UCD Clinical Research Centre
UCD School of Medicine

UCD CLINICAL RESEARCH CENTRE

ANNUAL REPORT 2019/20

CONTENTS

WELCOME

I am delighted to introduce the 2019-20 annual report for the UCD clinical Research centre. Despite the disruption and challenges of working, teaching and living in a pandemic, the UCD CRC has continued to contribute to cutting edge clinical research, which is benefiting our university, our hospital partners, our patients, their families and the wider community. We have strengthened our supports and grown our profile of activity across all domains, from investigator led trials, to cohort studies and from biomarker analysis to education programmes. The CRC team has responded to the challenges of Covid-19, by adapting and innovating, we have ensured that our investigators, our students and our patients have continued to be supported. New ways of working have been seamlessly integrated, in many cases enhancing the quality of what we do. This is clearly evidenced by the activity reported in this report. It is also clear that the UCD CRC's history of dynamism and responsiveness prevails. We are supporting multiple trials, enabling international registry studies and delivering the national infectious disease cohort- all in a disease that did not exist at the start of the year.

I am immensely grateful for the efforts of all the CRC staff who infuse everything we do with such professionalism, commitment, and focus. It is this effort that is reported herein.

Prof Peter Doran
Associate Dean for Research, Innovation and Impact,
UCD School of Medicine
Director, UCD Clinical Research Centre

MISSION

To conduct, support and promote high quality clinical research that improves clinical practice and patient outcomes.

VISION

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

UCD CLINICAL RESEARCH CENTRE

IN NUMBERS

CLINICAL RESEARCH

288
STUDIES

65
NEW STUDIES

3402
PATIENTS

138
CLINICAL TRIALS

SCIENTIFIC SERVICES

3,600
PATIENT SAMPLES BIOBANKED

50,200
BIOMARKERS TESTED
7,409 PATIENT SAMPLES

6,030
ELISA MARKERS ON 7,409
PATIENT SAMPLES

QUALITY & REGULATORY AFFAIRS

3
DSUR REPORTS

5
CSR REPORTS

>25
HPRA APPROVALS

58
UCD CRC SOPS

8
STAFF COMPLETED TRIANING REPORTS

10
INVESTIGATOR INITIATED TRIALS

EDUCATION

5
EDUCATION PROGRAMMES

10
MODULES

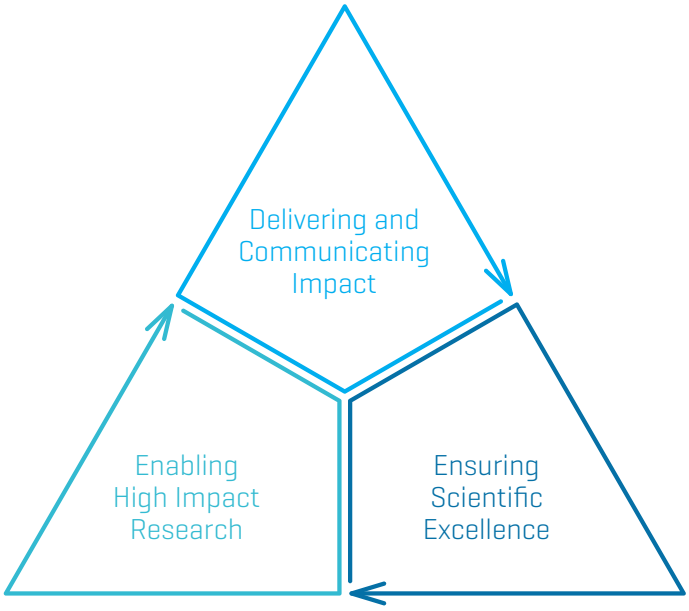
163
STUDENTS

UCD CRC STRATEGY

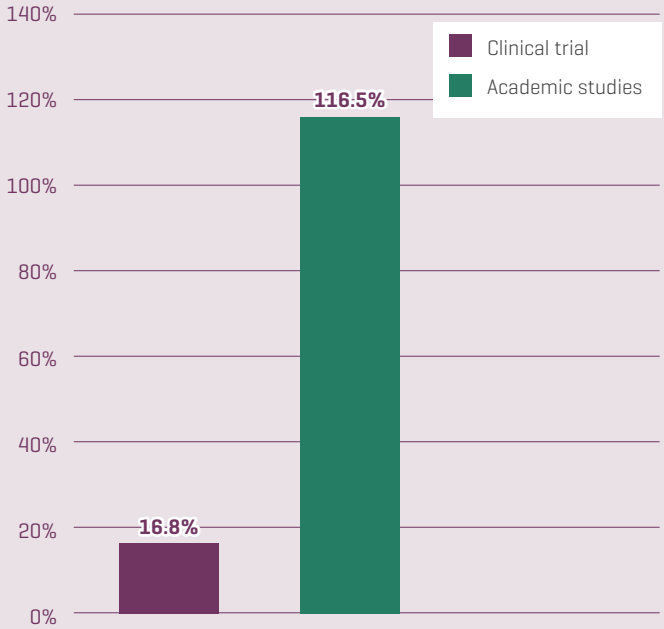
STRATEGIC DIRECTION

In 2019 the CRC commenced a strategic planning process to set its vision and objectives for the next 5 years. Strategic Plan 2020 build on the significant success over the previous 5 years and recognised that the CRC was now operating in a more complex and interdependent research environment.

The new strategic direction revolves around 3 major themes:



Research Growth at CRC (%) 2015/16 to 2019/20



Research Growth at the CRC 2015/16 to 2019/20.
Growth over base year 2015/16

Building off a strong base the Strategic Plan 2020 outlined an ambitious plan for growth that is captured in the following 8 strategic priorities:

1

Doubling Trial Number

Increase access for patients and clinicians to clinical trials by doubling the number of trials by 2025.

2

Expand the Site Network

Expand geographical access to research through expansion of the UCD CRC research network

3

Early Phase Trials

Expand into early phase clinical trials.

4

Align University Assets

Improve the quality of clinical trial design, coordination and methodology.

5

Partnership with a CRO

Enhance the integration of clinical research into the Health system at all our network sites.

6

Leadership/ Governance

Expand our educational programmes to train the researchers of the future.

7

Expand Education

Integrate research results into clinical practice through a knowledge sharing and dissemination programme.

8

Mechanisms of Growth

Ensure that the patient perspective is embedded in shaping and informing clinical trial design, development and delivery.

COVID-19 RESPONSE

COVID-19 RESPONSE

Since the beginning of the global COVID-19 pandemic in March 2020, the UCD CRC has been actively participating in the COVID-19 Response. UCD CRC has mobilized our expert research team in all the key areas of activity to rapidly facilitate the urgent clinical research on COVID-19.

- We have undertaken a role of the sponsor of 2 COVID-19 Pre-ICU trial – COVIRL001 and COVIRL002 with the recruitment open at the SVUH and MMUH and supported by UCD CRC staff at these clinical sites.
  The protocol and the preliminary results of the COVIRL002 trial – "Tocilizumab for management of severe, non-critical COVID-19 infection" have been published (Cotter et al., 2020; McCarthy et al., 2020).
- UCD CRC has enrolled patients to the All Ireland Infectious Disease Cohort study and MMUH, SVUH and General Hospital Wexford.
- SPRINT SARI – a global observational study of patients in hospitals and intensive care units with severe acute respiratory infection aiming to establish a research response capability for the future pandemic / epidemic, enrolling patients at the SVUH, MMUH and WGH
  More information:
  https://isaric.tghn.org/sprint-sari
- REMAP CAP – a global trial evaluating a treatment options for community acquired pneumonia
  More information: **www.remapcap.org**

UCD CRC is participating in the SOLIDARITY trial, led by the World Health Organisation, sponsored in Ireland by the Minister of Health and supported by Health Research Board. The SOLIDARITY Trial aims to test globally the efficacy of several antiviral and anti-inflammatory treatments. The trial is led by Prof Cormac McCarthy at SVUH and Dr Aoife Cotter and Dr Eavan Muldoon at MMUH.

UCD CRC has facilitated the biosample collection and antibody screening for the Prevalence study, led by Prof Donal Brennan. The study's objective is to develop a national registry of COVID-19 positive patients during pregnancy and to characterize the immune response to COVID-19 in pregnant women.

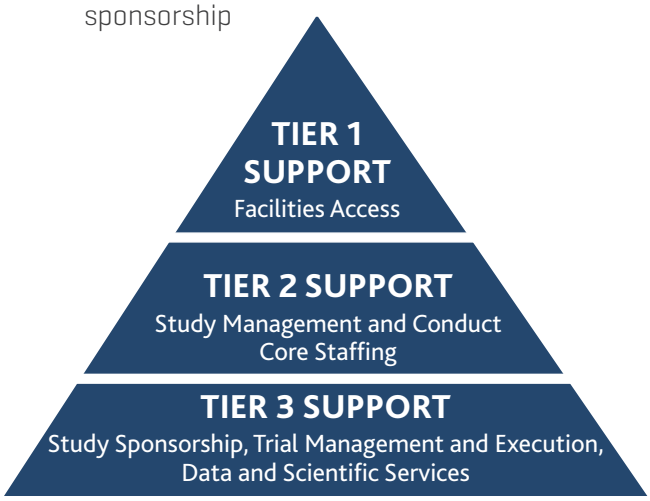
We have worked closely with Prof Jack Lambert and Prof Walter Cullen to enable their vital research exploring the clinical course of COVID-19 in North Dublin.

CLINICAL RESEARCH

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

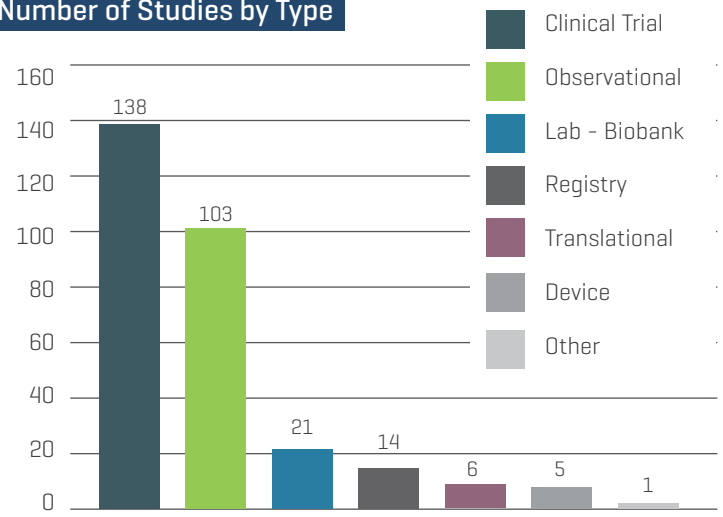


SUPPORT AVAILABLE TO INVESTIGATORS:

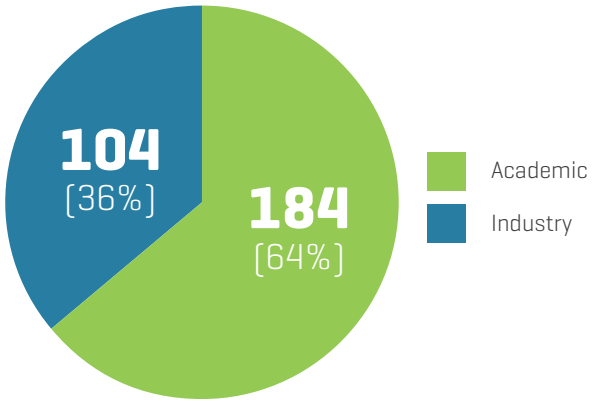
Proposal Phase	Pre-initiation Phase	Study Contact Phase	Reporting Phase
Grant Application	HPRA & Ethics submission	First Patient In	Last Patient Last Visit
Budget Review	Investigator Site File	ISF Maintenance	Study Close-out Visit
UCD Sponsorship	GCP Training	Study Monitoring	End of Trial Notification
EudraCT Number	Trial Registration	Amendments	Archiving
Study Design Review	Monitoring Plan	Data Collection & Cleaning	Data Lock and 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

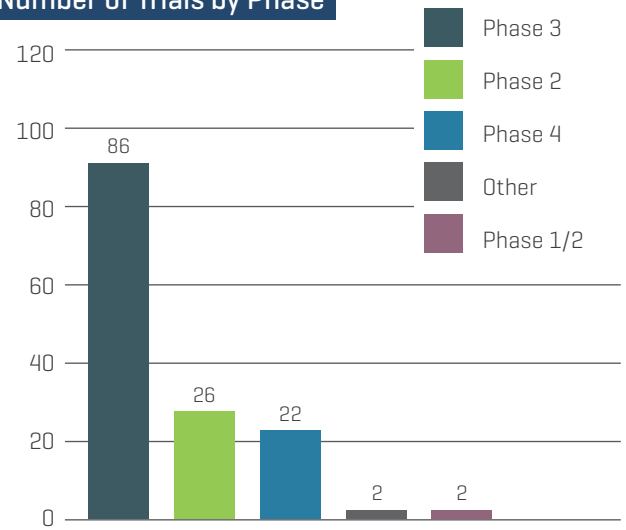
Number of Studies by Type



Number of Studies by Origin



Number of Trials by Phase



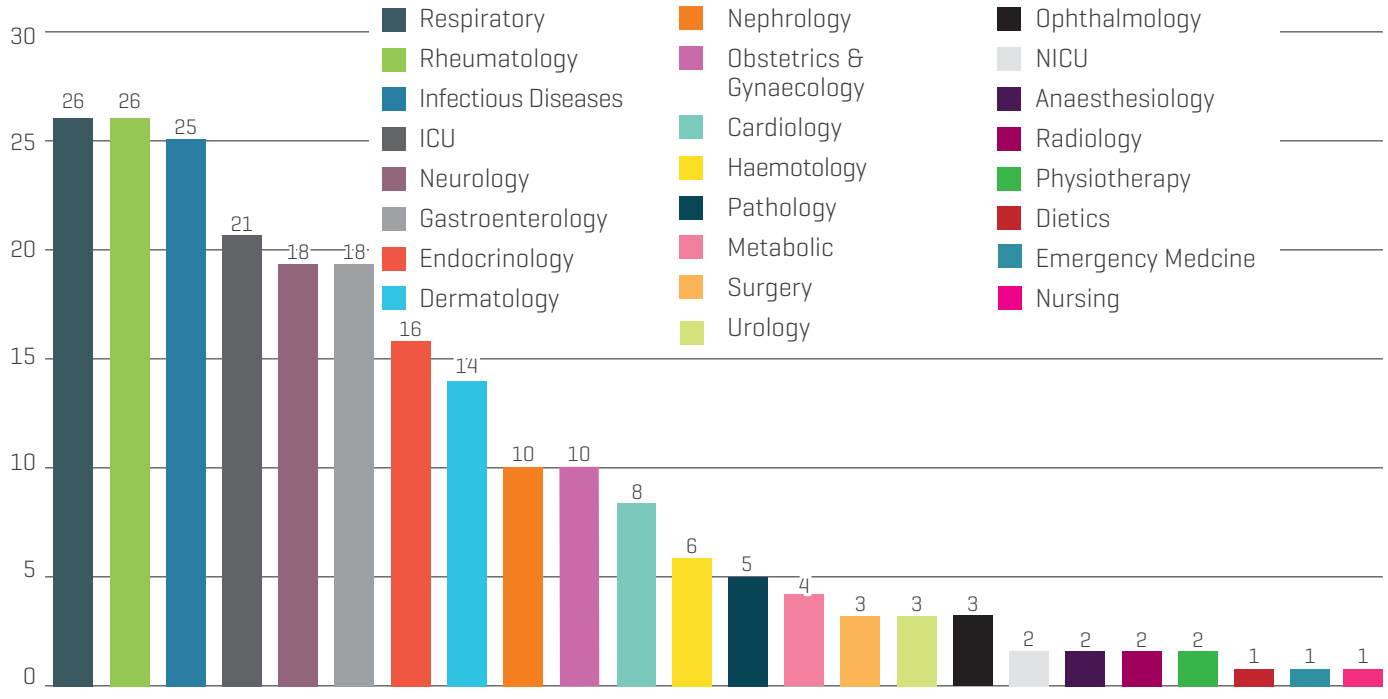
6,283

PATIENT CONTACTS ACADEMIC YEAR 2019/20

65

NEW CRC STUDIES 2019/20

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 – covering activity areas such as: Clinical, Regulatory, Laboratory, Pharmacovigilance
- 10 UCD Sponsored Clinical Trials approved by the HPRA currently active (HCC-TACE, BETTER B, COVIRL-001, COVIRL-002, DERMMARK, CONVINCE, POPART, TAISTER, APART, GOAL-ARC)
- 8 new CRC staff completed staff induction and orientation

UCD SPONSORED STUDIES ACTIVITIES:

Study Start-Up

- HCC-TACE
- BETTER-B
- COVIRL-001
- COVIRL-002
- RAPID
- ETAPA
- SWIFT
- EPO-TRAUMA

Recruitment

- POPART
- DERMMARK
- GOAL-ARC
- APART
- CONVINCE
- TAISTR

Actively Recruiting

Study Close Out

100% study reporting to EudraCT

QUALITY & REGULATORY AFFAIRS

QUALITY & REGULATORY AFFAIRS ACTIVITY DATA

- In support of research with the current pandemic, UCD has initiated on 3 regulated clinical trials as sponsor for COVID-19 research as well as participation and support of many research studies in different branches of research into COVID-19.
- Expedited Regulatory approvals granted for UCD sponsored COVID-19 clinical trials COVIRL001 and COVIRL002.
- UCD undertaking active role as Co-Sponsor with King's College London on the Horizon-2020 funded EU-wide clinical trial – BETTER-B
- UCD taken on role of Regulatory Support for 2 international clinical trials, REMAP-CAP and OVHIPEC-2.
- Interactive GCP training sessions provided across 4 hospital sites providing training for over 100 investigators, research staff and students.

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.

Over the academic year, 2 UCD CRC Clinical Research Associates have been actively working over UCD sponsored clinical trials monitoring within Ireland and internationally at affiliated research sites. CRA training provided to CRAs working for UCD-sponsored studies.

REGULATORY AFFAIRS

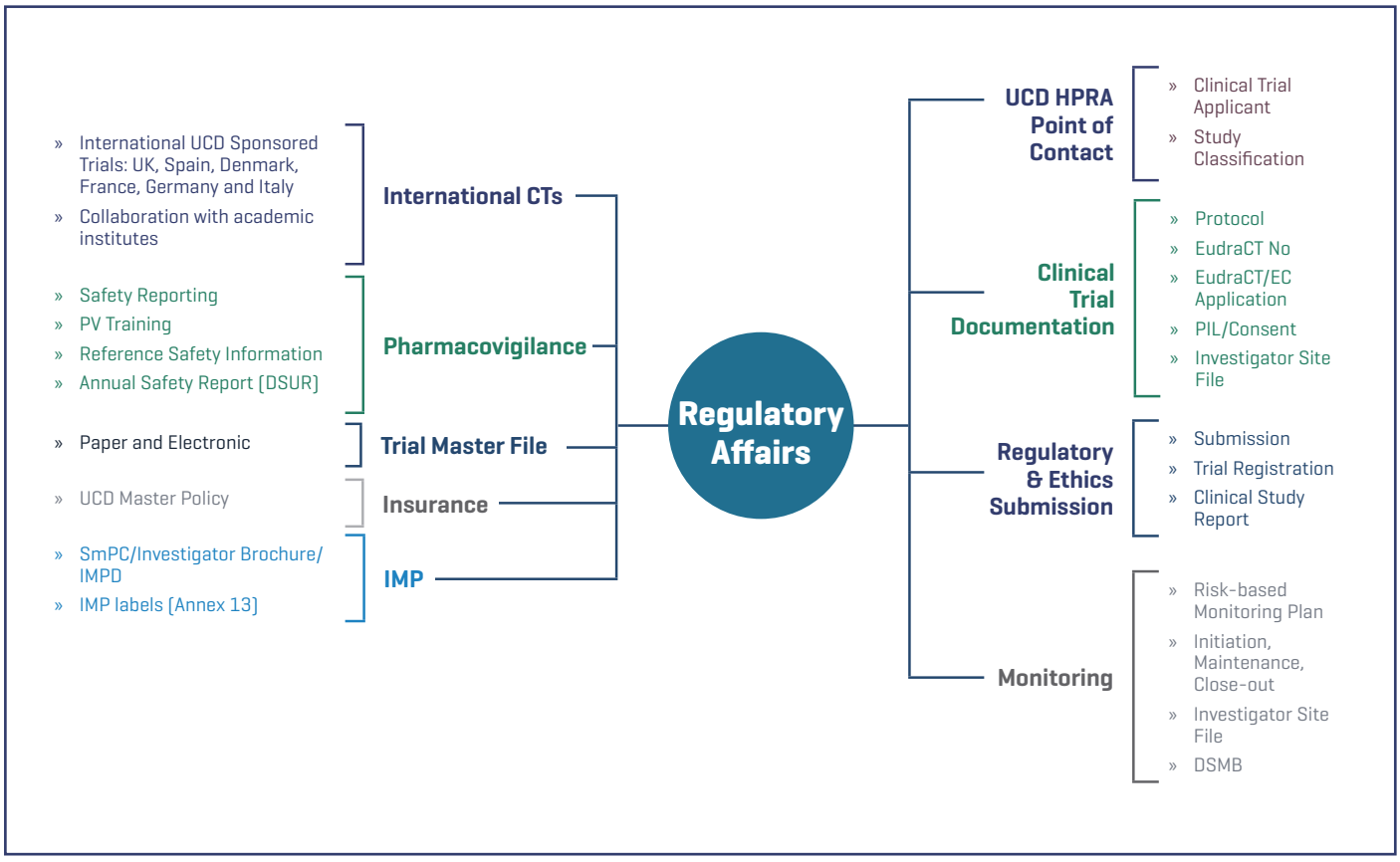
UCD CRC provides extensive regulatory support for clinical trials conducted at the research facilities with the goal to provide staff with the tools, training and support needed to navigate the complex regulatory pathways that come with undertaking clinical research.

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.

CSA Strengthening Training of Academia in Regulatory Sciences (STARS) project

UCD CRC is actively participating in the CSA Strengthening Training of Academia in Regulatory Sciences (STARS) project. CSA STARS aims to bridge the regulatory knowledge gap in academic research, improve direct regulatory impact of results obtained in medical research, and establish early exchange of information between academic researchers and regulators. The project will illustrate hurdles, and options to strengthen regulatory knowledge in general by reaching clinical scientists during professional training / qualification and improve the direct regulatory impact of results obtained in medical research. Amongst the EU regulators, numerous academic organisations and the EMA Head of Innovation and Science, UCD was invited to present on overcoming regulatory hurdles experienced by academic sponsors in investigator initiated trials, and is playing an active role in the future of the project.



DATA & INFORMATION SYSTEMS

CLINICAL DATA MANAGEMENT

The CRC supports research staff with the 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:

- HCC TACE: A Pilot Study of Combined Immune Checkpoint Inhibition in combination with ablative therapies in Subjects with Hepatocellular Carcinoma (HCC)
- COVIRL002: Tocilizumab for management of severe, non-critical COVID-19 infection
- The All Ireland Infectious Diseases Cohort (AI ID Cohort) - COVID-19 Subset
- Prevalence of asymptomatic SARS-CoV-2 infection in women attending Dublin Maternity Services - a cross sectional study
- SPRINT SARI Ireland
- APPROVE-CARE - Awake Prone Positioning to Reduce invasive VEntilation in COVID-19 induced Acute Respiratory failure
- Post-Intensive Care Nutrition Status in Patients with COVID-19

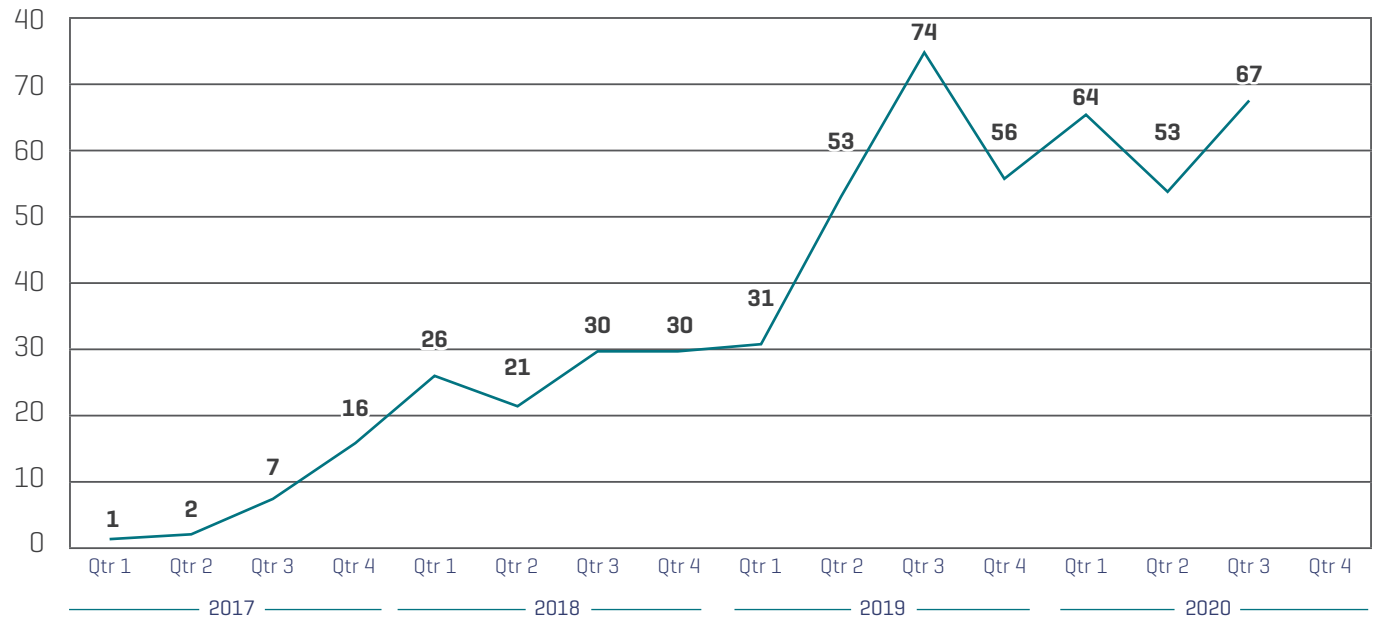
PHARMACOVIGILANCE

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

Pharmacovigilance services include:

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

Number of SAEs processed per quarter



INFORMATION SYSTEMS

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:

Pharmacovigilance Management System:

- **Clinical Database Management System:** collection, management, verification, validation and simple analysis of clinical research study data
  - 36 studies currently collecting data in REDCap: 6 Clinical Trials, 30 Observational Studies
- **Pharmacovigilance Management System:** support assessment, reporting and review of serious adverse event data relating to clinical trials at UCD CRC

Clinical Trials Management System: Data Logged

288 STUDIES	**3,402** PATIENT CONTACTS
77 INVESTIGATORS	**24** THERAPEUTIC AREAS

SCIENTIFIC SERVICES

The UCD CRC provides a range of core scientific services, which directly supports 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 at each level of clinical research. The laboratory infrastructure complements research facilities found in the biomedical departments of health care institutions. The laboratory comprises a wide range of amenities which include:

- 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 automated sample analysis. For manual based assay methodologies, the Core lab facility has at its disposal a Quanterix SR-X detector for single/ multiplex SIMOA analysis. In conjunction with the SR-X, the Core lab has at its disposal a number of spectrophotometric detectors for standard ELISA analysis.

CRC BIOLOGICAL RESOURCE CENTRE

The CRC Biological Resource Centre initiative has been established for over a decade and is continuing its expansion. Biobanks are systematic collections of biological samples such as blood, tissue or DNA taken from patients concurrently with their associated clinical 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-80°C (11 -20oC; 4 -40°C and 34 -80°C 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
- LIMS system necessary for the labelling and recorded storage of bio-banked samples

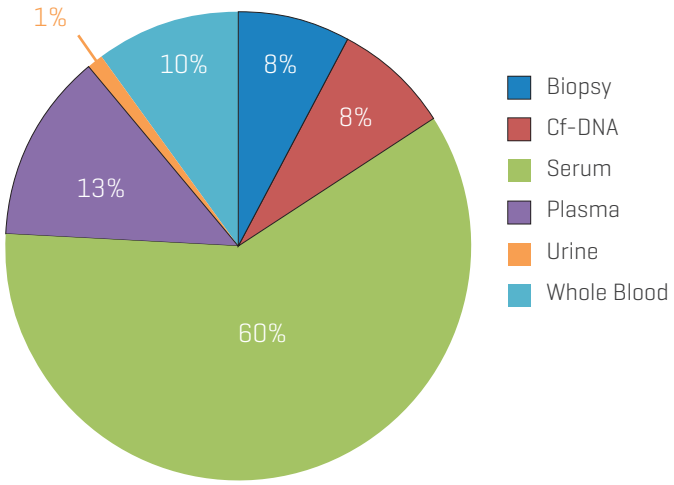
To date, there are over 40 biobank study collections facilitated by the CRC comprising a total of over 45,000 processed samples stemming from nearly 8,000 consented patients. Of this total, over 1,400 patients were recruited in 2019-2020 with a total of almost 3,600 samples processed.

CRC Biobank Collection

Research Focus	Associated Disease
Arthritis	Rheumatoid arthritis, Osteoarthritis, Gout
Infectious Diseases	Sars-CoV-2, Lyme Disease
Oncology	Ovarian, Pancreatic, Prostate, Lung, Liver, Uterine, Adrenal, Soft Tissue Sarcoma
Interstitial Lung Diseases	Idiopathic Pulmonary Fibrosis, Sarcoidosis
Nephrology	Acute Kidney Injury (AKI), Chronic Kidney Disease (CKD)
Cardiology	SADS, Myocardial Infarction
Inflammatory Bowel Disease	Ulcerative Colitis
Endocrinology	Diabetes
Neurology	Dystonia, Traumatic Brain Injury (TBI)

The CRC is responsible for generating patient kits for its biobank schemes and coordinates all logistical elements for multicentre collections. The Scientific Services team is also on hand to offer SME in relation to biobank setup and design.

Biobank Samples Collected 2019-2020



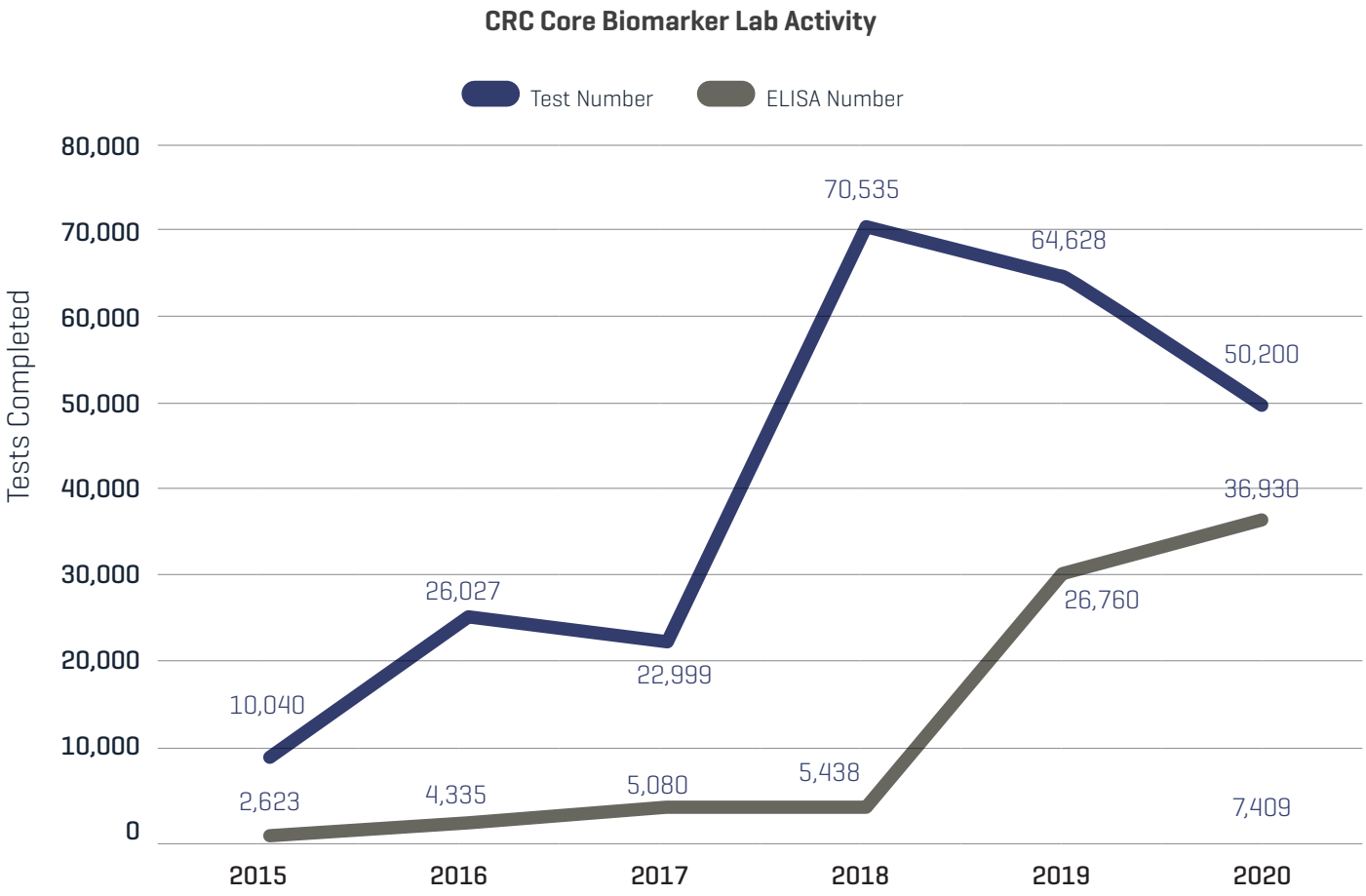
UCD CORE BIOMARKER LAB

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. An Abbot Alinity CI was installed in early 2019 offering the latest in integrated clinical chemistry and immunodiagnostic technology. The CRC was the second institution nationally to have the Alinity platform installed. 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 2019 a new digital ELISA platform Quanterix SR-X was installed which is capable of performing single or multiplex analysis. The acquisition for the SR-X further enabled the CRC to measure biomarkers whose levels are below detectable ranges for standard assays. In 2019-2020 the CRC carried out analysis on 2,200 patient samples using the SR-X platform producing over 11,000 tests.

The Core Biomarker lab has enabled the CRC to support local research programmes that would otherwise find difficulty in completing large cohort sample analysis. For over a decade the CRC has guaranteed reliable and quality data through the availability of high throughput analysers in conjunction with the centres implemented GLP and GCP standards. The Core lab has also played an instrumental part in investigating diagnostic kits through method comparisons as part of post market availability studies. In 2019 the CRC engaged in a collaboration with Abbott centred around assay method comparison that added 4 new projects to the Core labs study portfolio. In 2020 this portfolio was further expanded in response to the need for an investigation into market available Sars-Cov-2 antibody kits. The CRC analysed six separate COVID-19 cohort collections totalling over 1,800 patient samples, equating to over 11,000 tests in 2020.

In the last year, over 50000 tests have been completed on over 7000 patient samples by the CRC Core lab. The majority of research projects undertaken by the core lab in the last year predominantly focus on four main disease areas: Cardiology, TBI, Diabetes and endocrinology. In 2019-2020 two PI research lead translational studies were facilitated by the lab team on AKI and Aki complication in diabetes. Since March of 2020 the majority of projects have been related to COVID-19 Antibodies studies.

On the total of over 50000 tests completed by the CRC Core Lab almost 37000 were on ELISA's platform, with an increase of 20% in comparison with the previous academic year.



NOTABLE ACTIVITY 2019-2020

- **Sars-COV-2 Ab testing:** The CRC analysed six separate COVID-19 cohort collections totalling over 1,800 patient samples, equating to over 11,000 tests in 2020.
- **Core Lab:** Expanded our collaboration with Abbott including biomarker validation between multiple platforms, research projects undertaken predominantly focus on four main disease areas: Cardiology, TBI, Diabetes and endocrinology. Over 50000 tests have been completed with almost 37000 on ELISA's platform, with an increase of 20% in comparison with the previous academic year.
- **CRC Biobanks:** The CRC Biological Resource Centre is in continuous expansion with 4 more units added this year and with an increasing number of biobank collection hosted for our collaboration with external industrial partners.

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 2019/20 saw 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 further growth in popularity. Additionally, in 2019/20 we facilitated an Online Biostatistics, Study Design and SPSS course for hospital-based researchers and a Clinical Trials Masterclass for Interns.

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.

Covid-19 response plan

The suspension of all face to face teaching on March 12th 2020 necessitated changes to the delivery of teaching and assessment for the spring & summer trimesters. All teaching and assessment was delivered remotely / online. Teaching was facilitated by means of the Brightspace Virtual classroom. End of trimester presentation-based assessments were conducted via Zoom and change to existing assessment strategy was required in certain modules. These changes were implemented following completion of a Covid-19 response plan for each module.

In addition to changes in our own programmes the Clinical Research Centre offered a solution to undergrad final medicine students not being able to complete their clinical electives due to Covid-19. The programme structures of final year medicine students were amended to provide students additional Option modules, two of which were coordinated by Prof Peter Doran.

MDCS41980 Clinical Trials In Medicine – 10 Credit Module

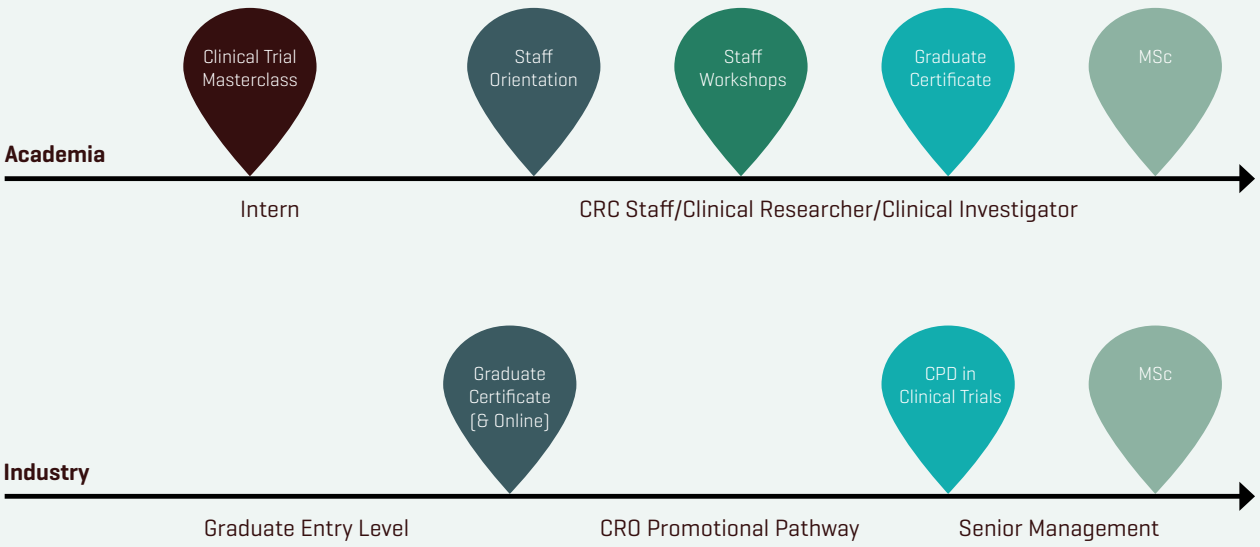
This pre-existing module is usually offered to postgraduate students in the spring trimester, this year an additional offering specifically for undergraduates was provided for the Summer trimester.

The overarching goal of this module is to introduce the student to the importance, design and conduct of clinical trials. By understanding the mechanisms through which medical knowledge is generated the student will appreciate the importance of properly conducted and executed clinical trials as a means to generate reliable, robust clinical evidence.

In addition to these units, there was a Clinical Trials in focus unit. This featured a set of talks from some UCD investigators about their trial activities in different clinical areas.

MDSA40260 Covid19 Medicine Research – 5 Credit Module

At the UCD School of Medicine, significant research efforts were underway to respond to the pandemic. This module provided students with an opportunity to engage with covid19 related researchers. Weekly live lectures by PI's and others involved in Covid 19 research were delivered via a virtual classroom, recordings, lecture slides and selected papers were uploaded also.



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 (X882)

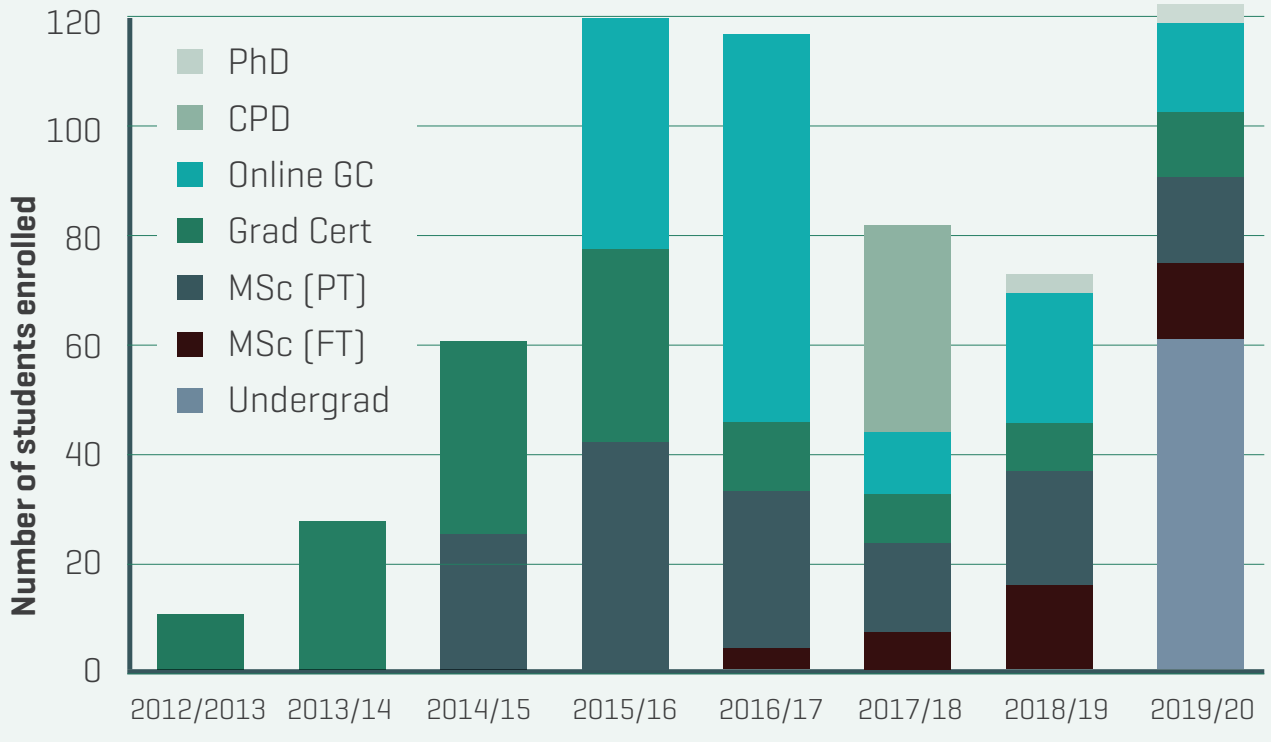
The strategy of the online graduate certificate course is to meet the staff development needs of the multinational Clinical Research Organisation and pharmaceutical sectors. Delivery of this programme utilises innovative Virtual Learning Environments such as recorded lectures, storyboards, videos, discussion 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 [X882]
MDCS41630 Principles and Practice in Clinical and Translational Research	AUT	AUT			
MDCS41950 Biostatistics and Data Management	AUT	AUT		AUT	
MDCS41640 Clinical Trials	AUT		AUT	AUT	
MDCS41900 Clinical Protocol Development	SPR	SPR			
MDCS41890 Principles of Laboratory Medicine	SPR	SPR			
MDCS41940 Clinical Trial Management	SPR		AUT	AUT	
MDCS41880 Research Project	SUM		SPR		
MDCS41890 Clinical Trials [online]					SPR
MDCS41990 Biostatistics and Data Management [online]					SPR SUM
MDCS41970 Clinical Trial Management [online]					SUM

AUT Autumn Trimester SPR Spring Trimester SUM Summer Trimester

STUDENT ENROLMENT



NETWORKS AND PARTNERSHIPS

CLINICAL RESEARCH COORDINATION IRELAND (CRCI)

CRCI is a national clinical research network, providing centralised support for multicentre clinical trials in Ireland. CRCI became operational in May 2015 as a partnership of five university based Clinical Research Facilities/Centres and their associated hospitals. In 2018 two new partner centres joined the group, which now includes Clinical Research Facilities/Centres (CRF/Cs) at University College Cork, National University of Ireland Galway, Royal College of Surgeons Ireland, University College Dublin (2 centres), Trinity College Dublin, University Hospital Limerick and the National Children's Research Centre at Our Lady's Children's Hospital, Crumlin, Dublin. CRCI It is supported by the Health Research Board, Enterprise Ireland, supported by its partner Universities and hosted by Clinical Research Development Ireland (CRDI). The HRB CRCI central office provides overarching support and expertise, through a range of services and activities to academia and industry. The CRCI coordinator at UCD CRC, Edel Meaney, has continued to spread awareness of the CRCI network throughout the UCD-affiliated clinical sites.

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.

WEXFORD GENERAL HOSPITAL

Working closely with the Ireland East Hospital Group (IEHG) and UCD the Clinical Research Centre (CRC) expanded its research programme in 2020 to Wexford General Hospital. This is part of UCD's commitment to ensure that patients, regardless of geography, are provided access to cutting edge research and care. Supported by the CRC's core team a Research Oversight Committee has been formed, with Dr David Honan as chair and a Research Nurse has been recruited.

Two Covid-19 studies initiated at the site during the course of the year. The All-Ireland Infectious Disease Cohort study, established as a prospective, observational study began recruitment in June 2020 while SPRINT SARI, a global observational study of patients in hospitals and intensive care units with severe acute respiratory infection, began in July 2020.

COLLABORATORS AND SPONSORS OF CURRENT STUDIES INCLUDE:

UCD CLINICAL RESEARCH CENTRE

WWW.UCD.IE/MEDICINE

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

THE MATER
HOSPITAL

ST. VINCENT'S
UNIVERSITY HOSPITAL
Elm Park

Ireland East
HOSPITAL GROUP