UCD Clinical Research Centre
UCD School of Medicine

UCD CLINICAL RESEARCH CENTRE

ANNUAL REPORT 2020/21

CONTENTS

WELCOME

It is my great pleasure to present the Ucd Clinical Research Centre Activity Report for the 2020/21 academic year. Despite the challenging environment, the Centre continues to make a significant contribution to research, benefiting our school, the College of Health and Agricultural Sciences and UCD broadly. Our staff are supporting and enabling research programmes that continue to have a significant impact on patients lives. Our facilities and expertise, coupled to our ambition and strategy are creating an environment that is world leading, and we are delivering world class outputs.

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 our hospitals. The UCD CRC team has developed comprehensive research facilities and investigator supports to enable investigators , the results of which are communicated clearly in this report.

I am grateful to all of the CRC team, whose expertise and commitment continues to ensure we are performing at the highest level. Over the next 12 months we will onboard significant new funding, expand to multiple new sites and transform our programme through technology deployment. I have no doubt that this team will rise to the challenge.

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.

1

UCD CLINICAL RESEARCH CENTRE IN NUMBERS

CLINICAL RESEARCH

315	66	7871	143
STUDIES	NEW STUDIES	PATIENTS	CLINICAL TRIALS

SCIENTIFIC SERVICES

2,171	1,054	63,837	11,368
PATIENT SAMPLES BIOBANKED	SAMPLES RELATED TO PI INITIATED CLINICAL TRIALS	BIOMARKERS TESTED ON 14,670 PATIENT SAMPLES	ELISA/ DIGITAL ELISA MARKERS ON 2,640 PATIENT SAMPLES

QUALITY & REGULATORY AFFAIRS

6	>25	58	8	9
DSUR REPORTS	HPRA APPROVALS	UCD CRC SOPS	STAFF COMPLETED TRIANING REPORTS	INVESTIGATOR INITIATED TRIALS

EDUCATION

5	10	162
EDUCATION PROGRAMMES	MODULES	STUDENTS

OUR OUTPUTS

68	208	2.7
PRINCIPAL INVESTIGATORS ACROSS UNIVERSITY & HOSPITAL	PUBLICATIONS 39,000+ CITATIONS 46% IN TOP 10%	FIELD WEIGHTED CITATION 3.43 FOR INTERATIONAL

UCD CRC STRATEGY

2

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.


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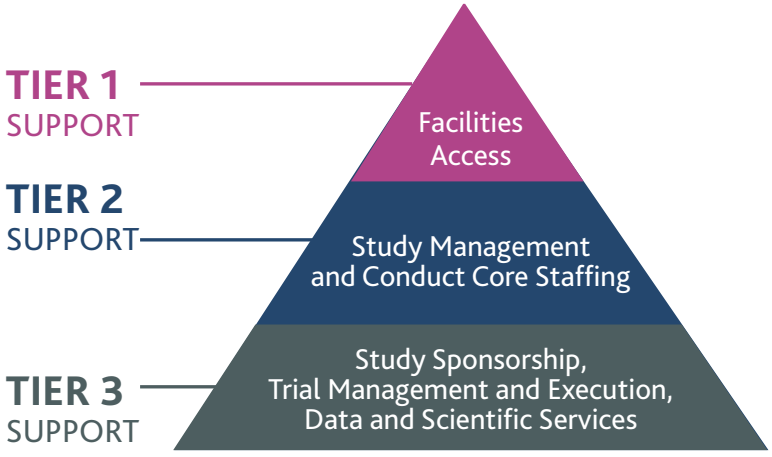
CLINICAL RESEARCH

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
- Grant Application
- Budget Review
- UCD Sponsorship
- EudraCT Number
- Study Design Review
- Statistical Planning
- Protocol Finalisation
- PIL & Consent Form
- Insurance
- Contracts

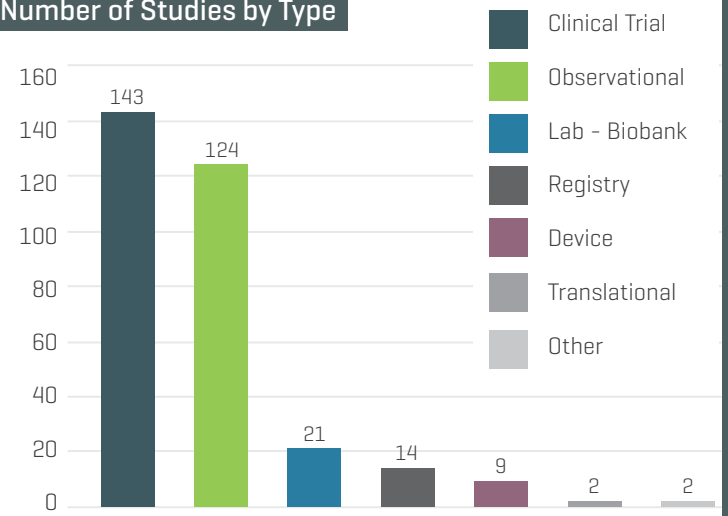
Pre-initiation Phase
- HPRA & Ethics submission
- Investigator Site File
- GCP Training
- Trial Registration
- Monitoring Plan
- Randomisation and Blinding Procedures
- Site Initiation

Study Contact Phase
- First Patient In
- ISF Maintenance
- Study Monitoring
- Amendments
- Data Collection & Cleaning
- Pharmacovigilance
- DSMB/Interim Analysis
- DSUR Submission
- Audits/Inspections

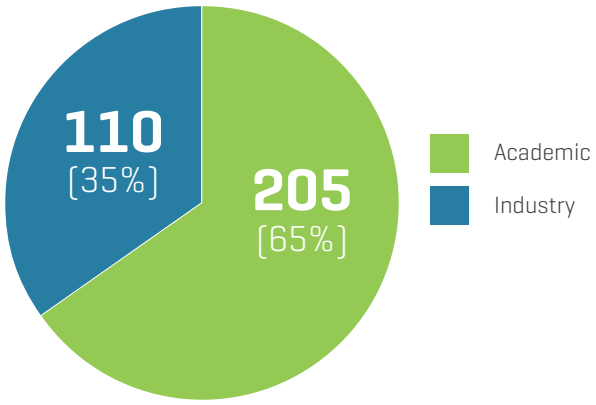
Reporting Phase
- Last Patient Last Visit
- Study Close-out Visit
- End of Trial Notification
- Archiving
- Data Lock and Cleaning
- Data Transfer
- Statistical Analysis
- Budget Close Review
- Clinical Study Report Submission

CLINICAL RESEARCH ACTIVITY

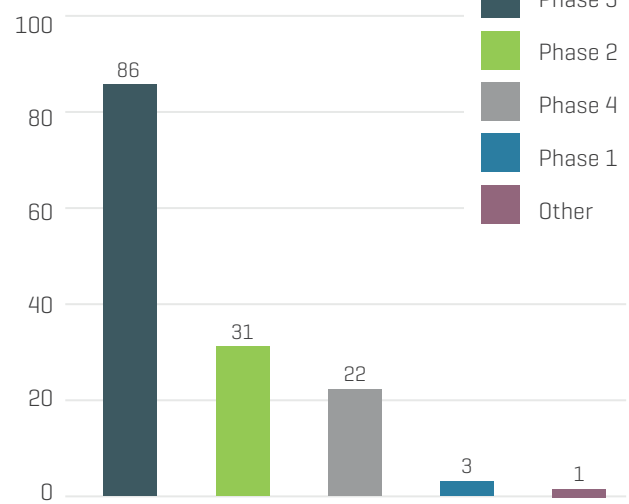
Number of Studies by Type



Number of Studies by Origin



Number of Trials by Phase



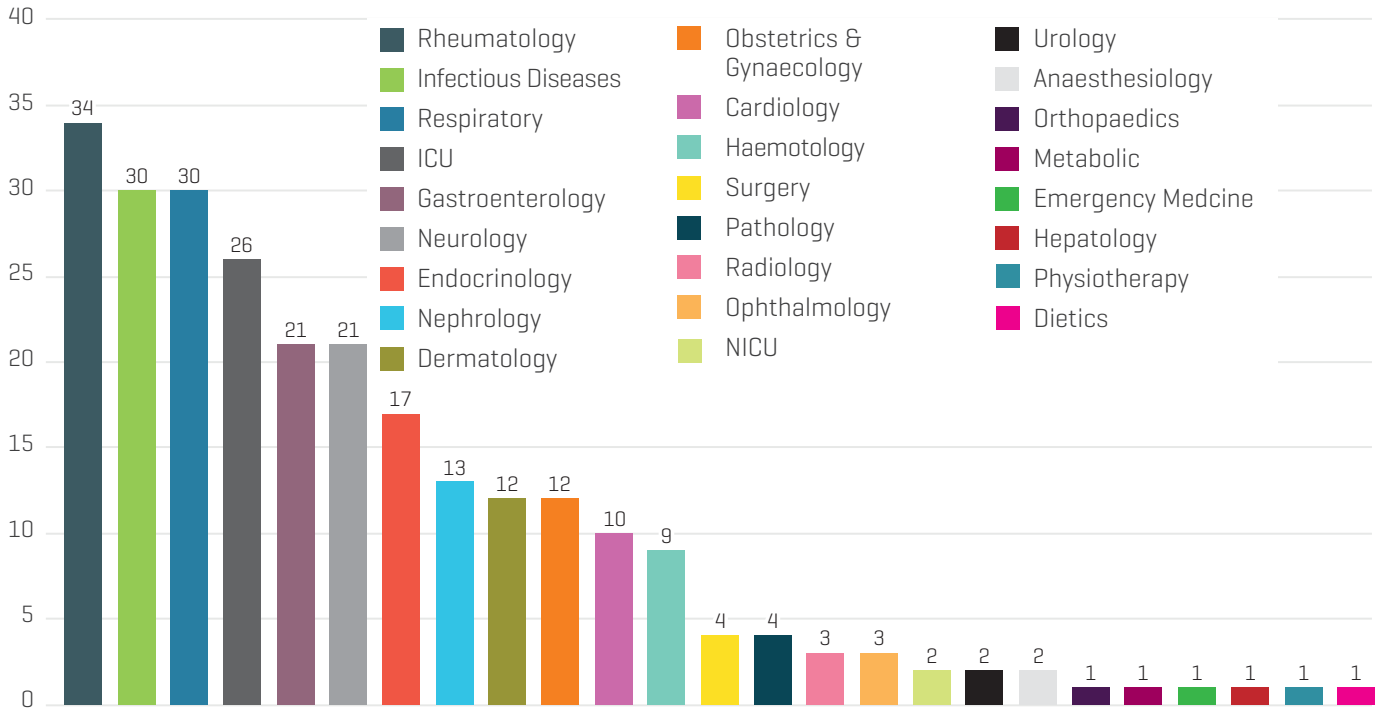
7,871

PATIENT CONTACTS
ACADEMIC YEAR 2020/21

66

NEW CRC STUDIES
2020/21

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. UCD has sponsored over 25 clinical trials. Not only has the number of clinical trials increased but the size, reach and complexity of trials has increased with trials recruiting at sites internationally and working with external collaborators. Funding was provided via industry, public funding agencies and charities.

As UCD's clinical trial sponsorship activity has markedly increased and the volume of interest from researchers and collaborators has also increased, UCD have appointed a Sponsorship Oversight Committee. The UCD Clinical Trial Sponsorship Oversight Committee has overseen the review, approval, and conduct of investigator-initiated clinical trials since 2019, when it was formed by Prof. Doran. Prof. Patrick Murray (UCD CRC Clinical Lead, and Prof. of Clinical Pharmacology in the UCD School of Medicine) has Chaired this committee since July 2020.

ACTIVITY DATA

- 58 UCD CRC SOPs – including areas: Clinical, Regulatory, Laboratory, Pharmacovigilance and Data Management
- 9 UCD Sponsored Clinical Trials approved by the HPRA currently active (HCC-TACE, ETAPA, BETTER B, COVIRL-002, CONVINCE, GOAL-ARC, EPO-TRAUMA, BOOSTAVAC, SWIFT)

UCD SPONSORED STUDIES ACTIVITIES:

Study Start-Up

- **HARP-X**
- **ELIVE-HF**
- **Iron Deficiency in Pregnancy**

Recruitment

- **HCC-TACE**
- **BETTER-B**
- **GOAL-ARC**
- **CONVINCE**
- **COVIRL-002**
- **ETAPA**
- **BOOSTAVAC**
- **SWIFT**
- **EPO-TRAUMA**

Actively Recruiting

Study Close Out

- POPART
- RAPID
- DERMMARK
- TAISTR
- APART

QUALITY & REGULATORY AFFAIRS

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QUALITY & REGULATORY AFFAIRS ACTIVITY DATA

- In support of research into COVID-19, UCD has sponsored 3 regulated clinical trials in this very important area of research to provide impactful data which could impact the treatment and prevention of COVID-19.
- Expedited Regulatory approvals granted for UCD sponsored COVID-19 clinical trials BOOSTAVAC, RAPID 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 and UCD also has further clinical trial collaborations planned with other academic institutes for research activity.
- Interactive transcelerate-accredited GCP training sessions provided across UCD affiliated hospital sites providing training for over 100 investigators, research staff and students, provided remotely to allow inclusion during the pandemic.

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.

Due to the challenges with monitoring experienced during the pandemic, UCD have adapted their monitoring processes in order to ensure that clinical trial sites receive the required support and oversight of their clinical trial activities despite the challenges with inaccessibility of the sites directly.

CRA training has also been a main focus for UCD CRC, providing Clinical Trial Monitoring training to many staff and researchers who are active CRAs as well as research staff expanding their training and qualifications within 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.

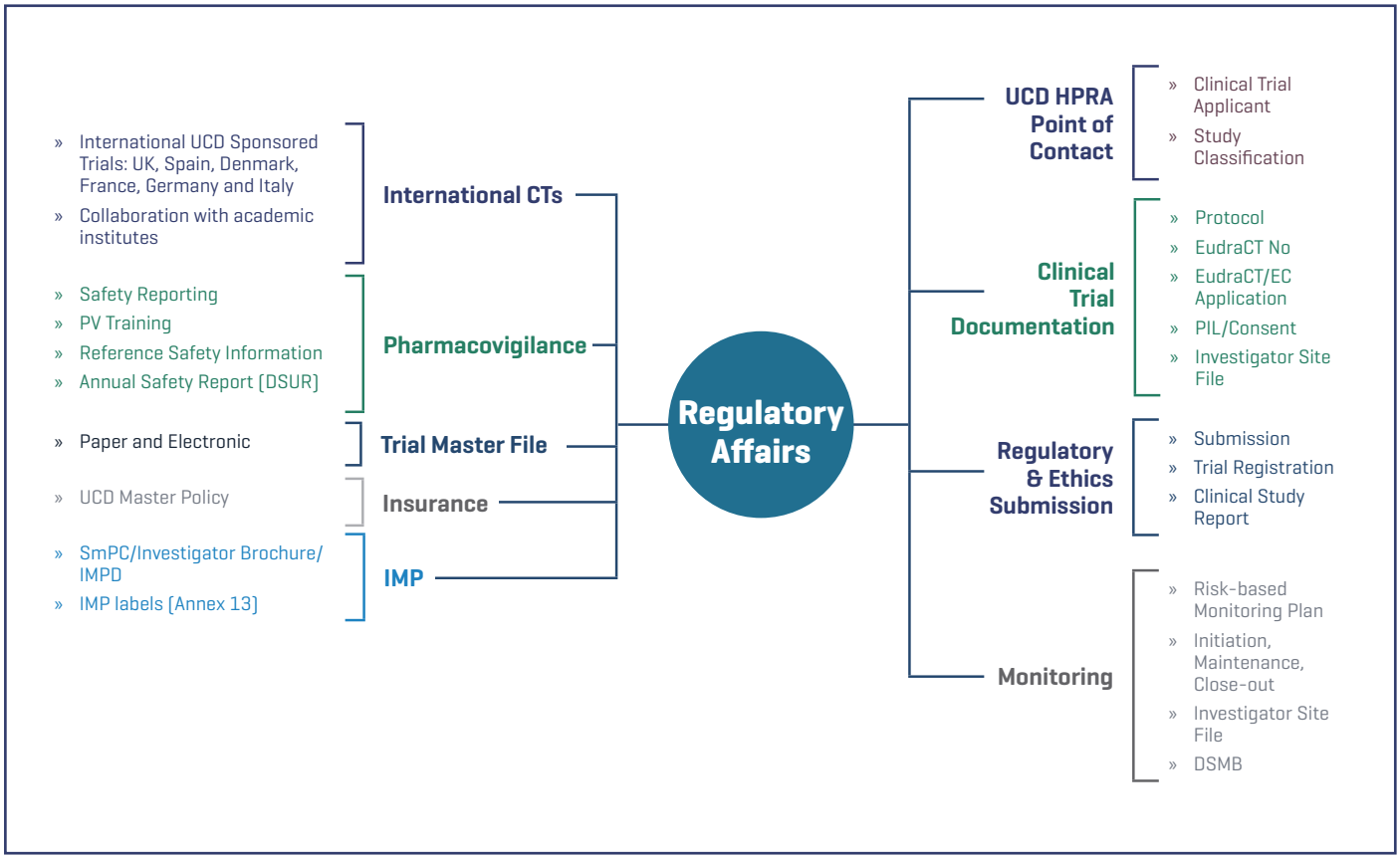
All clinical trial functional obligations are achieved through providing services to investigators which combines the quality and regulatory requirements for the conduct of robust and successful clinical trials, compliant and to high standard with the oversight. UCD CRC has also engaged with the Irish regulatory authority, the HPRA, in order to explore research activities with Medical Devices.

In support of the Quality and Regulatory Affairs function, UCD also plays an active role in Ireland's the NCTO's Quality Working Group.

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

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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:

- **ETAPA** - Randomised Placebo-Controlled Trial of Early Targeted Treatment of Patent Ductus Arteriosus with Paracetamol in Extremely Low Birth Weight Infants (ETAPA)
- **E-StOIC** - An Observational Study of Diagnostic Criteria, Clinical Features and Management of Opioid-Induced Constipation (OIC) in European Patients with Cancer Pain
- **UniCoV** - Multi-site study to develop a SARS-CoV-2 Infection Surveillance System for Third Level Students and Staff in Republic of Ireland (UniCoV Study)
- **CARAT** - Continual Assessment of Rapid Antigen Testing - CARAT Study
- **SARI** - European Severe Acute Respiratory Infections (SARI) Surveillance
- **DIMPLES** - Paediatric diabetes - onset and decompensation in the COVID-19 pandemic

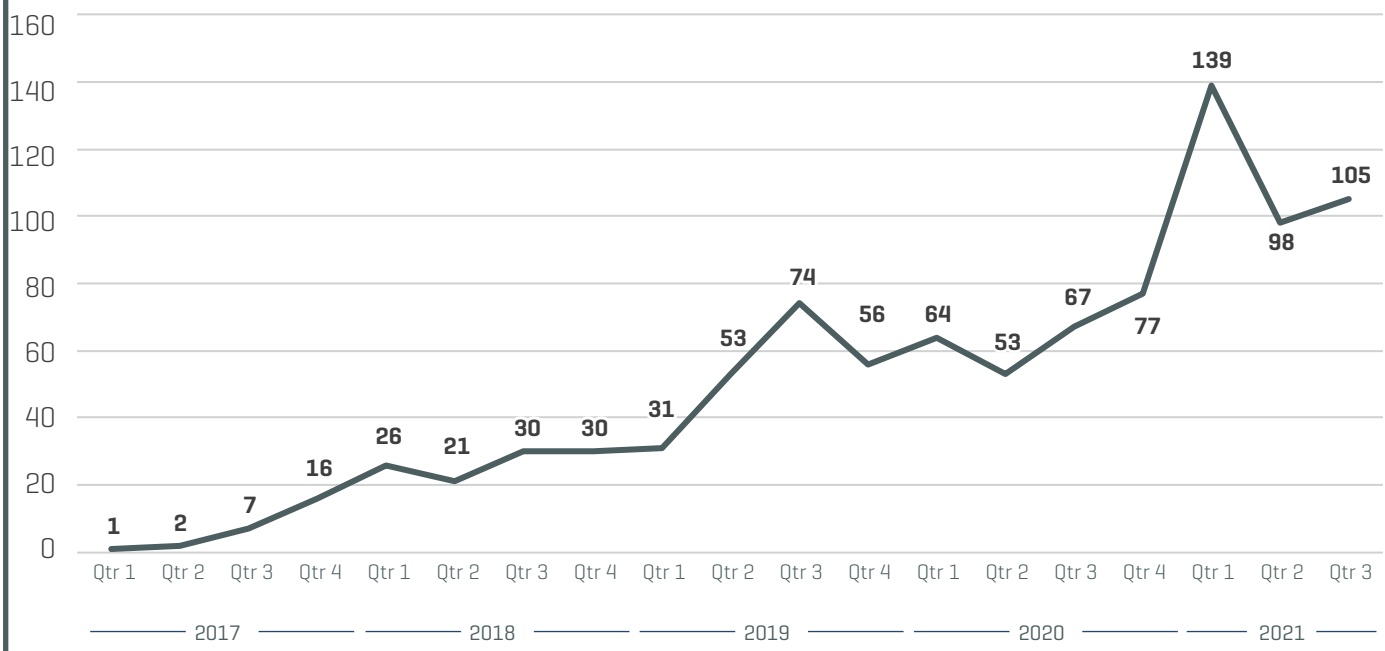
PHARMACOVIGILANCE

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 500 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
  - 40 studies currently collecting data in REDCap: 5 Clinical Trials, 35 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

315	7,871	91	26
STUDIES	PATIENT CONTACTS	INVESTIGATORS	THERAPEUTIC AREAS

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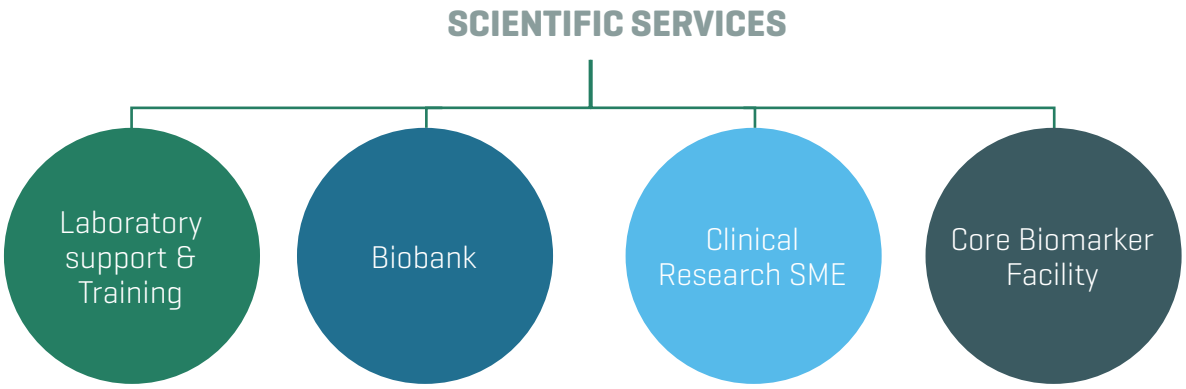
SCIENTIFIC SERVICES

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.



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:

1. Cell and tissue culture suites for primary cultures, equipped with sterile cell culture hoods & incubators
2. Biomedical laboratories with standard equipment and facilities for sample processing and analysis
3. Imaging Laboratory (with contrast and fluorescence microscopy)
4. Molecular biology laboratory
5. UCD-CRC Core Biomarker Laboratory houses the following instruments for high throughput automated sample analysis :
    - An Abbott ARCHITECT I2000SR,
    - An Abbott ARCHITECT CI4100,
    - An Abbott Alinity CI and
    - A Roche Cobas e411
6. UCD- CRC Core Biomarker Laboratory houses the following instruments for manual based assay methodologies
    - A Quanterix SR-X detector for single/ multiplex SIMOA bead-based technology and
    - A Quanterix SP-X for single/ multiplex SIMOA planar array technology.
    - In conjunction with the SR-X and SP-X, the Core lab has at its disposal a number of spectrophotometric detectors for standard ELISA analysis.

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 2021, 19 new users received training to access the CRC Laboratories, bringing the total number of current users to 90 between both SVUH and MMUH sites.

CRC BIOBANK

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
- 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.

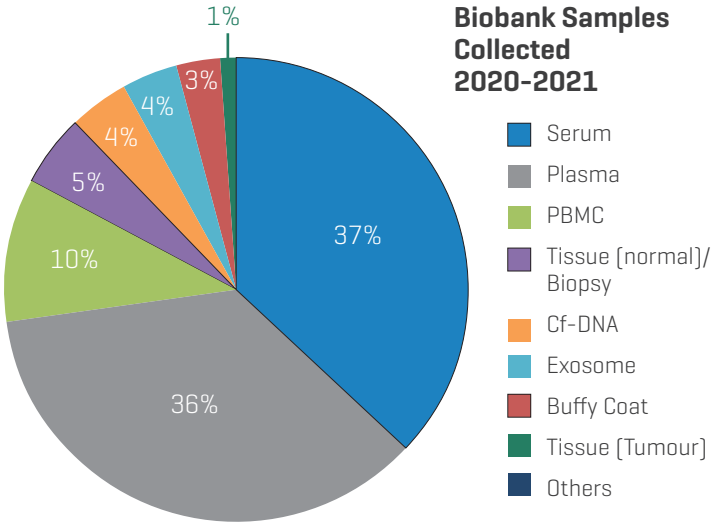
To date, there are over 40 biobank study collections facilitated by the CRC comprising a total of over 45,000 processed samples stemming from nearly 8,000 consented patients.

Of this total, over 1,250 patients were recruited in 2020-2021 with a total of almost 5000 samples processed.

CRC Biobank Collection

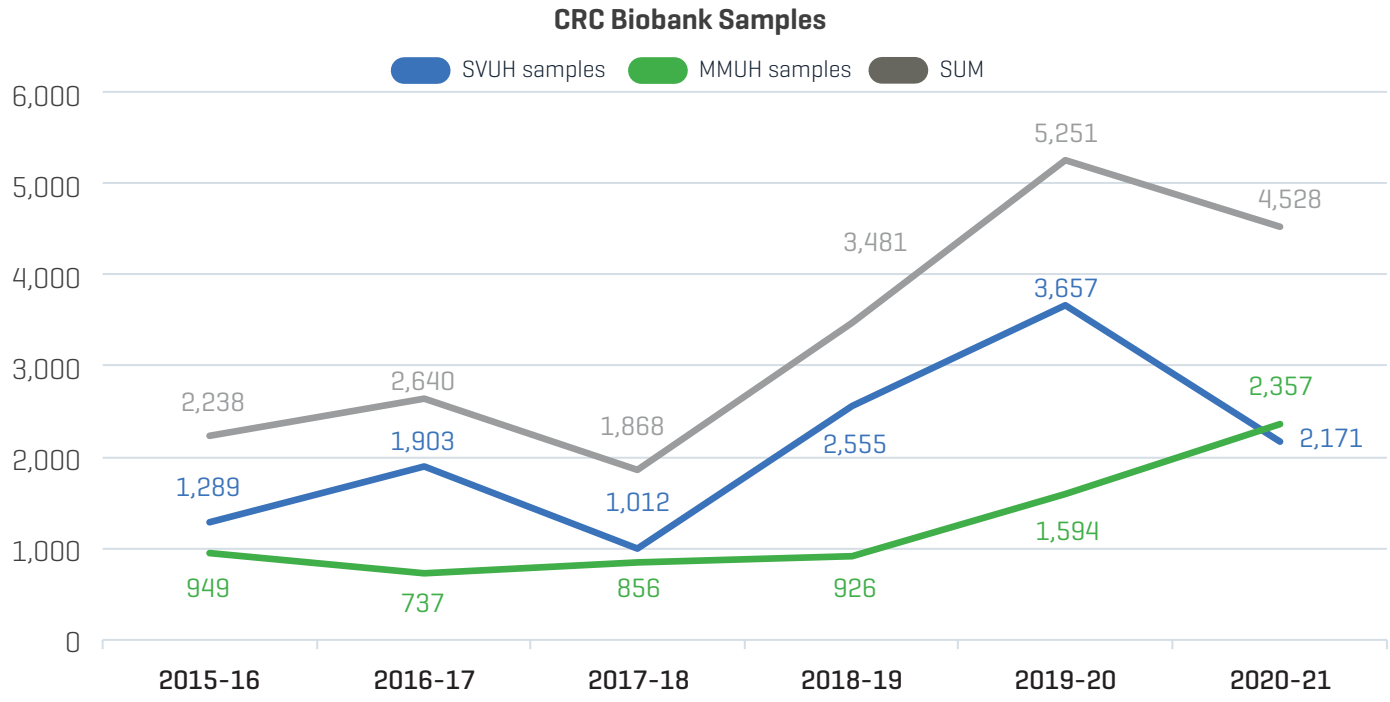
Research Focus	Associated Disease
Arthritis	Rheumatoid arthritis, Osteoarthritis, Gout
Infectious Diseases	Sars-CoV-2, Lyme Disease
Oncology	Ovarian, Pancreatic, Prostate, Lung, Liver, Uterine, Adrenal, Soft Tissue Sarcoma
Interstitial Lung Diseases	Idiopathic Pulmonary Fibrosis, Sarcoidosis
Nephrology	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.



From the beginning of 2017, the CRC has continued to collect for and support two biobank registries; ENSAT (European Network for the Study of Adrenal Tumours) and PEG (Prostate Cancer Epigenetics Study). The CRC at SVUH is the first Irish based healthcare institution to be registered on the ENSAT network. The number of patients recruited since the initiation of both registries exceeds 80, generating over 1000 biobank samples. The CRC's most recent collections concern gynaecological cancer and Lyme disease. In 2020-2021, the uterine cancer collection expanded its repository by over 1600 samples from a recruited 88 patients (256 patients recruited for a total of 5700 samples collected since the start of the collection). Similarly, the Lyme disease collection expanded its repository by over 1500 samples from an enrolled 52 patients.

The extensive nature of the CRC's biobank repository can be attributed to an ongoing collaboration with both pathology departments in SVUH/ MMUH, along with resident PIs of both institutions. The construction of the CRC Bioresource centre (BRC), a biobank designated facility, has significantly contributed to the expansion of the CRC's biobank operations. The BRC has enabled greater accessibility to the CRCs biobanks resources, an increased footprint for the addition of ULT devices, and the incorporation of a LIMS system for sample labelling, storage and tracking. The acquisition of the laboratory information system (LIMS) has also helped further enhance the biobank's efficiency, sophistication and standing within the research community. In addition to its own repository, the CRC has recently consolidated its sample collection with cohort batches originating from translational research studies sponsored by our external collaborators and industry partners. This new development greatly enhances the diversity of its collections.



CRC SCIENTIFIC SERVICES RESEARCH ACTIVITIES SUPPORT

The Scientific Services division provides support to both clinical translational 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.

INVESTIGATOR INITIATED TRIAL SUPPORT

The scientific services team directly supports two CRC sponsored investigator initiated trials; GOAL-ARC and HCC-TACE.

The investigator-initiated 'GOAL-ARC' study coordinated by Prof. Glen Doherty, 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 supporting this trial since its initiation. Our support has included:

1. Providing patient kits to each of the six sites registered with this study
2. Successful completion of a GLM stability study to elucidate optimum storage temperatures of patient samples
3. Extraction of FCAL from patient stool samples for analysis in MMUH
4. Analysis of serum GLM levels via the CRC Core Biomarker Lab

Over 850 samples have been processed from 113 recruited patients. 426 samples from this cohort were analysed for serum GLM levels and 424 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 the GLM Assay. Proficiency testing has been successfully completed on a monthly basis since May 2017 for FCP and on a quarterly basis from January 2018 for GLM.

The investigator-initiated 'HCC-TACE' study coordinated by Dr. Austin Duffy was initiated in 2020. The primary objective of this Pilot study is to preliminarily evaluate the 6-month progression free survival in patients with advanced Hepatocellular Carcinoma (HCC) by combining Tremelimumab and Durvalumab with TACE (Trans-arterial Chemoembolization). The Scientific Services team has been actively involved in supporting this trial since its initiation. Our support has included:

1. Patient kit provision for the SVUH collection
2. Sample processing which includes PBMC extraction

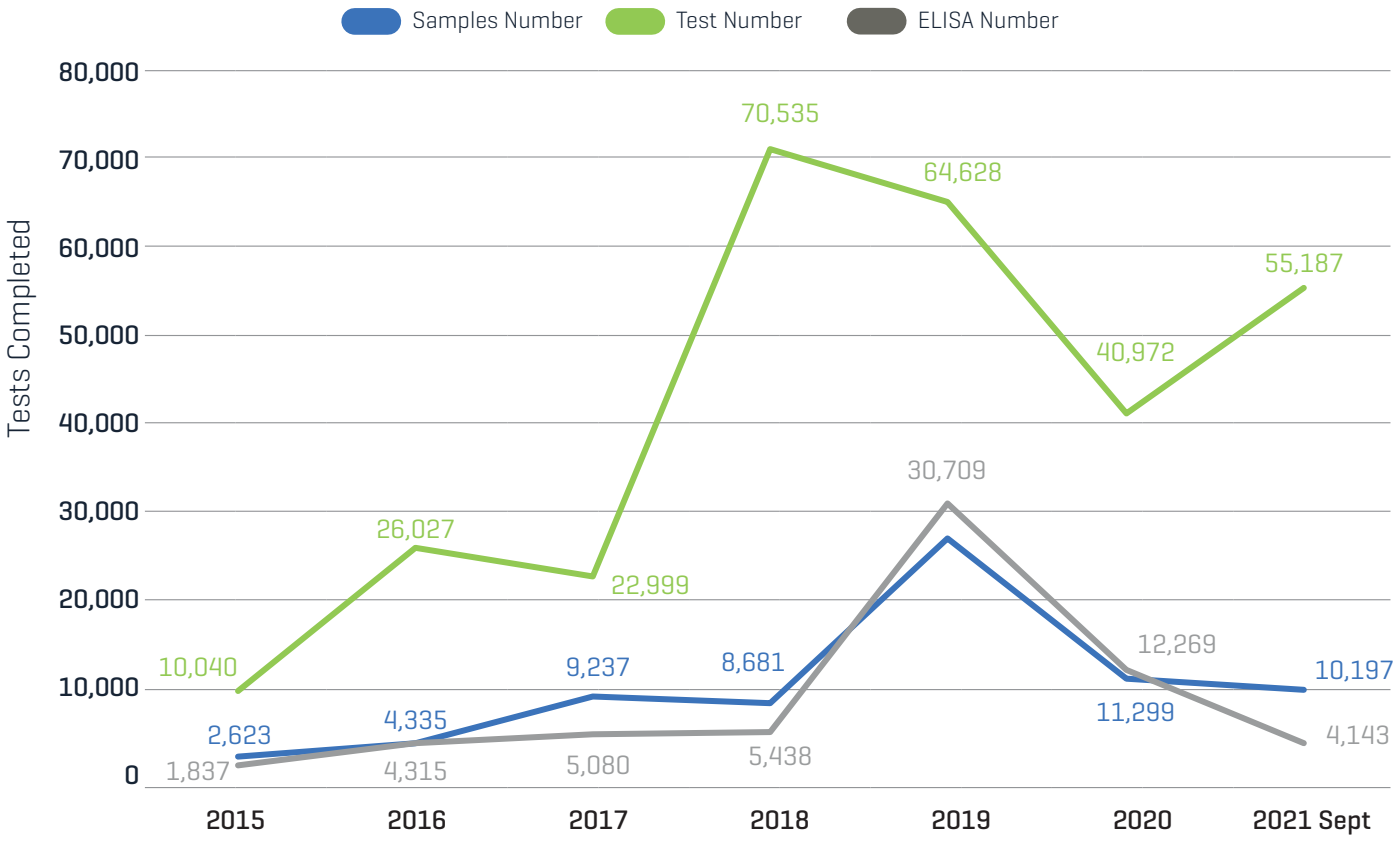
Over 1037 samples have been processed from a recruited 13 patients. The preanalytical integrity of the processed samples are maintained by appropriate storage and remote temperature monitoring provided as part of the CRCs infrastructural service.

UCD CRC 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 and in 2021 a new ELISA platform Quanterix SP-X was installed, both platforms are capable of performing single or multiplex analysis. The acquisition of the SR-X and SP-X further enabled the CRC to measure biomarkers whose levels are below detectable ranges for standard assays. In 2021 a new digital ELISA platform Quanterix SP-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 2020-2021 the CRC carried out analysis on 800 patient samples using the SR-X platform producing over 4000 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 2020-2021 this portfolio was further expanded in response to the need for an investigation into market available Sars-Cov-2 antibody kits.

CRC Core Biomarker Lab Analysis



In the last year, over 55000 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.

On the total of over 55000 tests completed by the CRC Core Lab over 4000 were on ELISA's platform.

6 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 2020/21 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, a cohort of full time MSc students (X928) funded through the Higher Education Authority July Stimulus Programme commenced their studies in January 2022.

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 continued suspension of face to face teaching for 2020/21 saw changes yet again to the delivery of teaching and assessment. Only essential activities such as laboratory practical sessions for MDCS41890 were completed in person, with all other teaching and assessment 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 undergraduate 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 optional modules, one of which was coordinated by Prof Peter Doran.

MDCS4230 Clinical Trials In Medicine (10 Credit Module)

This module was offered to undergraduates in the spring trimester and an additional offering was provided for the Summer term. 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 UCD investigators about their trial activities in different clinical areas. In addition to the above modules, two new research-based modules were delivered in 2020/21 by the Clinical Research Centre and coordinated by Dr. Deborah Wallace

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)

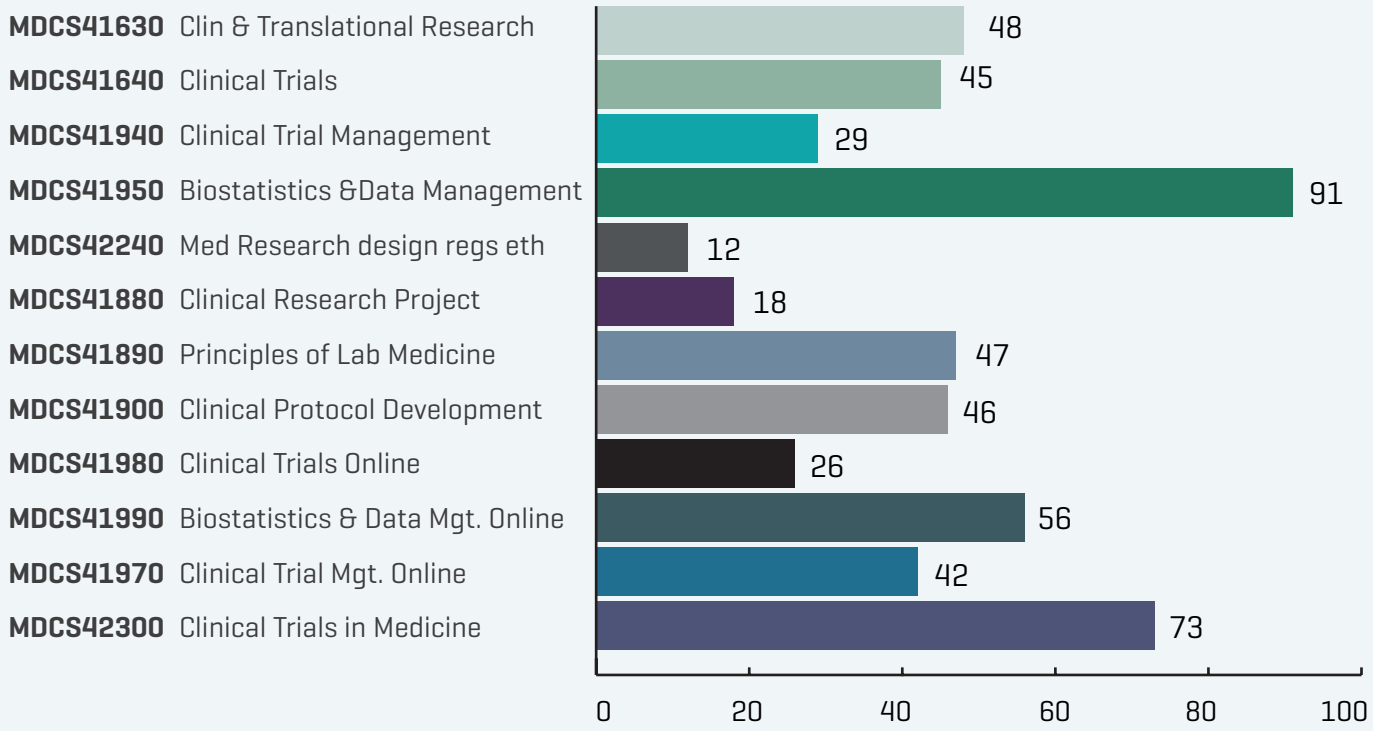
The strategy of the online graduate certificate course is to meet the staff development needs of the multinational Clinical Research Organisation and pharmaceutical sectors. Delivery of this programme utilises innovative Virtual Learning Environments such as recorded lectures, storyboards, videos, discussion boards and 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

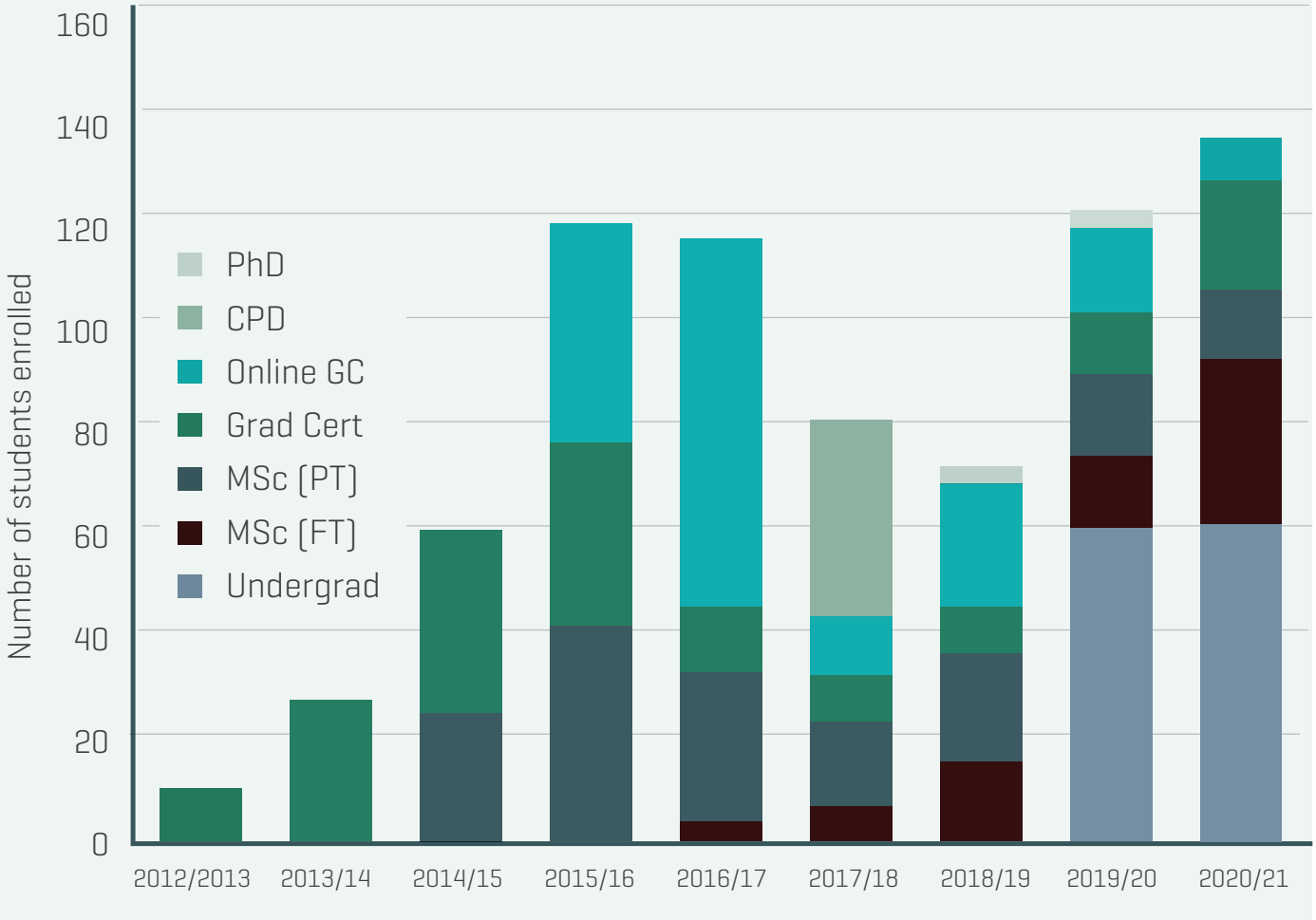
Module/Major	MSc FT [X789]	MSc PT Yr 1 [X427]	MSc PT Yr 2 [X427]	Grad Cert [X635]	Online Grad Cert [X882]	MSc FT [X928]
MDCS41630 Principles and Practice in Clinical and Translational Research	AUT	AUT				SUM
MDCS41950 Biostatistics and Data Management	AUT	AUT		AUT		SPR
MDCS41640 Clinical Trials	AUT		AUT	AUT		SPR
MDCS41900 Clinical Protocol Development	SPR	SPR				SUM
MDCS41890 Principles of Laboratory Medicine	SPR	SPR				SPR
MDCS41940 Clinical Trial Management	SPR		AUT	AUT		
MDCS41880 Research Project	SUM		SPR			AUT
MDCS41970 Clinical Trial Management (online)					SPR	SUM
MDCS41890 Clinical Trials (online)					SPR	
MDCS41990 Biostatistics and Data Management (online)					SPR	

AUT Autumn Trimester SPR Spring Trimester SUM Summer Trimester

STUDENT MODULE ENROLMENT 2020/21



STUDENT ENROLMENT



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