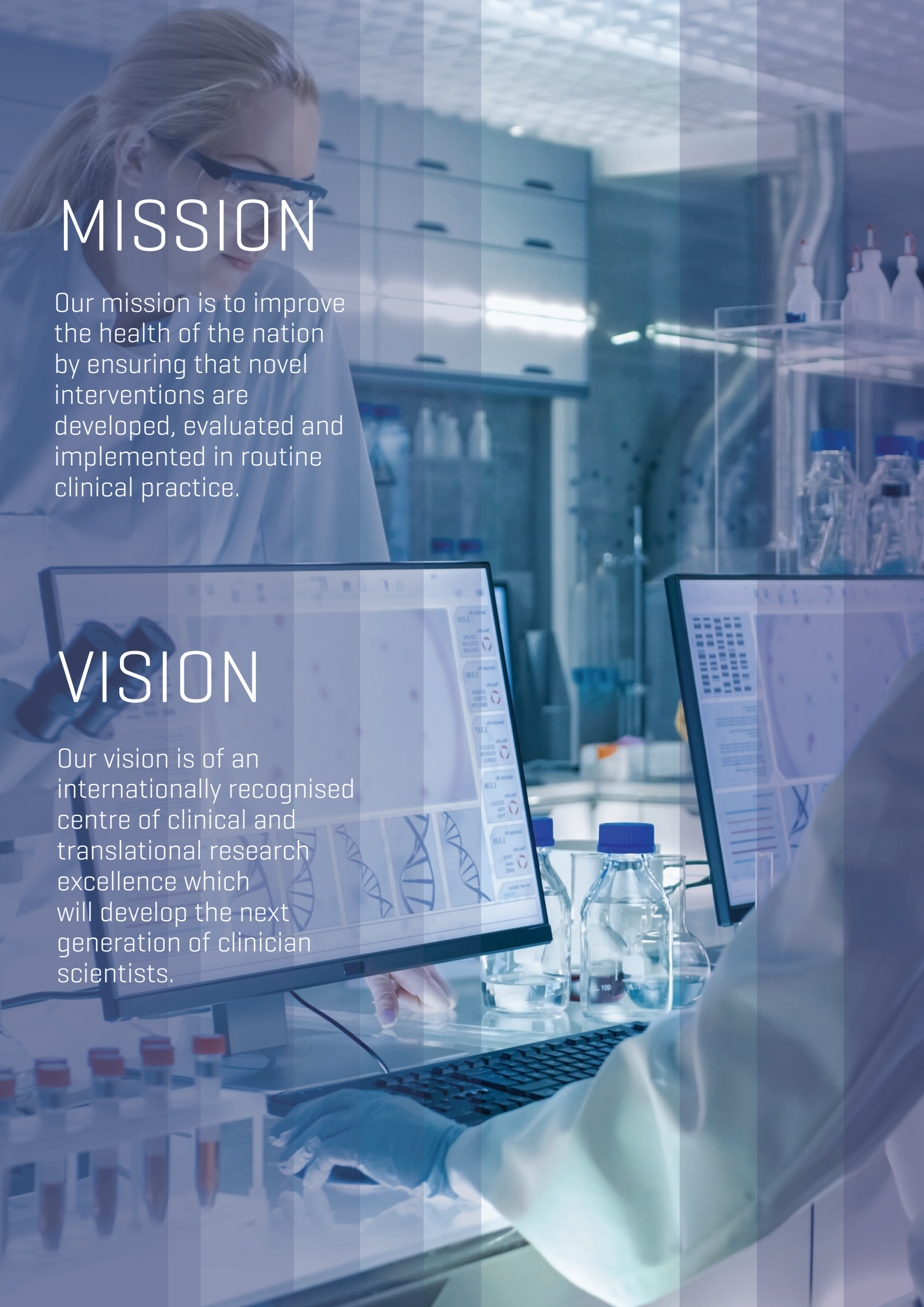
UCD Clinical Research Centre
UCD School of Medicine

UCD CLINICAL RESEARCH CENTRE

ANNUAL REPORT 2017/2018



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 welcome you to the 2017/18 annual report of the UCD Clinical Research Centre. This report describes in great detail the continued achievements and success of the UCD CRC across all of its activity domains. From increases in the number of investigator initiated clinical trials to significant growth in activity in our biomarker laboratory we continue to show strong growth in areas of importance to our hospitals, to our investigators and to our patients. This is the third in a series of reports which provides an update on progress in delivering the ambitions of the UCD Clinical Research Centre – Strategic Priorities 2015-19 document.

In addition, during the 2017/18 academic year we have taken on a leadership role within the Ireland East Hospital Group. By expanding the remit of the UCD Clinical Research Centre across the hospital group, we stand to further increase our activity and support additional hospital sites. Substantial progress on developing additional sites is expected over the coming year

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. The support of the School of Medicine and the College of Health and Agricultural Sciences is critical to our continued success.

Like all major programmes, ours is dependent on the expertise, passion and commitment of the CRC team, without whom we would not be at the leading edge of clinical research nationally and internationally.

Prof Peter Doran & Prof Patrick Murray

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I am delighted to introduce the UCD Clinical Research Centre 2018 Annual Report. As stated in the UCD College of Health & Agricultural Sciences Vision, Mission and Strategic Objectives document, the Research objective of the College is to increase the quality, quantity and impact of our research, scholarship and innovation. New knowledge is at the heart of what a university is, and the College is strongly committed to excellence in research and innovation to deliver impact locally, nationally and globally. By building an outstanding base of scholarship within all our disciplines, we deliver knowledge and ideas that inform policy, support enterprise, deliver innovation, and enrich society. 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 has a vital role within the College and is integral to this strategy. 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. The CRC has been recently charged with supporting research for the IEHG, which serves as an important mechanism to further embed the university hospital relationships.

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 would like to congratulate the UCD Clinical Research Centre team on the significant progress reported in this annual report. As a component of the UCD School of Medicine, the UCD CRC is founded on commitment to research and education and a shared vision of improving patient outcomes. It is very encouraging to see the continued strength of this programme in delivering this vision.

The UCD School of Medicine is the largest school in the University and is part of the College of Health and Agricultural Sciences, which contains a range of cognate disciplines. Research within the School of Medicine includes basic biomedical research as well as clinical and translational research. The School boasts some of the leading researchers in the University, and some of the leaders worldwide within their research domains, as recognised by prestigious awards, citation metrics and other esteem indicators. This includes clinician academics, whose research activities account for a very significant fraction of school funding and performance. The UCD CRC is a major component of the School of Medicine's research focus and has been created to deliver the strategic objective of advancing high-quality, impactful investigator-led translational and personalised medicine research. It is aligned with UCD's vision of being a research-intensive university by supporting the 'bench to bedside' translational research continuum. Importantly, the centre also delivers high quality education programmes to serve the future staffing needs of the academic and industry sectors both domestically and internationally.

By providing leadership in patient-focused research, the Clinical Research Centre is enabling investigators to complete impactful studies, is a focus for the training of new research professionals and is enhancing our partnership with our hospitals.

I want to thank all of the UCD CRC team for their continued hard work and I look forward to its continued growth and impact.

Prof Michael Keane
Head of UCD School of Medicine

UCD CLINICAL RESEARCH CENTRE

IN NUMBERS

CLINICAL RESEARCH

242 STUDIES

65 NEW STUDIES

5959 PATIENTS

132 CLINICAL TRIALS

SCIENTIFIC SERVICES

2921 PATIENT SAMPLES BIOBANKED

253 GOLIMUMAB ASSAYS

76,000 BIOMARKERS ON 100,000 PATIENT SAMPLES

7,470 ELISA MARKERS ON 1,900 PATIENT SAMPLES

QUALITY & REGULATORY AFFAIRS

6 DSUR REPORTS

3 CSR REPORTS

3 HPRA APPROVALS

58 UCD CRC SOPS

48 STAFF COMPLETED TRIANING RECORDS

19 INVESTIGATOR INITIATED TRIALS

EDUCATION

6 EDUCATION PROGRAMMES

10 MODULES

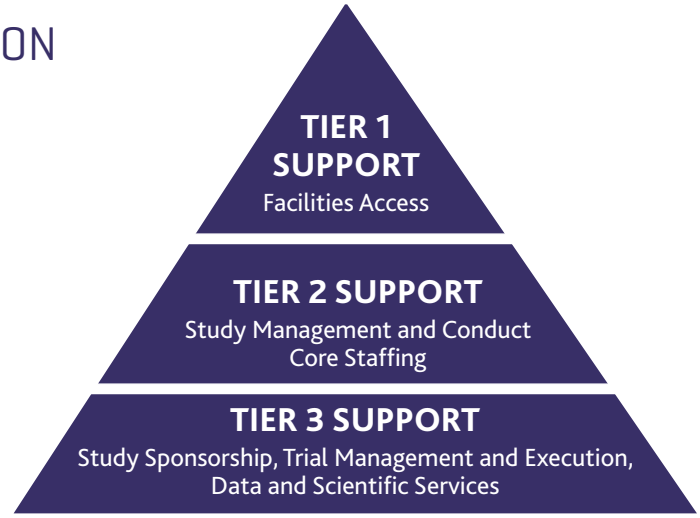
76 STUDENTS

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



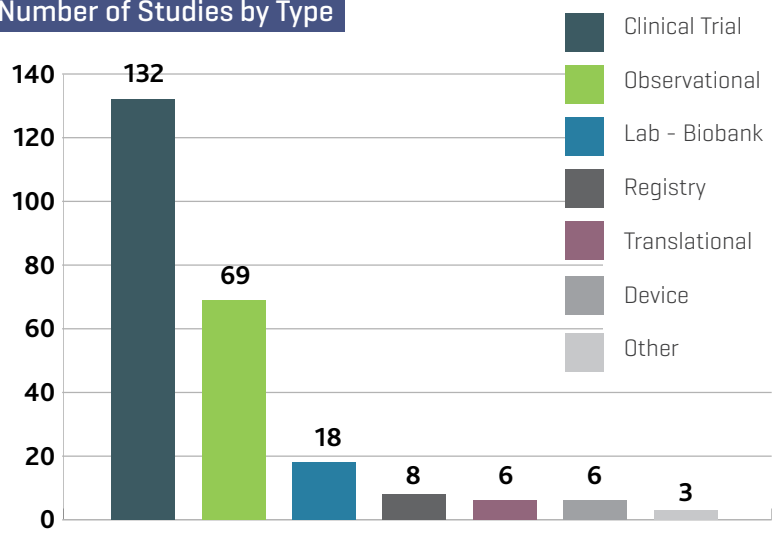
- A cohort of professional and experienced research scientists, data managers and clinical research nurses that can ensure studies are conducted and managed to the highest levels of quality
- Complete study management, oversight and sponsorship

SERVICES AVAILABLE TO INVESTIGATORS

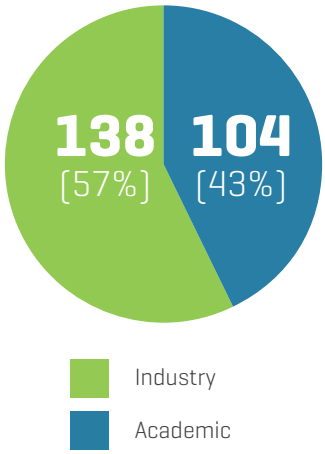
Proposal Phase	Pre-initiation Phase	Study Contact Phase	Reporting Phase
Grant Application	HPRA & Ethics submission	First Patient In	Last Patient Last Visit
Budget Review	Investigator Site File	ISF Maintenance	Study Close-out Visit
UCD Sponsorship	GCP Compliance & Training	Study Monitoring	End of Trial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

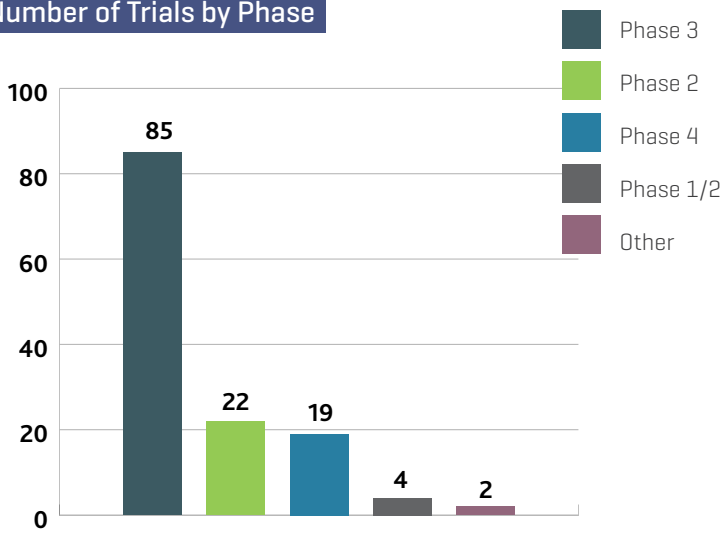
Number of Studies by Type



Number of Studies by Origin



Number of Trials by Phase



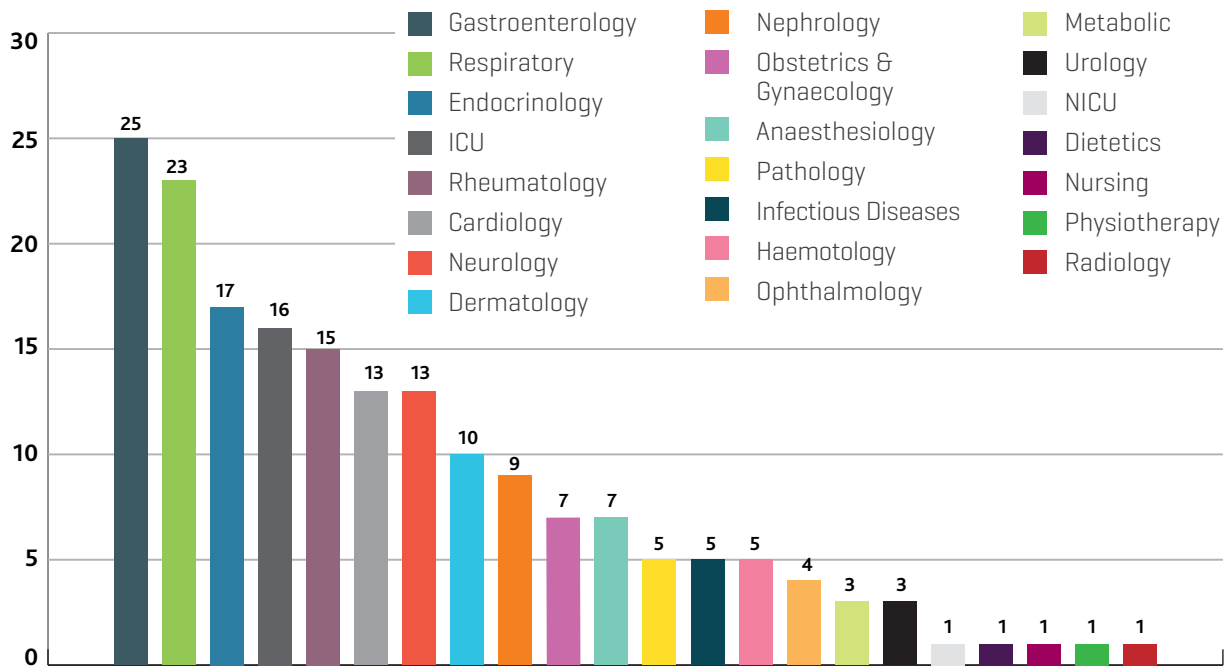
5,959

PATIENT CONTACTS ACADEMIC YEAR 2017/18

62

NEW CRC STUDIES 2017/18

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 sponsored 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
- 48 Staff completed SOP Training and Training Record Review with UCD Quality & Regulatory Affairs Manager.
- 2 International UCD Sponsored Clinical Trials approved by the HPRA currently active (CONVINCE & POPART)
- Active participation with the HRB-CRCI across 5 academic clinical research facilities in Ireland.
- 15 New CRC staff completed staff induction and orientation

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

DERMMARK

GOAL-ARC

TAISTR

APART

CONVINCE

NAPRESSIM - Statistical analysis being completed

TEST - CSR submitted

VITAMIN-D – CSR submitted

GLP-1 – CSR submitted

DIP – Study completed

DINUP – Study completed

Sponsored studies include:

Study	Chief Investigator	HPRA Approval Date	No of Patients in Ireland	Update
GOAL-ARC	Prof. Glen Doherty	Dec-2015	61	6 sites in Ireland. Protocol Amendment implemented in all sites
POPART	Prof. Colm O'Donnell	Jan-2017	50<	EU submissions – Czech, Finland, Sweden, Norway, Spain, Portugal, Italy, Denmark Non-substantial Amendment EU Approvals CRA Training & SIVs scheduled
GLOBE	Prof. Fionnuala McAuliffe	Mar-2017	2	Consenting issues addressed – re-training, increased monitoring, additional SOPs
DERMMARK	Prof. Brian Kirby	Aug-2016	9	DSUR #2 submitted. Protocol Amendment pending
CONVINCE	Prof. Peter Kelly	Jun-2016	222	12 sites in Ireland. Plans for expanding the trial to further countries
TAISTR	Prof. Patrick Mallon	Feb-2017	18	Actively recruiting
APART	Prof. Patrick Mallon	Jun-2016	33	Actively recruiting – expanding to Spain

QUALITY & REGULATORY AFFAIRS

During this academic year, the CRC completed their obligatory biennial SOP and quality management system review, with all SOPs which CRC staff operate under, completing a review and approval by the Management team. New SOPs were also introduced in areas such as research compliance, handling deviations and computer systems validation, in accordance with regulatory and GCP requirements. The HRB-CRCI Quality Working Group conducted a 2-day audit of the research facilities following which a Letter of Mutual Recognition was issued to certify UCD meeting the HRB-CRCI's Mutual Recognition Scheme requirements. The CRC has adapted quality management on research activities taking a risk-based approach. In order to support this regular quality review meetings have been scheduled among the research group with pertinent quality activities outlined and discussed with the Management group.

UCD CRC STAFF TRAINING

All staff at the CRC undertook and certified to complete IMP management and Compliance and Management of Deviations training as well as completing a detailed review of staff records for training and compliance with the CRC Quality & Regulatory Affairs Manager, in compliance with CRC SOPs. New staff are also provided with GCP training.

52 staff in total across St Vincent's and the Mater Misericordiae University Hospitals completed the Clinical Research and SOP training as well as a detailed 1-2-1 training record review.

5 CRC Staff members also completed CRA Training with UCD. 6 SIVs completed with complete training given to external research site staff and investigators on UCD CRC Sponsored studies, including areas such as pharmacovigilance, consenting etc.

Qualifications/training of the research staff

- ☑ Staff Orientation
- ☑ Qualification
- ☑ GCP Certificate
- ☑ SOP Training & Compliance
- ☑ Laboratory Induction
- ☑ Basic Life Support Training
- ☑ Hospital Training Completed
- ☑ Fire Training

TRIAL MONITORING

UCD CRC Clinical Research Associates (CRA) work diligently to ensure that clinical trials 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. 2 UCD CRC Clinical Research Associates actively working over 7 clinical trials with 6 SIVs completed for research sites, 22 routine monitoring visits completed and 1 close-out visit completed across UCD and externally sponsored clinical trials. Risk-based monitoring adopted with regular monitoring review meetings with the sponsor Quality & Regulatory Affairs Manager to adapt frequency and level of monitoring for UCD sponsored clinical trials.

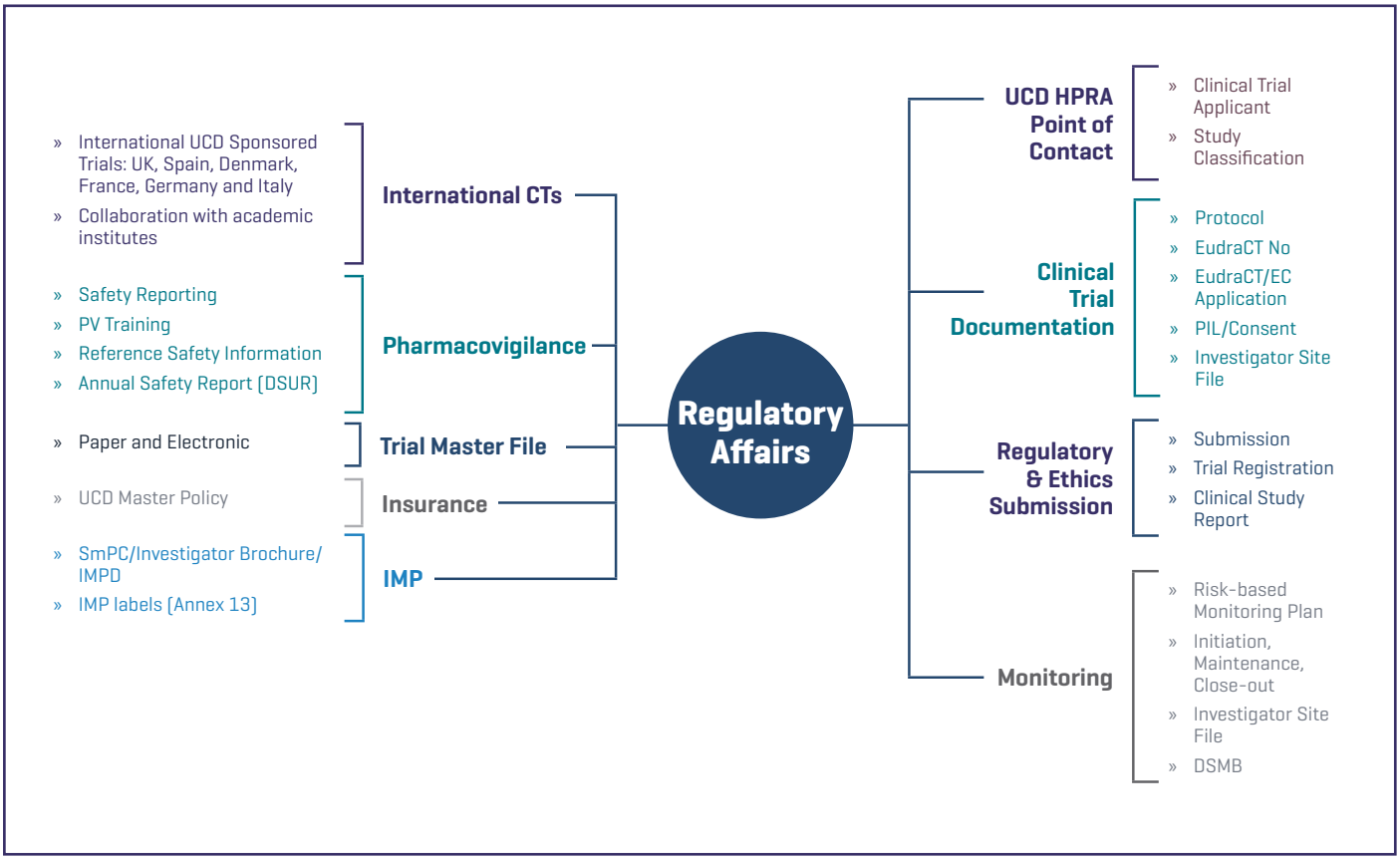
REGULATORY AFFAIRS

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 a 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.

- 2 Protocol Amendments approved for UCD sponsored studies
- 6 Development Safety Update Reports submitted to the HPRA
- HPRA feedback on 8 research studies by UCD CRC researchers – including study classification and general study queries.



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:

- Prospective cohort study on development of a precision medicine framework for the treatment of ovarian cancer
- Observational study on the evaluation of Outcomes in Adult Patients with an Inborn Error of Metabolism
- The OPTImised Computed Tomography Pulmonary Angiography in Pregnancy Quality and Safety (OPTICA) Study

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. 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 supports the following CRC functions:

- **Clinical Database Management System:** collection, management, verification, validation and simple analysis of clinical research study data
  - 13 studies currently collecting data in REDCap: 3 Clinical Trials, 10 Observational Studies
  - 5 studies in development in REDCap: 1 Clinical Trial, 4 Observational Studies
- **Pharmacovigilance Management System:** support assessment, reporting and review of serious adverse event data relating to clinical trials at UCD CRC

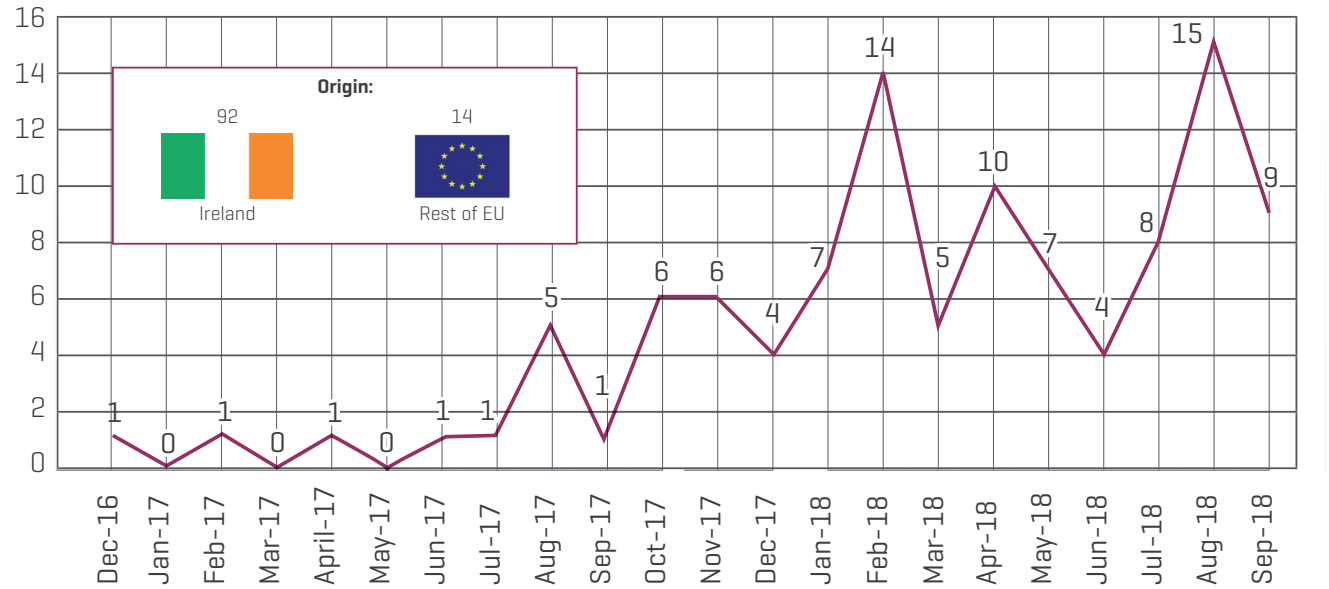
Over the coming year, REDCap will also support:

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

Clinical Trials Management System: Data Logged

242 STUDIES	**5959** PATIENT CONTACTS
53 INVESTIGATORS	**24** THERAPEUTIC AREAS

Number of SAEs processed per month



EU GENERAL DATA PROTECTION 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. The CRC is providing researchers with practical advice and support to comply with these new regulations, and will continue to do so into 2019 as the regulation is fully implemented.

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
- CRC 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 and a Roche Cobas e411 for high throughput analysis. OPENTRONS O-2 robot.

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.

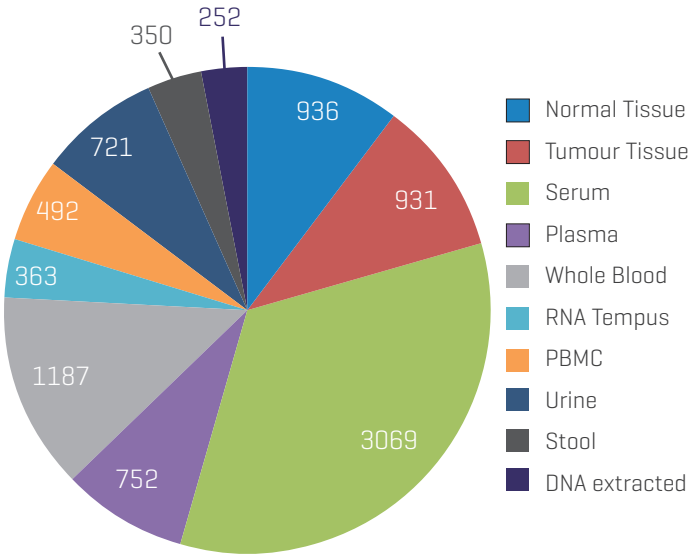
CRC BIOBANK

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; 5 -80oC were added to the Biobank in 2018)
- 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 7966 collected samples. Of this total, nearly 2921 samples were processed alone in 2017-2018. The CRC is responsible for generating over 4000 patient kits for its biobank schemes. The Scientific Services team is also at hand to offer SME in relation to biobank setup and coordination.

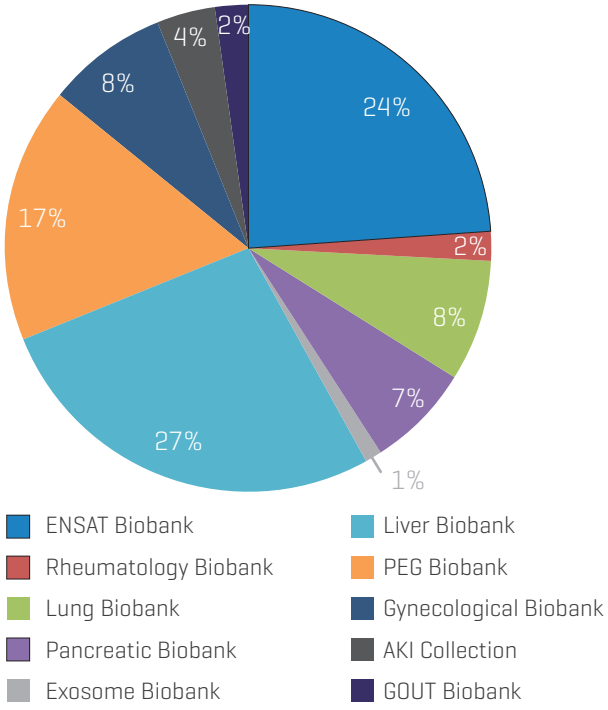
Total Biobank Samples Stored



In 2017-2018, 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 over the first year were of 30 across both registries have been recruited providing over 400 samples, during the second year the patients collected for PEG have been 99 and for ENSAT have been 20 . The CRC at SVUH is the first Irish based healthcare institution to be registered on the ENSAT network.

In 2017-2018 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 30. 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.

Biobank Study Composition



In 2018, we also consolidated our existing strengths in biobanking through infrastructural development and the CRC 'Bioresource Centre' was established. 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. Over 400 of these samples are PBMCs while 390 are extracted DNA.

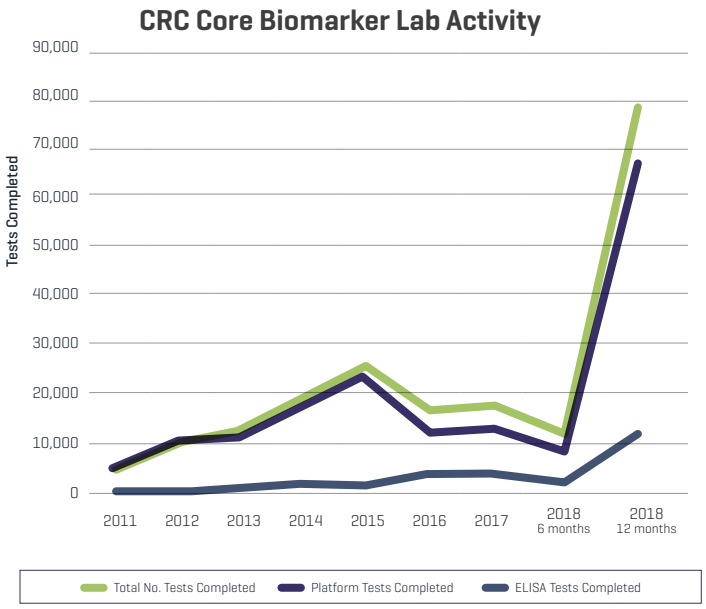
The investigator-initiated 'GOAL-ARC' study is a randomised, multi-centred 2-arm trial studying the effect of dose optimisation of Golimumab based on FCP and GLM drug levels versus standard treatment. The Scientific Services team has been actively involved in this trial since its inception. Our support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

- Providing patient kits to each of the six sites registered with this study (over 500 kits provided 2017/2018)
- 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

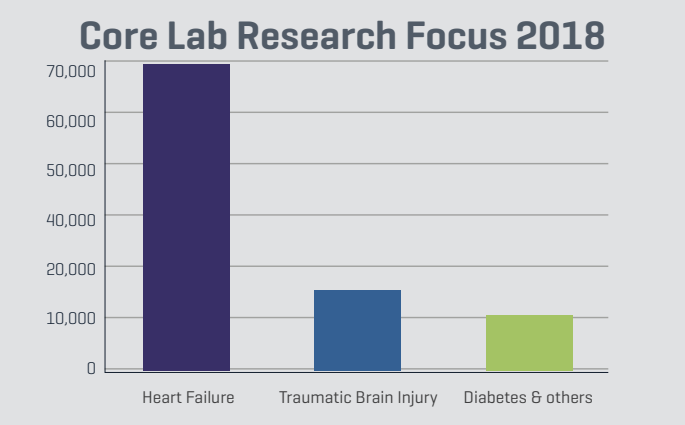
In 2017/2018 a total of 184 samples were analysed for serum GLM levels and 194 stool samples were extracted for FCAL. The CRC facilitated the registration of the FCAL assay for proficiency testing with the accreditation agency NEQAS and in 2018 we joined an Alternative Assessment for GLM Assay. Proficiency 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 three 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. Coupled with the installation of automated platforms, 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 in the Core Lab, this will help the Lab team to meet the target of all the incoming collaboration projects.



In the last year, nearly 100,000 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.



In 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. A total of 39000 tests have been completed by the start of the study on 10804 samples. During the 2017/2018 academic year, for TBI over 16000 tests were completed on 6994 patient samples, of which 2720 were ELISAs. In 2018 TBI study added a new TBI Cohort A and Adaptive for which a schedule to run until the end of 2020. 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.

In 2018 our study collaboration with Abbott has expanded further to include 6 different cardiology studies Promise, VINO, GIFT, STOP-HF, Pediatric Hearth Transpland and Seattle Paeds.

During the 2017/2018 academic year, for the Cardiology study over 60000 tests were completed on around 5000 samples, of which 1500 were ELISAs.

A new study AROMI is due to start Q1 2019. In total all this study have a projection of around 23000 samples for a total of almost 89000 test of which 11000 will be ELISA assays. Some of the Cardiology studies will progress for up to 5 year follow up.

Study	Commencing	Samples	Analytes	Tests	ELISA TEST	Status
TBI Cohort 1	Q1 2016	3400	ApoA1, hsCRP, S100* NSE*, NFL**, Free BDNF**, Total BDNF**, Tau**, P-Tau**	30600	17000	Ongoing
TBI Cohort 2	Q2 2016	1200	ApoA1, hsCRP, S100* NSE*, NFL**, Free BDNF**, Total BDNF**, Tau**, P-Tau**	10800	6000	Ongoing
TBI Cohort 3	Q3 2017	5000	hsCRP, S100*, NSE*	15000	0	Ongoing
Promise	Q2 2018	4100	hsTnI, Gal-3, NTpro BNP, Cystatin C, Creatinine, Homocysteine, Beta2, LipA, Glucose, Insulin, ALT, Free T3, Uric Acid	53300	0	CONCLUDED 2018
Paed Heart Transplant	Q2 2018	719	hs-TnI, Gal-3, NTpro BNP, BNP, hs-CRP, IGFBP7**, ST2**	5033	1438	CONCLUDED 2018
VINO	Q2 2018	3000	ST2**, GDF-15**	6000	6000	Samples not received yet
GIFT	Q2 2018	1578	Gamma Prime Fibrinogen**	1578	1578	STARTED 2018
STOP-HF	Q3 2018	2500	hs-TnI, Gal-3, NTpro BNP, SUPAR**	10000	2500	STARTED 2018
TBI A and Adaptive	Q4 2018-Q12019	1000	11 ELISAs, 3 Roche markers, 9 Architect markers	23000	11000	STARTED 2018
Paeds Seattle	Not defined					To continue for next 5 years
Total		22497	*Roche, **ELISA	155311	45516	

NOTABLE ACTIVITY 2017-2018

- **GOAL-ARC:** 184 samples analysed for the bioavailability of Golimumab (GLM) in patient serum by ELISA. Extraction of Calprotectin from 194 stool samples for analysis at the MMUH immunology department. Accreditation for both markers.
- **Core Lab:** Expanded our collaboration with Abbott from 6 studies in 2017 to 11 studies in 2018, promising a cumulative test completion of nearly 165,000 tests by 2018/2019 of which almost 50,000 on ELISAs platform.
- **Biobank:** CRC Bioresource Centre has been created and 6 new freezers were added to the previous resources.

EDUCATION

PROGRAMME OVERVIEW

The academic year 2017/18 has yet again seen an expansion of our educational programme in clinical and translational research. In addition to an industry focused Graduate Certificate in Clinical Research (delivered in-class and online) and the MSc in Clinical and Translational Research, the taught graduate programme now also includes a short intensive Continuous Professional Development (CPD) course in Clinical Trials designed for those from a non-science background. Additionally in 2017/18 we developed an online course in Biostatistics, facilitated Intern teaching and delivered a patient education programme.

The motivation for establishing our graduate programmes is 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 encompasses the integration of research into all 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.

The capability of the CRC to deliver career-spanning relevant and innovative educational programmes is evident through facilitation of education and training opportunities for both academic and industry-orientated students and staff.

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. Over 90% 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 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.

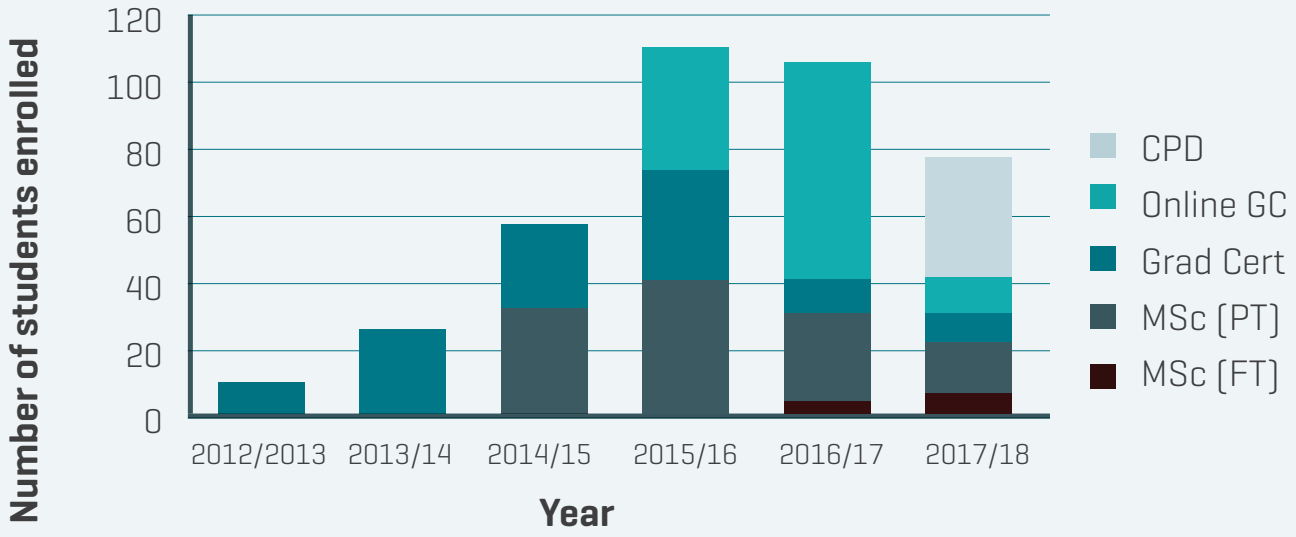
Introduction to Biostatistics

This course is designed to provide introductory-level statistical training to staff in St Vincent's University Hospital. Staff are taught basic statistical theory and provided with introductory training in the statistical software, IBM SPSS. The course is taught over 7 weeks (approximately 1-2 hours/week) and is divided between live and online lectures. Students are also given weekly online exercises. The last enrolment consisted of 85 students. In the future, this course will also be taught at the Mater Misericordiae University Hospital and Midland Regional Hospital Mullingar.

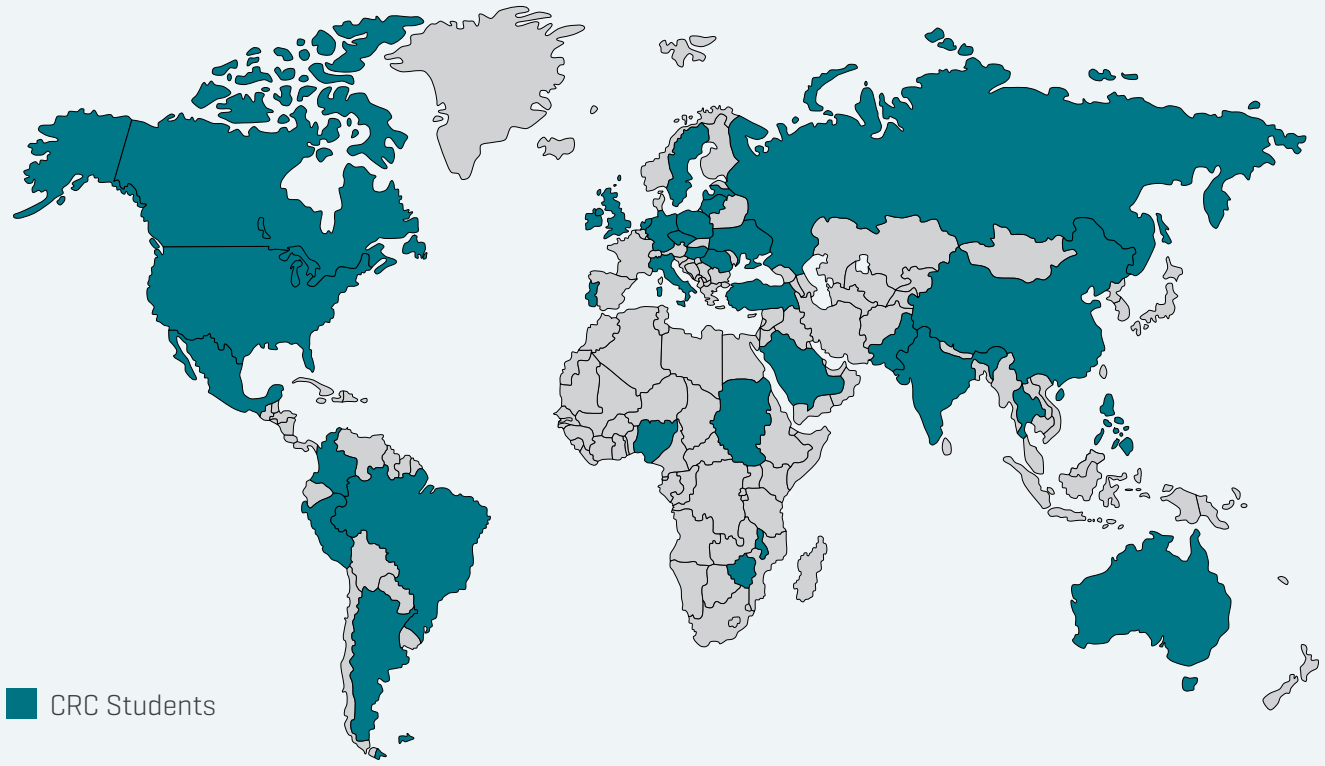
PROGRAMME STRUCTURE

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

STUDENT ENROLMENT



GLOBAL STUDENT ENROLMENT INTO OUR EDUCATION PROGRAMMES



Continuous Professional Development course in Clinical Trials

The CPD Course in Clinical Trials (OCHSS001) arose in response to needs of senior ICON employees 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.

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 in September 2017. UCD Interns including 11 Academic Track interns from UCD, RCSI, NUIG, UL & UCC attended the event. This Masterclass was the opening 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.

Intern teaching

A series of Clinical Trials lectures was delivered as part of the Intern Teaching programme at St Vincent's University Hospital. These lectures provided an opportunity for doctors at the beginning of their clinical careers to learn about key topics in Clinical and Translational Research.

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. Approximately 40 purposely designed online lectures, weekly discussion forums, two face-to-face workshops, as well as significant support from CRC administration and School of Medicine Technology Enhanced Learning permitted the successful provision of this module. 20 students were enrolled by IPPOSI and undertook the Clinical Trials module, commencing in September 2017 with a face-to-face session at UCD. This was followed by five weeks of online lecture content, incorporating weekly quizzes and a discussion forum, after which there was a second CRC-facilitated workshop. Subsequently, students completed modules delivered by the Health Products Regulatory Authority and Trinity College Dublin and Certificates of Completion were presented in March 2018. A second patient education programme is due to commence in early 2019. The envisaged outcome of this programme is to create a research-informed patient group, which will in turn be beneficial to them in their role as patient advocates and as part of the wider research-driven Patient and Public Involvement (PPI) initiative.

"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" .

MSc graduate]

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

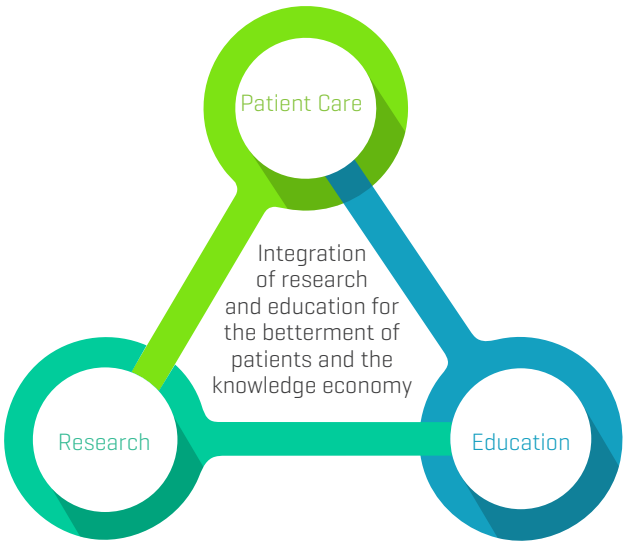
NETWORKS AND PARTNERSHIPS

IEHG RESEARCH NETWORK

Strategic Context

The Ireland East Hospital Group, with its academic partner UCD, is evolving into an Academic Health Science Centre (AHSC). This strategic shift reflects international experience that demonstrates that the integration of research and education in an Academic Health Science Centre Model improves patient care and accelerates the translation of knowledge and innovation into patient benefits.

This firmly puts research at the centre of the development of the AHSC and reflects the IEHG-UCD decision in 2018, to develop a Research Directorate. The Research Directorate will provide oversight and support to all research across the group and will build on the success of the UCD Clinical Research Centre (CRC). It will utilise the CRC as the vehicle to deliver the Research Directorate's programme, with the objective of centralising all research in the partner institutions under the one governance structure.



RESEARCH AT THE IRELAND EAST HOSPITAL GROUP

The key strength of the 11 hospitals within the Ireland East Hospital Group (IEHG) is the breadth and width of the clinical care that they provide. The wide range of clinical services drives research in all hospitals, with particularly high concentration in our Level 4 hospitals (Mater Misericordiae University Hospital and St Vincent's University Hospital) and the National Maternity Hospital. In addition, there is specialty specific research in our specialty hospital (National Orthopaedic Hospital, Cappagh and the Royal Victoria Eye and Ear Hospital) as well broad research in our general hospitals.

The focus of the Research Directorate is to:

- Enhance the current research programmes in major disease areas like cancer, obesity and cardiovascular.
- Encourage the development of early phase clinical trials to provide more options for patients.
- Ensure all patients in our hospital group, regardless of geography, are provided access to cutting edge care.

"For me research is all about patient care and by supporting research, we are ensuring that novel interventions are developed and translated into routine clinical practice in the fastest possible time, thereby improving outcomes for patients".

Prof Mary Day, CEO, Ireland East Hospital Group

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

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

LIST OF CRC PEOPLE

CRC CORE TEAM

Amar Nath
Anna Malara
Anthony McDermott
Aoife Kelly
Brenda Molloy
Carita Bramhill
Colm O'Brien
Debbie Wallace
Denise Gosling
Doireann Dickinson
Douglas Veale
Edel Meaney
Elaine Cawley
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Gareth Shaw
Helen Campion
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Laura Feeney
Laura Helbert
Loai Shakerdi
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Michael Keane
Michelle Groarke
Niamh Redmond
Patrick Murray
Peter Doran
Rabia Hussain
Rosanna Inzitari
Sarah Griffin
Sean Kearns
Sebastian Vencken
Siobhan Smith

CRC EXECUTIVE COMMITTEE

Alistair Nichol
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
Terri Martin

CRC BASED RESEARCHERS

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Catherine Lynch
Ciara Fahey
Ciara Keane
Claire Marmion
Deirdre Collison
Deirdre McDonnell
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Gillian Horgan
Giulio Calzaferri
Hazel Bergin
Helen Keane
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Jillian McCue-Musarra
Jo Ballott
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Joe Duffy
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Jun Zhao
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Marion Rowland
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Mustapha Irnaten
Myra Walsh
Natasha Kapoor
Nicola Hyde
Nuala Edwards
Phil Gallagher
Robert Maughan
Susan Cairney
Tara O'Connor
Werd Al-Najim
Willard Tinago

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Brian Marsh
Brian McCullagh
Carel le Roux
Catherine Doody
Chris McGuigan
Colm O'Brien
Colm O'Donnell
Colman O'Loughlin
David Keegan
David Kevans
Deborah Wallace
Denise Sadlier
Donal Brennan
Donal Buggy
Donal O'Shea
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Ed McKone
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Niall Swan
Niamh Conlon
Oliver Fitzgerald
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Sean Murphy
Stephen Stewart
Tim Lynch
Walter Cullen

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