UCD Clinical Research Centre
UCD School of Medicine

UCD CLINICAL RESEARCH CENTRE

ANNUAL REPORT 2021/22

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WELCOME

I am delighted to introduce the 2021/2022 UCD Clinical Research Centre Annual Report. As we have emerged from the Covid-19 pandemic our centre has rapidly ramped up all areas of investigation as shown in this report. Across all activity domains the UCD CRC team has delivered exceptional activity, contributing to our continued success. We have also undertaken a significant work programme to commence the HRB funded activities at the UCD CRC. This new investment is enabling us to expand our team and will deliver significant benefits for our investigators, our patients and the wider community. Through the HRB support we will undertake extensive activities across a number of specific workpackages:

1. Widening Participation & Ensuring Access

2. Modernising Delivery & Enhancing Support

3. Improving Design & Supporting Outputs

4. Strengthening Understanding & Increasing Engagement

5. Coordination & Collaboration

The funding leveraged through this award allows us to expand our supports to the investigator community, expansion that will be driven

Geographically. Additional sites, including specialist and general hospitals and general practice

Methodologically. Dedicated pharmacy, biostatistics and systematic review staff will enhance our trials

Scientifically. By focusing on investigator-initiated trials, we will improve translation of our best science into clinical practice

We are well on the way to delivering this programme and look forward to seeing its impact.

We have also continued to contribute significantly to the growth in research income and activity at the UCD School of Medicine. Indeed the CRC's citation performance with a field weighted citation index of 2.91, is delivering real impact for the School, the College and the University.

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

As the founding director of the UCD CRC, I have had the great privilege of leading this centre since 2006. In the intervening years, we have established a programme of which we can all be proud. Across all measures, both quantitative and qualitative we have created a centre which is impactful, which is a great place to work and which is improving outcomes for our patients. I wish my successor and the team the very best in the future.

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

373
STUDIES

62
NEW STUDIES

177
CLINICAL TRIALS

SCIENTIFIC SERVICES

3,177
PATIENT SAMPLES BIOBANKED

1,623
SAMPLES RELATED TO PI INITIATED CLINICAL TRIALS

39,635
BIOMARKERS TESTED ON 12,319 PATIENT SAMPLES

5,477
ELISA/ DIGITAL ELISA MARKERS ON 13,651 PATIENT SAMPLES

QUALITY & REGULATORY AFFAIRS

6
DSUR REPORTS

>25
HPRA APPROVALS

58
UCD CRC SOPS

8
STAFF COMPLETED TRIANING REPORTS

9
INVESTIGATOR INITIATED TRIALS

EDUCATION

5
EDUCATION PROGRAMMES

10
MODULES

151
STUDENTS

3
PROFESSIONAL DEVELOPMENT

OUR OUTPUTS

68
PRINCIPAL INVESTIGATORS ACROSS UNIVERSITY & HOSPITAL

402
PUBLICATIONS
45,000+ CITATIONS
47% IN TOP 10%

2.91
FIELD WEIGHTED CITATION
4.08 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.

Prof Peter Doran received funding of €5.3 million to build on and strengthen significant positive achievements realised since opening in 2006. This funding from the HRB has allowed the UCD CRC to provide additional supports to investigators and to widen our research network, thereby ensuring that more of our hospitals, staff and patient share access to cutting edge research. The funding has allowed us to expand, into four more sites during 2022, the National Rehabilitation Hospital (NRH), the National Maternity Hospital (NMH), St Luke's Hospital Kilkenny and Wexford General Hospital to support new studies focused on rehabilitation, women's health, and primary care and in doing so, to improve patient access to new trials. In addition, it is enhancing the way in which we do trials, by focusing on enabling technologies and creating pathways to enhanced patient participation and involvement.

In summary this HBR funding awarded to UCD CRC is enabling:

- Increased access to patients and clinicians to trials
- Expansion of geographical access to research
- Improvement in clinical trial, design, co-ordination, and methodology
- Enhancement of integration of clinical research into health system at six network sites
- Expansion of educational programmes to train researchers and clinicians of the future
- Integration of research results into clinical practice
- Embedding of patient perspective in shaping and informing clinical trial design, development and delivery

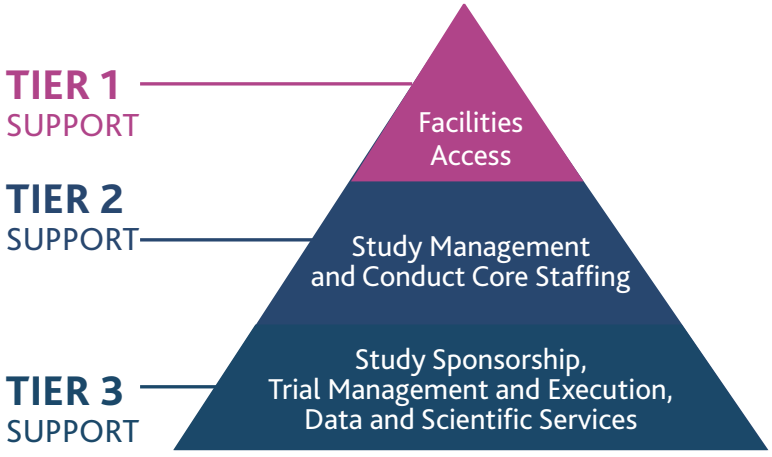
3

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

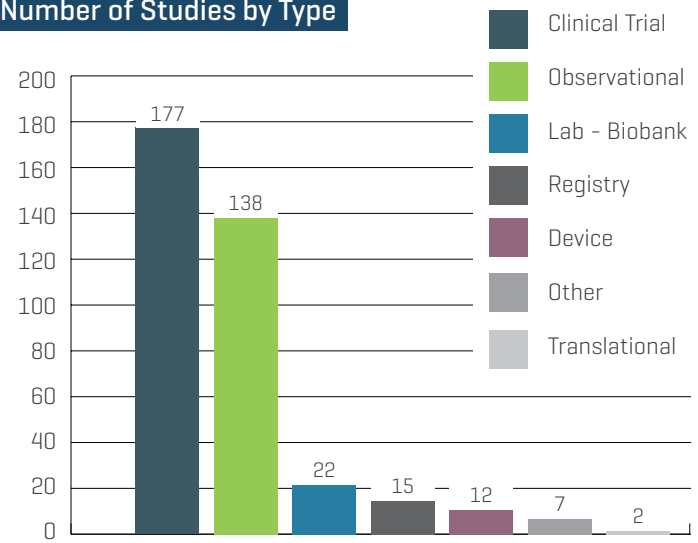
Pre-initiation Phase
- HPRA & Ethics submission
- Investigator Site File
- GCP Training
- Trial Registration
- Monitoring Plan
- Randomisation and Blinding Procedures
- Site Initiation

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

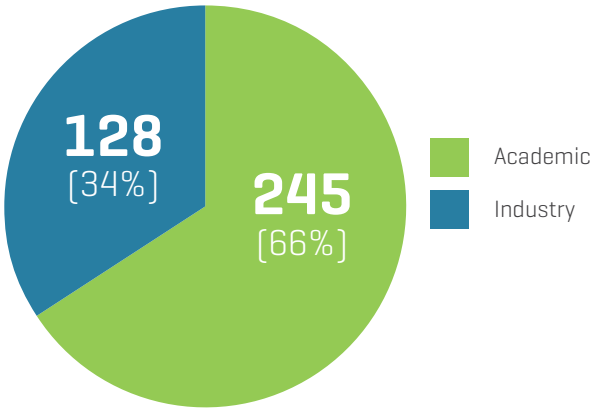
Reporting Phase
- Last Patient Last Visit
- Study Close-out Visit
- End of Trial Notification
- Archiving
- Data Lock and Cleaning
- Data Transfer
- Statistical Analysis
- Budget Close Review
- Clinical Study Report Submission

CLINICAL RESEARCH ACTIVITY

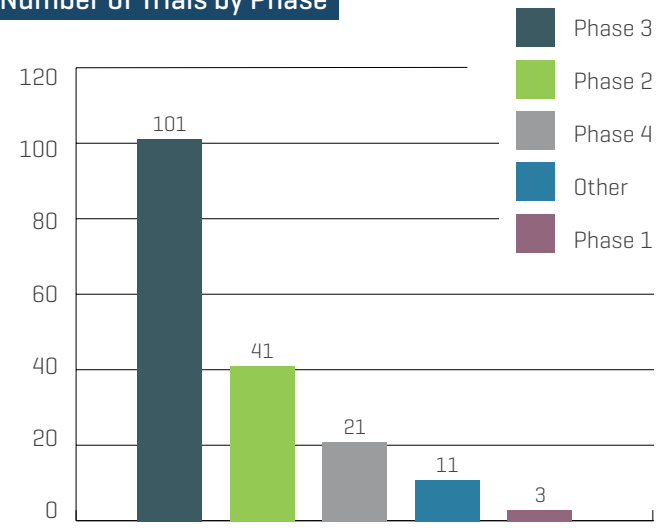
Number of Studies by Type



Number of Studies by Origin



Number of Trials by Phase



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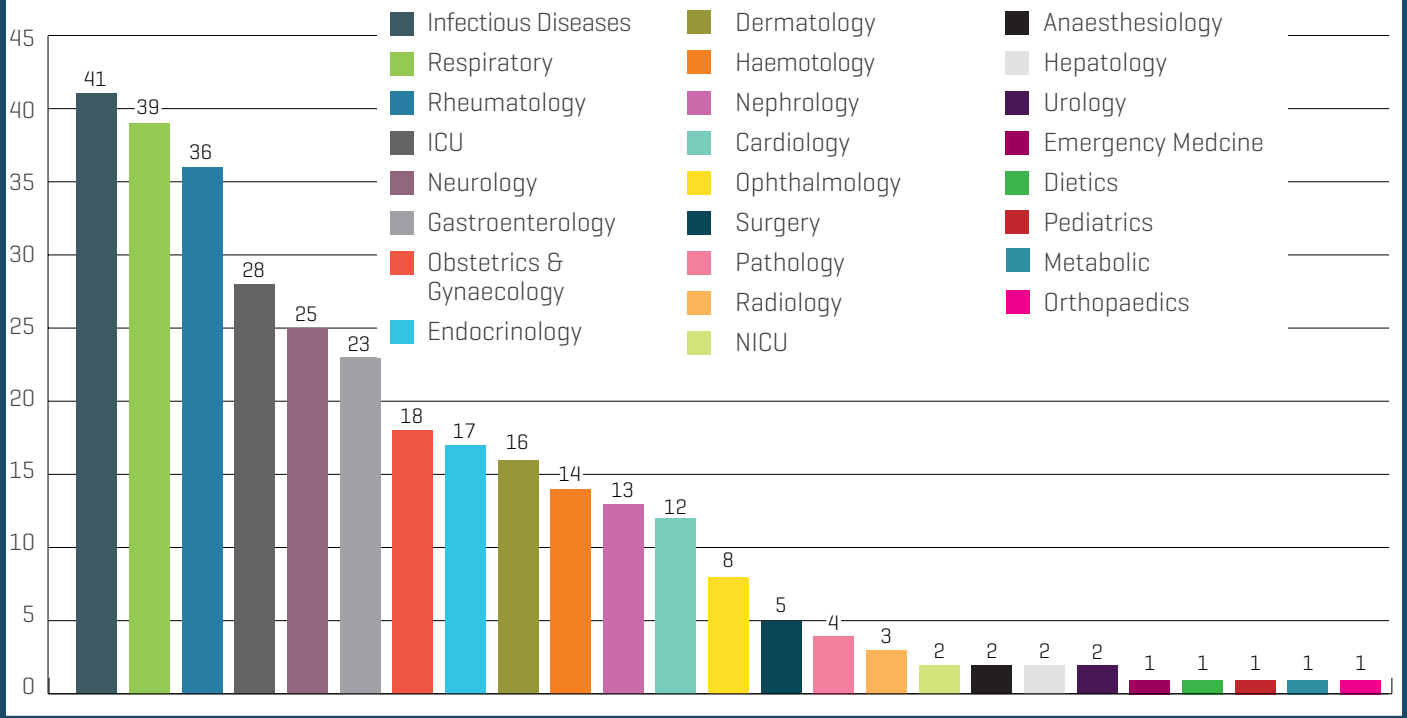
NEW CRC STUDIES
2021/2022

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

- All UCD sponsored clinical trials have progressed over the academic year and will advance to completion over the coming months, including our recent COVID-19 related clinical trial COVIRL-002.
- 5 UCD sponsored clinical trials have expanded internationally and have been activated in countries including UK, Germany, Italy, Czech Republic, Sweden, Norway, Spain, Poland, Slovakia and Switzerland.
- Interactive transcelerate-accredited GCP training sessions provided across UCD affiliated hospital sites providing training for over 120 investigators, research staff and students.

MONITORING

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).

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.

Over the past academic year UCD CRC CRAs have completed a total of 26 monitoring visits across the affiliated clinical trial sites in Ireland, including 9 Site Initiation Visits for our investigator-initiated clinical trials.

REGULATORY AFFAIRS

Clinical trials in the EU have been conducted in accordance with the EU Clinical Trial Directive 2001/20/EC, introduced to simplify and harmonise the administrative provisions governing clinical trials in Europe. The directive was transposed into national law in Ireland in 2004 and has been repealed by the Clinical Trials Regulation 536/2014 upon its application in 2022.

In preparation for the transition to implementation of the new clinical trial regulations, UCD CRC Quality and Regulatory Affairs staff have been completing training which will allow UCD to submit clinical trial application centrally through the Clinical Trial Information System (CTIS).

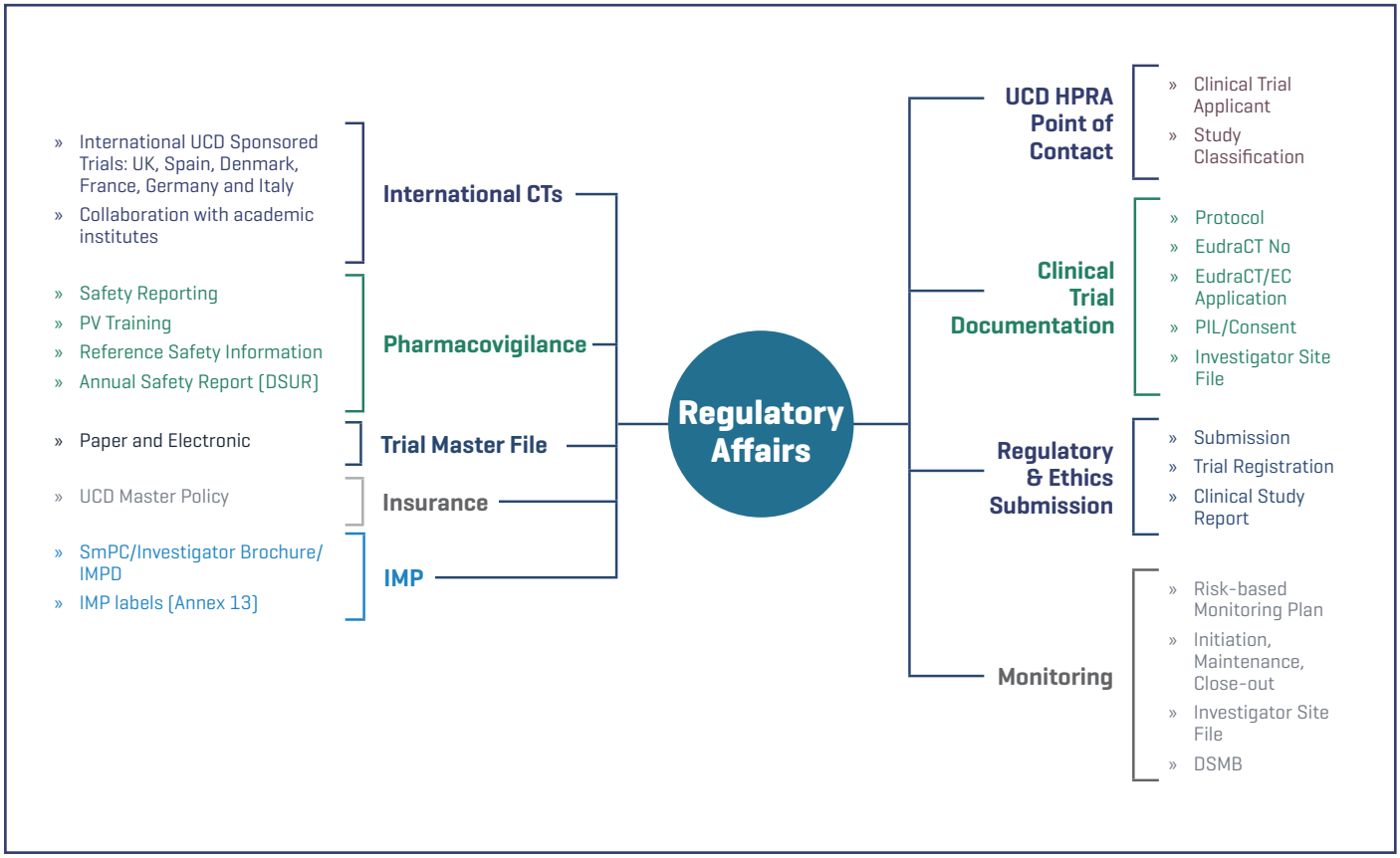
With the addition of a Quality & Regulatory Affairs Officer, Research Pharmacist and Sponsorship Officer, all new roles within the CRC team, UCD CRC has also developed a streamlined training plan for all these new hires in addition to the training plan already established for new Clinical Research Associates joining the organisation. This has been pivotal in harnessing and developing new staff, increasing quality of research activity and team morale, and providing consistency in each new hire's deliverables within their area of expertise.

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

CSA STRENGTHENING TRAINING OF ACADEMIA IN REGULATORY SCIENCES (STARS) PROJECT

The STARS initiative is an EU-funded project to build connections between academia and health authorities in order to strengthen regulatory excellence. The project illustrates the hurdles, and options to strengthen regulatory knowledge by reaching clinical scientists during professional training / qualification and improve the direct regulatory impact of results obtained in medical research.

In May 2022, UCD CRC QRA staff were invited to participate in the final event for the initiative in Brussels hosted by European regulatory authorities, including HPRA, BfArM and HPRA. Ms Rabia Hussain, Head of Trial Operations at UCD CRC was invited to provide an impulse talk on regulatory science in academic clinical research and the role of an academic sponsor.



5 DATA & INFORMATION SYSTEMS

CLINICAL DATA MANAGEMENT

The UCD 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 UCD CRC studies this year:

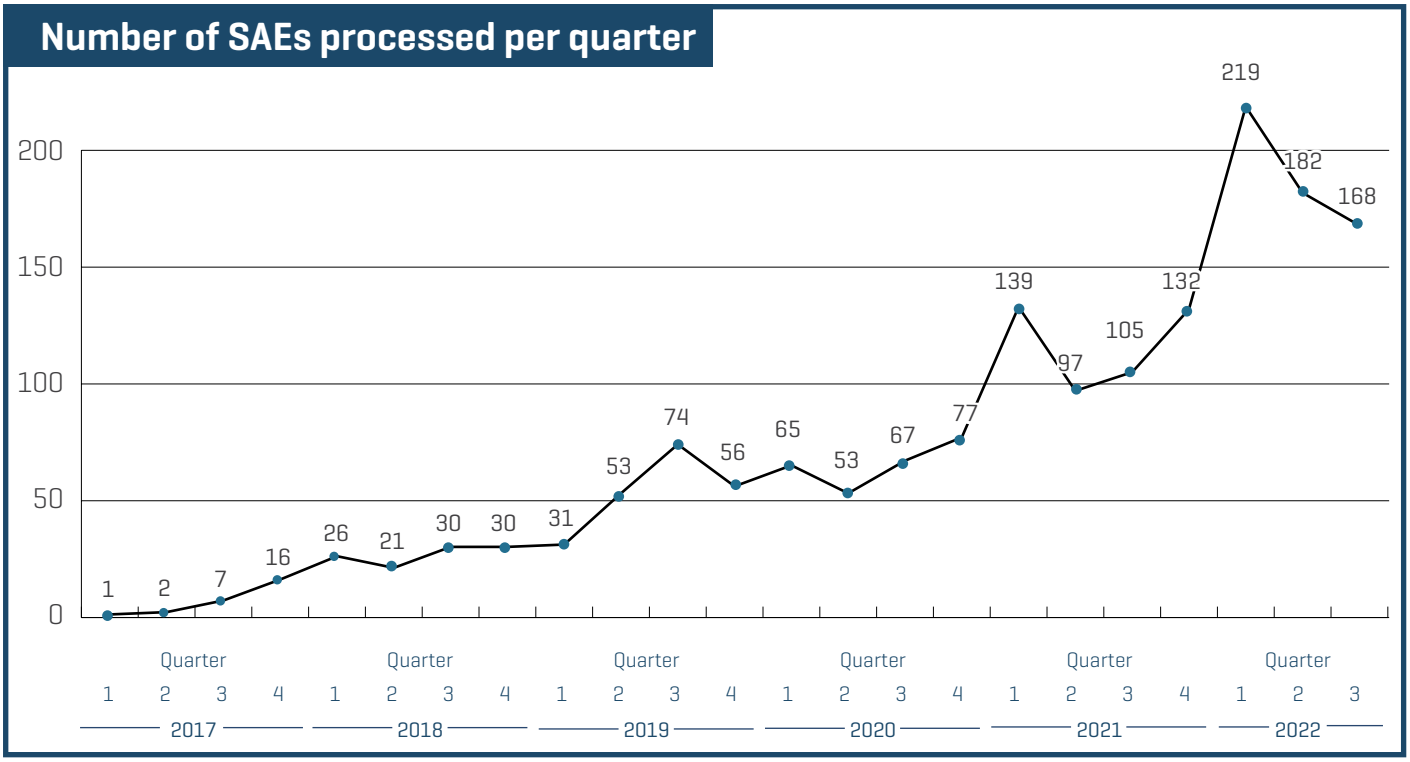
- **SWIFT** - A randomised, controlled, parallel group, open-label trial evaluating the impact of treatment with the GLP-1 analogue semaglutide on weight loss in people living with HIV and obesity.
- **EMPRESS** - MEchanisms of hypercoagulability in MyeloProlifeRative nEoplaSmS
- **PREPOP** - PREterm birth Prevention with Oral Probiotics
- **COMFORT** - A randomised control trial comparing group-based COMpassion FOcused Therapy and breathing pattern ReTraining with Treatment As Usual on the psychological functioning of patients diagnosed with cancer recurrence during COVID.
- **DAPPA** - Diagnosis, Disease Activity and Prognosis of Psoriatic Arthritis
- **Interstitial Lung Disease Registry**

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

REDCap is managed by UCD CRC on secure servers located in Ireland and is widely used by our investigators and research teams, with approximately 400 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 UCD 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: 6 Clinical Trials, 34 Observational Studies
- **Pharmacovigilance Management System:** support assessment, reporting and review of serious adverse event data relating to clinical trials at UCD CRC

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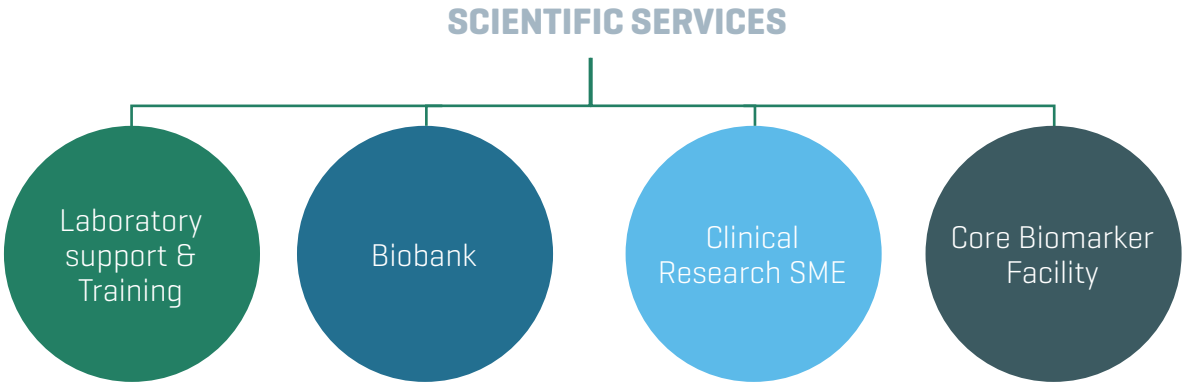
SCIENTIFIC SERVICES

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.
   - A ELLA Device for single/ multiplex 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 UCD 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 UCD CRC's educational programs, so that they may receive practical training in clinical laboratory diagnostics. In 2021-2022, 14 new users received training to access the UCD CRC Laboratories, bringing the total number of current users over 100 between both SVUH and MMUH sites.

UCD CRC BIOBANK

The UCD CRC biobank 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-80oC (11 -20oC; 4 -40oC and 38 -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

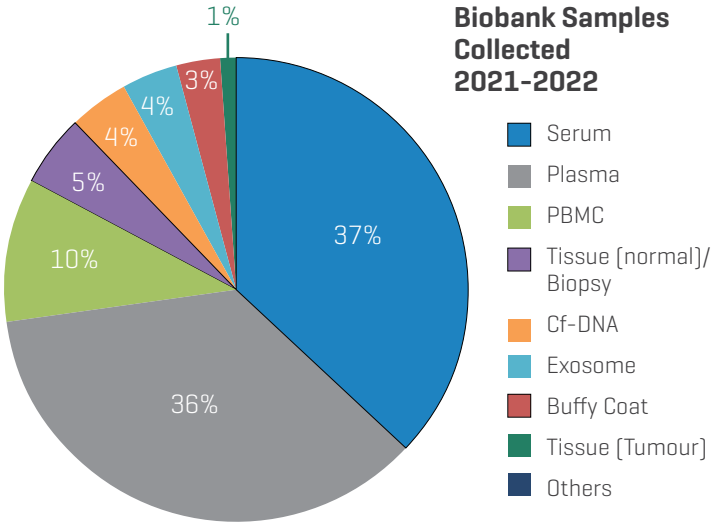
To date, there are over 40 biobank study collections facilitated by the UCD CRC comprising a total of over 47,000 processed samples stemming from nearly 9,000 consented patients.

Of this total, over 1300 patients were recruited in 2021-2022 with a total of almost 3177 samples processed.

CRC Biobank Collection

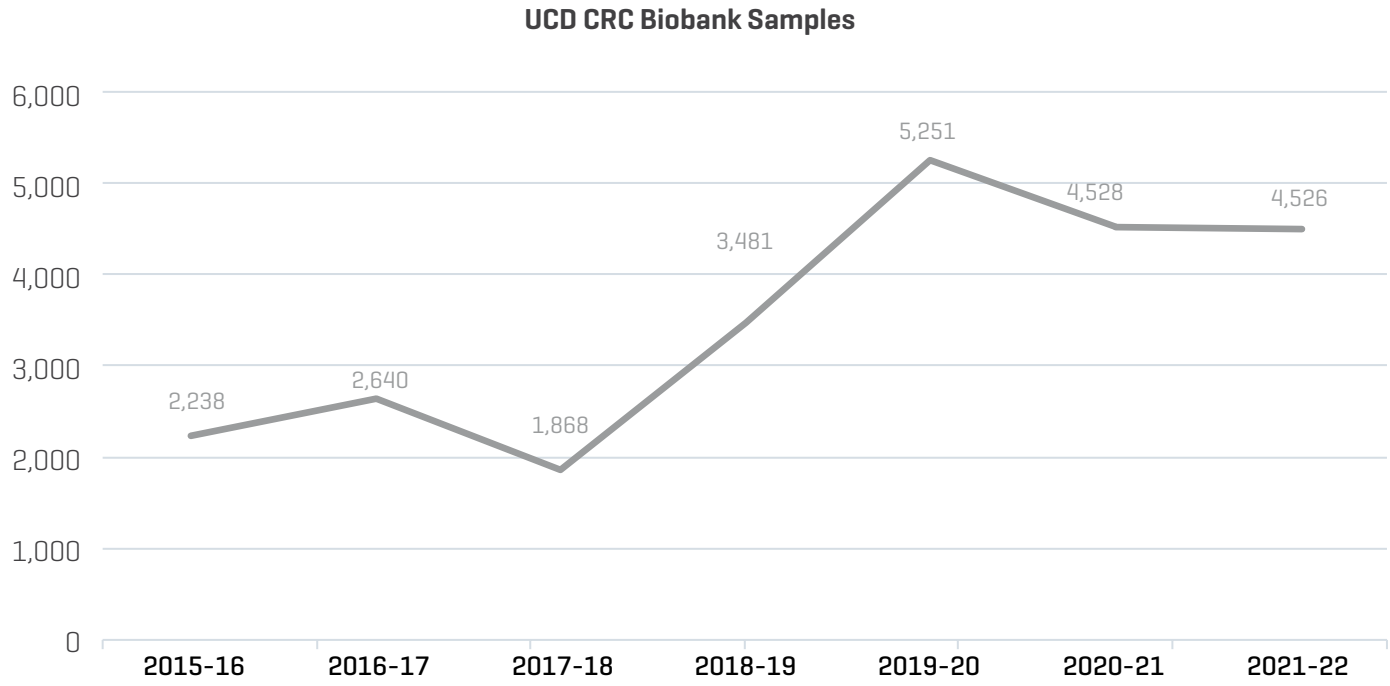
Research Focus	Associated Disease
Arthritis	Rheumatoid arthritis, Osteoarthritis, Gout
Infectious Diseases	Sars-CoV-2, Lyme Disease
Oncology	Ovarian, Pancreatic, Prostate, Lung, Liver, Uterine, Adrenal, Soft Tissue Sarcoma
Interstitial Lung Diseases	Idiopathic Pulmonary Fibrosis, Sarcoidosis
Nephrology	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 UCD 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 UCD 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 UCD CRC's most recent collections concern gynaecological cancer and Lyme disease. In 2021-2022, the uterine cancer collection expanded its repository by over 1200 samples from a recruited 58 patients (314 patients recruited for a total of 6825 samples collected since the start of the collection).

The extensive nature of the UCD 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 UCD CRC Bioresource centre (BRC), a biobank designated facility, has significantly contributed to the expansion of the UCD CRC's biobank operations. The BRC has enabled greater accessibility to the UCD CRC's 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 UCD 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.



UCD 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 UCD 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 UCD 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 UCD CRC Core Biomarker Lab

Over 980 samples have been processed from 116 recruited patients. 426 samples from this cohort were analysed for serum GLM levels and 424 stool samples were extracted for FCAL. The UCD 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

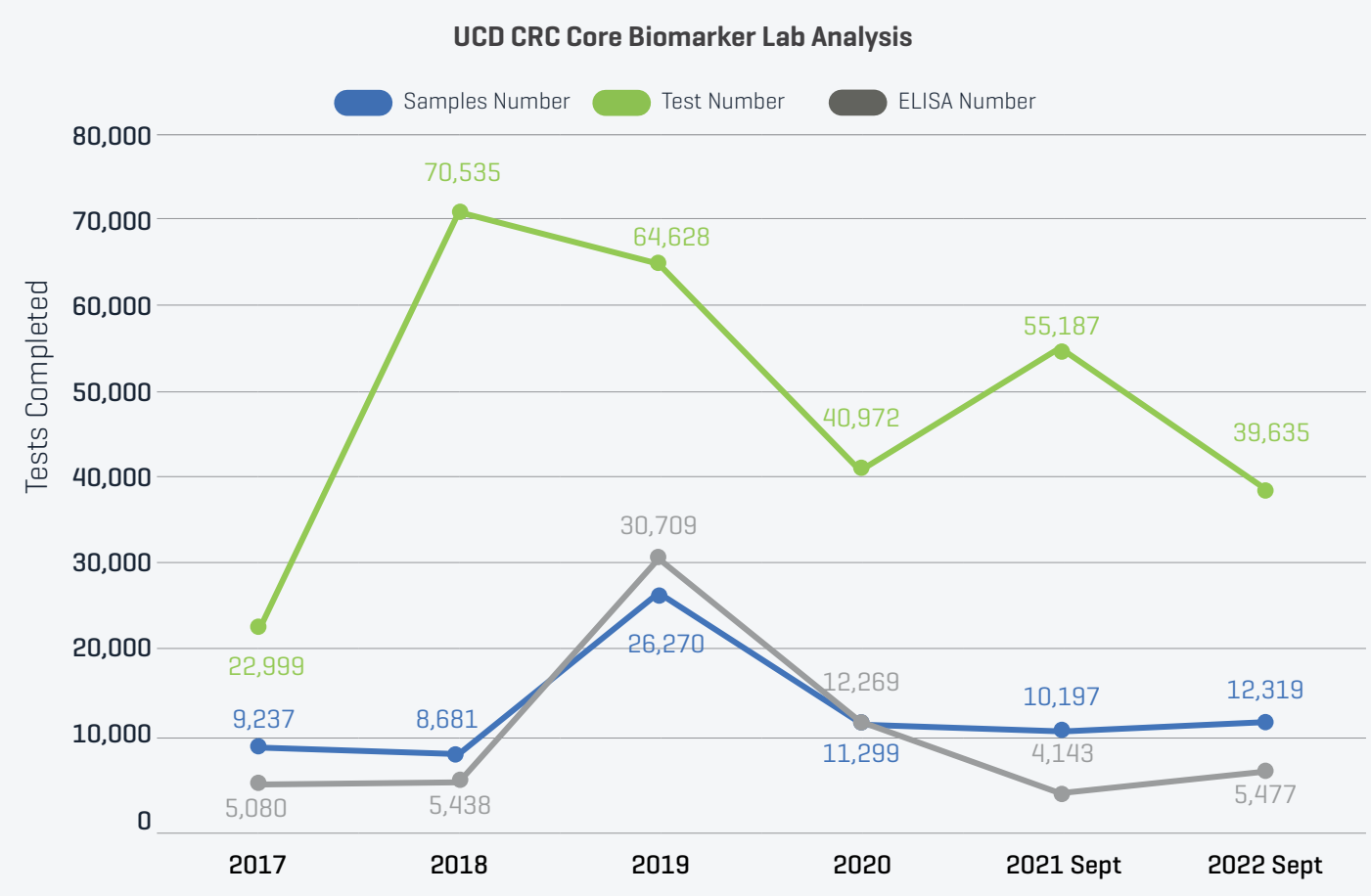
Over 1037 samples have been processed from a recruited 13 patients. The preanalytical integrity of the processed samples are maintained by appropriate storage and remote temperature monitoring provided as part of the UCD CRC's infrastructural service.

A second HCC-TACE phase is under review and will be supported by the UCD CRC Core Lab.

UCD CRC CORE BIOMARKER LAB

The UCD CRC Core lab facility is a biomarker testing laboratory located at the UCD CRC in St Vincent's University Hospital. Founded through an extensive collaboration between UCD CRC and Abbott Diagnostics, the UCD 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 UCD 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 UCD CRC to measure biomarkers whose levels are below detectable ranges for standard assays. In 2022 a new ELLA elisa platform was installed which is capable of performing single or multiplex analysis.

The Core Biomarker lab has enabled the UCD CRC to support local research programmes that would otherwise find difficulty in completing large cohort sample analysis. For over a decade the UCD 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 UCD CRC engaged in a collaboration with Abbott centred around assay method comparison that added 4 new projects to the Core labs study portfolio. In 2021-2022 this portfolio was further expanded in response to the need for an investigation into market available Sars-Cov-2 antibody kits and new markers been developed on the new Alinity platform.



In the last year, over 39,000 tests have been completed on over 12,000 patient samples by the UCD CRC Core lab. The majority of research projects undertaken by the core lab in the last year predominantly focus on following main disease areas: Cardiology, TBI, Diabetes, AKI and endocrinology .

On the total of over 39,000 tests completed by the UCD CRC Core Lab over 5,400 were on ELISA's platform.

NOTABLE ACTIVITY 2021-2022

- **Core Lab:** Expanded our collaboration with Abbott including biomarker validation between multiple platforms, research projects undertaken predominantly focus on following main disease areas: Cardiology, TBI, Diabetes, AKI and endocrinology. Over 39,000 tests have been completed.
- **CRC Biobanks:** CRC Biobank is in continuous expansion with 3 more units added this year and with an increasing number of biobank collection hosted for our collaboration with external industrial partners.

7

EDUCATION

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

PROGRAMME OVERVIEW

The academic year 2021/22 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 concluded their studies in December 2021

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 taught by 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.

Full time One year MSc in Clinical and Translational Research (X789 / X928)

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 a 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.

Modules delivered outside Core Programme

The UCD CRC offered modules to students outside of our programmes. These included a 10 credit module, MDCS42300 Clinical Trials in Medicine offered to final year medicine students and coordinated by Prof Peter Doran. 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.

Two 10 credit research-based modules were delivered in 2021/22 by the Clinical Research Centre and coordinated by Dr. Deborah Wallace, MDCS42130 Scholarship Enhancing Clinical Practice and MDCS42240 Medical Research Design, Regulations & Ethics as part of the MSc in Primary Care and MSc in Data Analytics for Precision Medicine / MSc Precision Medicine / MSc Artificial Intelligence (AI) for Medicine & Medical Research respectively.

PROFESSIONAL DEVELOPMENT

Clinical Trial Masterclass: National Academic Track for Internship

The Intern Network Executive oversees intern training in collaboration with medical schools. The academic track internship initiative provides an early and dedicated focus on research skills among doctors, and builds on research opportunities that are available from undergraduate training across the Irish medical schools. A UCD Masterclass Programme on Clinical Trials open to all Academic Track interns from around the country was held on Saturday September 25th 2021 at the UCD Catherine McAuley Centre. 23 academic track interns were in attendance. This Masterclass is a formal teaching event facilitated by the UCD Intern Network and the UCD Clinical Research Centre supporting the Academic Track Intern Programme with the aim of fostering participants' curiosity in pursuing a career as an academic clinician. The Masterclass covered topics such as Drug Discovery and Development, Preclinical Trials, Knowledge Generation, Trial Principles & Design, Statistical Considerations, Hypothesis Testing, Power, Sample Size & Randomisation/ Blinding, and Study Endpoints.

Introduction to Biostatistics, Study Design and SPSS

This six week online course was targeted at hospital staff engaged in, or interested in engaging in, research, who have a desire to better understand the fundamentals of study design and biostatistics. In January 2022, UCD Clinical Research Centre offered this course free of charge to hospital staff at IEHG-affiliated hospitals. The course provided introductory training in statistics, including principles of study design, critical appraisal of research and the use of statistical software via online lectures and exercises. Sixteen students completed the course this year and obtained a certificate of completion.

Trialist Programme

The UCD CRC has a long tradition of working with investigators to conduct high quality clinical trials which are improving patient outcomes. As trials have become more complex and the environment more challenging, this course provided an opportunity for investigators to undertake specific training to enhance their Trialist skills. Delivered by the UCD Clinical Research Centre Team and external experts, this programme provided 34 attendees with one day of face to face training along with two days of online training in July 2022.

This course was targeted at those interested in taking part in clinical trials, investigators, site leads, chief investigators, research nurses etc. Whether entirely new to clinical trials or an experienced investigator, this course aimed to enhance the attendees understanding, develop their network and open up new opportunities to engage in trials.

A Certificate of Completion and 15 CME credits from RCPI was awarded to all attendees on successful completion of this course.

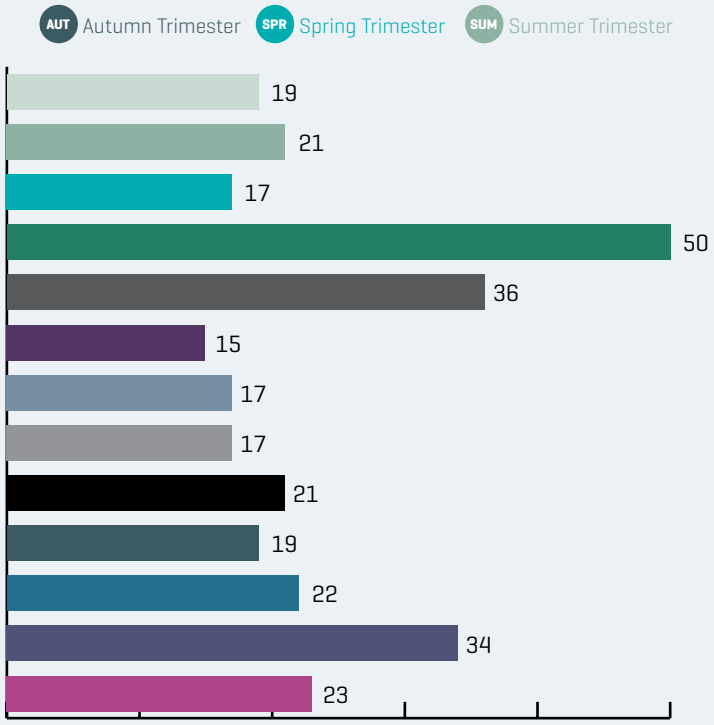
PROGRAMME STRUCTURE AND MODULES

Trimesters: AUT Autumn SPR Spring SUM Summer

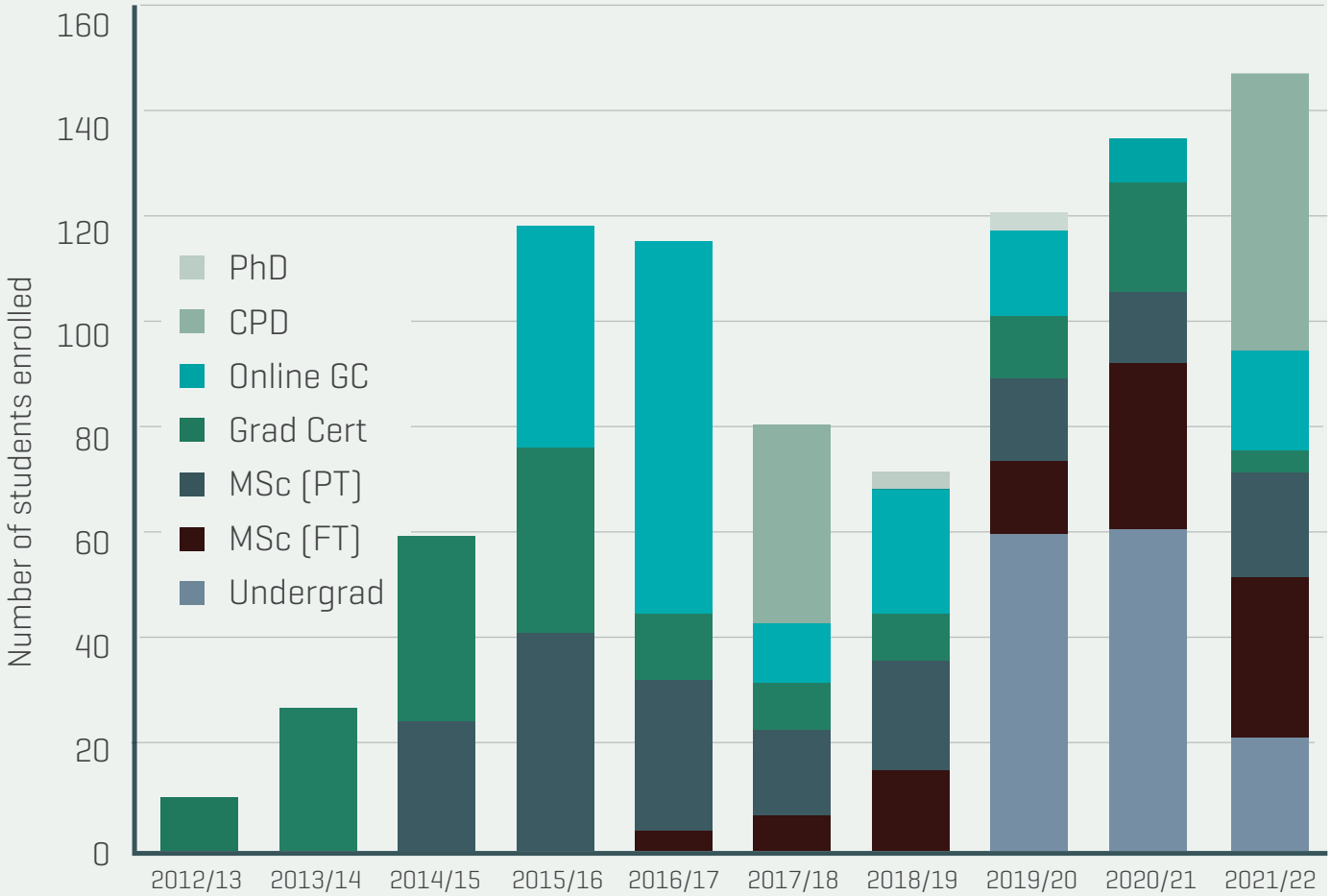
Module/Major	MSc FT [X789]	MSc PT Yr 1 [X427]	MSc PT Yr 2 [X427]	Grad Cert [X635]	Online Grad Cert [X882]	MSc FT [X928]
MDCS41630 Principles and Practice in Clinical and Translational Research	AUT	AUT				SUM
MDCS41950 Biostatistics and Data Management	AUT	AUT		AUT		SPR
MDCS41640 Clinical Trials	AUT		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	

STUDENT MODULE ENROLMENT 2021/22

MDCS41630	Clinical & Translational Research	AUT
MDCS41640	Clinical Trials	AUT
MDCS41940	Clinical Trial Management	AUT SPR
MDCS41950	Biostatistics & Data Management	AUT
MDCS41880	Clinical Research Project	AUT SPR SUM
MDCS41890	Principles of Lab Medicine	SPR
MDCS41900	Clinical Protocol Development	SPR
MDCS41980	Clinical Trials Online	SPR
MDCS41990	Biostatistics & Data Mgt. Online	SPR SUM
MDCS41970	Clinical Trial Mgt. Online	SUM
MDCS42300	Clinical Trials in Medicine	SPR
MDCS42130	Scholarship Enhancing Clinical Prac	AUT
MDCS42440	Medical Res Design, Reg & Ethics	AUT



STUDENT NUMBERS BY MAJOR 2021/2022



COLLABORATORS AND SPONSORS OF CURRENT STUDIES

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