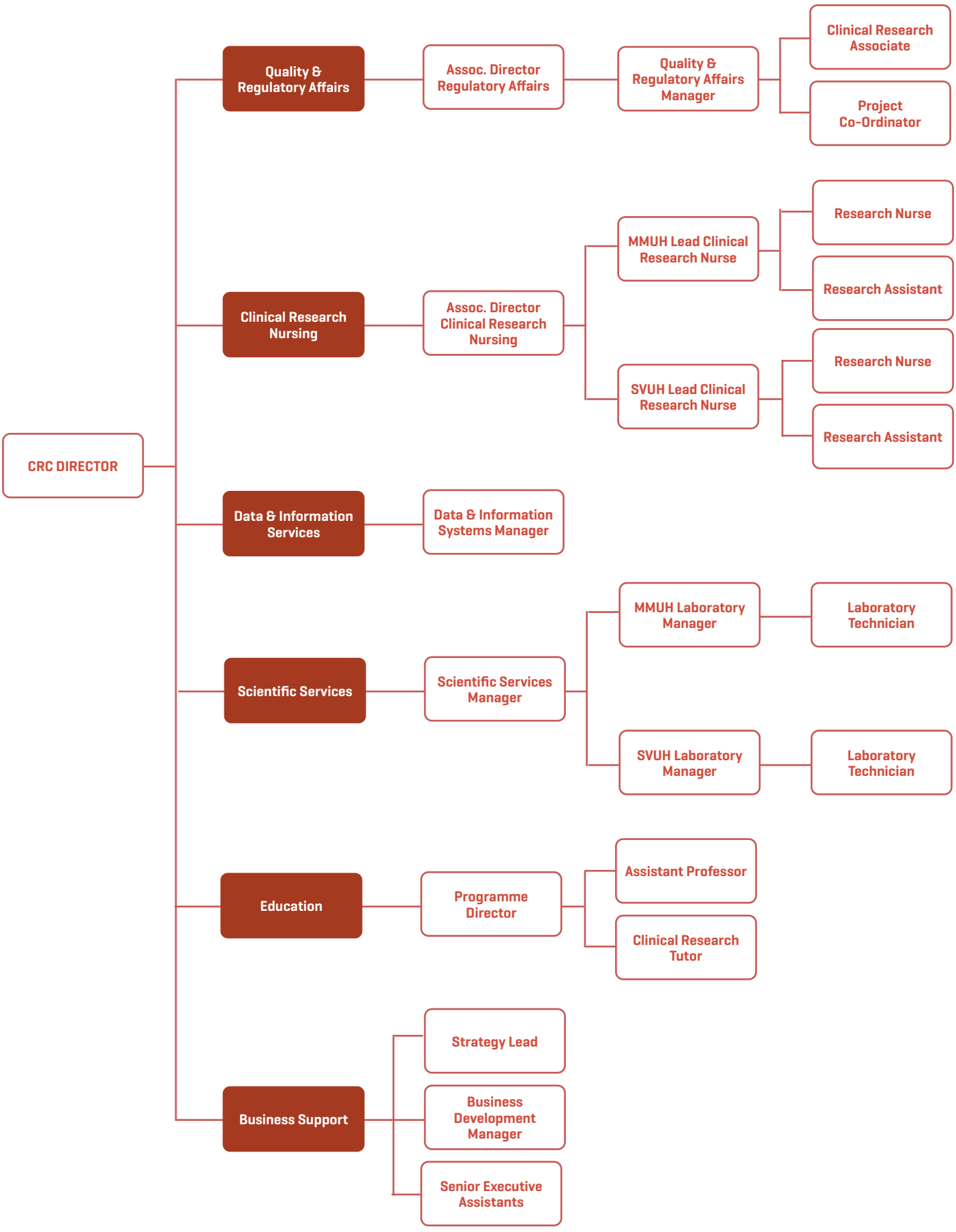
The management of nurse workload assignments, training and recruitment are coordinated through the Nurse Management Group. Chaired by Terri Martin, the group reports to the UCD CRC Operations Committee.

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

UCD CLINICAL RESEARCH CENTRE ORGANOGRAM



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

UCD CLINICAL RESEARCH CENTRE

WWW.UCD.IE/MEDICINE

T: +353 1 716 4587
E: CRC@UCD.IE