



UCD School of Medicine

INNOVATION COLLABORATION PATIENT-FOCUSED RESEARCH

UCD CLINICAL RESEARCH CENTRE ANNUAL REPORT 2015/2016



MISSION

Our mission is to improve the health of the nation by ensuring that novel interventions are developed, evaluated and implemented in routine clinical practice.

VISION

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

WELCOME

We are delighted to present this summary of UCD Clinical Research Centre activity for the 2015/16 academic year.

The UCD CRC is an academic-led, multi-site, patient-focused facility for clinical and translational research integrated under a single governance structure within the UCD School of Medicine. It has been created to deliver the School's strategic objective of advancing high quality, impactful investigator-led translational and personalised medicine research. The UCD CRC is aligned with UCD's vision of being a research-intensive university by supporting the 'bench to bedside' translational research continuum. The centre also delivers high quality education programmes to serve the future staffing needs of the academic and industry sectors both domestically and internationally.

Since opening in 2006, the UCD CRC has had a significant impact on the national research landscape. We have created an environment which is supportive of investigators, recognised by regulators and attractive to patients. These efforts have underpinned significant growth in research outputs. The launch and implementation of the UCD CRC Strategy 2015-19 further expanded our activity. With the support of the UCD School of Medicine, core expertise in Quality and Regulatory Affairs, Business Development, Education and Information Management has been added to the centre over the last year. By making strategic investments in key roles, we have delivered major impact, as evidenced in this report. We have delivered significant activity across all of the CRC activity domains of Clinical Trials, Scientific Services, Education and Networks & Partnerships. This report shows the major metrics of success and provides illustrative examples of impact. We also highlight how the UCD CRC is helping to deliver the University objectives, articulated in the UCD Strategy for Research, Innovation and Impact.

The UCD CRC is impacting patient's lives, supporting our hospitals and delivering the School and University Research strategy. This impact is delivered by the expert team of CRC staff and associated researchers and investigators. On behalf of the CRC leadership team, we want to thank all of the staff whose commitment, skill and hard work has driven the progress detailed in this report.

Peter Doran
Patrick Murray
Michael Keane

UCD CLINICAL RESEARCH CENTRE

IN NUMBERS

189
STUDIES

47
NEW STUDIES

15
INVESTIGATOR INITIATED
TRIALS

121
CLINICAL TRIALS

>6500
PATIENT CONTACTS

72
ACADEMIC COLLABORATIONS

40
BIOBANKS

1,300
BIOBANKED SAMPLES

300
PBMC PREPARATIONS

3,000
PATIENT KITS

6,675
SAMPLES ANALYSED

31,091
BIOMARKER ASSAYS
COMPLETED

5
PROGRAMME MAJORS

110
GRADUATE STUDENTS

27
STUDENTS FROM 27
COUNTRIES

60
PEOPLE INITIATED THROUGH THE CRC
INDUCTION PROGRAMME

70
STANDARD OPERATING PROCEDURES IN
USE

CRC OVERSIGHT AND GOVERNANCE

The UCD CRC is led by Peter Doran and reports to the Head of UCD School of Medicine, through the Head of Clinical Pharmacology. A number of groups contribute to the oversight and management of the Centre:

CRC STRATEGIC ADVISORY BOARD

The UCD CRC Strategic Advisory Board, chaired by Prof Ravindra Mehta, University California San Diego, UCSD, plays a major role in advising the CRC strategy by completing annual reviews of the centre's activities and finances. The committee includes representatives of external clinical research facilities, industry and patient organisations.

CRC EXECUTIVE COMMITTEE

The UCD CRC Executive Committee is chaired by the Head of Clinical Pharmacology, Prof Pat Murray, and includes UCD CRC directors and research leaders. The CRC Executive Committee advises the Head of School on governance and leadership of the Centre and meets quarterly.

CRC OPERATIONS COMMITTEE

The UCD CRC Operations Committee oversees the general management of the centre and is chaired by the CRC Director, Peter Doran. The Committee deals with all operational activities of the Centre and reviews and approves all items relating to the ongoing functions of the CRC, including the review of access requests, SOPs, work instructions and strategic projects. The committee meets monthly and is the primary operational and management group of the Centre.

CRC FACILITIES GROUPS

The management and development of the CRC's facilities and physical infrastructure are coordinated through Facilities Management Groups at St Vincent's University Hospital and Mater Misericordiae University Hospital. The groups, chaired by Gareth Shaw, report to the UCD CRC Operations Committee.

AN INTER-DISCIPLINARY TEAM PROVIDING FULL SERVICE TO INVESTIGATORS

The core UCD CRC team members have a broad range of knowledge and expertise in the fields of clinical research and research management. The inter-disciplinary team work together to provide bespoke guidance and support to clinical investigators. With backgrounds in academic research, academic leadership, healthcare and industry, in-house fields of expertise include:

- » Research Leadership
- » Research Planning
- » Quality & Regulatory Affairs
- » Data Management
- » Scientific Services & Lab Management
- » Biostatistics
- » Research Nursing
- » Finance & Budgeting
- » Business Development
- » Teaching & Learning
- » Project management & planning

CONTRIBUTIONS TO THE UCD STRATEGY FOR RESEARCH, INNOVATION & IMPACT:

OBJECTIVES:

- 5 Attract and retain an excellent and diverse cohort of students, faculty and staff
- 9 Adopt governance, management and budgetary structures which enable the vision
- 10 Overcome financial, human resource management and other external resource constraints

FACILITIES AND INFRASTRUCTURE

CLINICAL INFRASTRUCTURE

Core research infrastructure has been created to support clinical investigations at the Mater Misericordiae and St Vincent's University Hospitals. The clinical research infrastructure includes:

1. Eight out-patient interview rooms for patient examination and tissue collection
2. Four procedure rooms for more complex patient studies
3. An endoscopy suite for internal medical examination, including arthroscopy and bronchoscopy
4. Recovery room facilities for patients post-procedure
5. Dual Energy X-ray Absorptiometry (DEXA) Scanner with full body composition analysis capabilities which support osteoarthritis/osteoporosis studies
6. Climate-controlled storage facilities for Investigational Medicinal Product materials

INFORMATION SYSTEMS

The appropriate use of intelligent and secure IT solutions is key to the translational research mission, permitting the generation and exchange of data and information between the 'bed' and the 'bench'. The UCD CRC is addressing these challenges by implementing cost-effective IT solutions which combine to create a sophisticated clinical research information infrastructure that supports all aspects of clinical research.

LABORATORY INFRASTRUCTURE

UCD CRC on-site laboratory facilities support the immediate processing of biological samples collected during research studies. The laboratory infrastructure complements biomedical research facilities on the University campus and includes:

1. Cell and tissue culture suites for primary cultures, equipped with sterile cell culture hoods & incubators
2. A molecular biology laboratory with standard equipment and facilities for molecular analysis
3. Imaging Laboratory (with contrast and fluorescence microscopy)
4. UCD-Abbott Core Biomarker Laboratory including Architect i2000 and Ci1200 high throughput analysers

Recognising the importance of access to appropriately consented, well phenotyped quality controlled biological samples to translational research, the UCD CRC has developed a network of biological resource centres for sample receipt, storage and processing across the hospital campuses. These include:

- » Dedicated biobank rooms with temperature monitoring and control
- » Twelve -80°C and four -20°C sample freezers
- » Large Liquid Nitrogen storage capacity
- » 24/7 monitoring of freezer and temperature controlled storage
- » Comprehensive security and emergency response plans

CASE STUDY:

EXPANDING THE CRC-ABBOT CORE LABORATORY INFRASTRUCTURE: I2000SR

In 2016 the range of testing equipment housed in the UCD-Abbott Core Biomarker Laboratory was further augmented with the addition of an i2000SR immunoassay analyser, which provides maximum throughput of 800 tests per hour. The €500,000 machine, funded by Abbott Diagnostics, further enhances the portfolio of laboratory and testing equipment housed within the UCD CRC laboratory facilities.

CONTRIBUTIONS TO THE UCD STRATEGY FOR RESEARCH, INNOVATION & IMPACT:

OBJECTIVES:

- 8 Further develop world-class facilities to support the vision

CLINICAL RESEARCH

SUPPORTING CLINICAL INVESTIGATION

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

- » State-of-the-art facilities within major acute hospitals for high quality clinical research
- » An environment which is:
 - » Supportive to clinicians to undertake hypothesis-driven investigator-led clinical studies
 - » Recognised by regulators, pharmaceutical companies and clinical research organisations as being professional, of the highest quality and suitable for the conduct of clinical trials
 - » Attractive to patients and encourages participation in clinical research and trials by providing excellent clinical care and access to latest clinical interventions
 - » Managed under a dedicated and approved quality policy
- » A cohort of professional and experienced research scientists, data managers and clinical research nurses that can ensure studies are conducted and managed to the highest levels of quality
- » Complete study management, oversight and sponsorship



CASE STUDY: CRC EXPERTISE PROVIDING FULL SERVICE TO INITIATE A TRIAL: GOAL-ARC

The investigator-initiated "GOAL-ARC" study [Golimumab (GLM) dose Optimisation to Adequate Levels to Achieve Response in Colitis], was fully supported by the CRC throughout the proposal, initiation and study conduct phases. As well as providing study sponsorship at an institutional level, the UCD CRC team worked with the PI - Dr Glen Doherty - providing supports in areas such as protocol development, trial registration & regulatory filings, budgeting, contracting, ethics submission, study kick-off meeting, monitoring planning. The study, forecast to recruit 136 patients and due to complete in 2018, is currently active at SVUH, with further sites across Ireland due to commence in late 2016.

SERVICES AVAILABLE TO INVESTIGATORS

| Proposal Phase | Pre-initiation Phase | Study Contact Phase | Reporting Phase |
|-----------------------|---------------------------------------|----------------------------|----------------------------------|
| Grant Application | HPRA & Ethics submission | First Patient In | Last Patient Last Visit |
| Budget Review | Investigator Site File | ISF Maintenance | Study Close-out Visit |
| UCD Sponsorship | GCP Compliance & Training | Study Monitoring | End of Trial Notification |
| EudraCT Number | Trial Registration | Amendments | Archiving |
| Study Design Review | Monitoring Plan | Data Collection & Cleaning | Data Lock & Cleaning |
| Statistical Planning | Randomisation and Blinding Procedures | Pharmacovigilance | Data Transfer |
| Protocol Finalisation | Site Initiation | DSMB / Interim Analysis | Statistical Analysis |
| PIL & Consent Form | | DSUR Submission | Budget Close Review |
| Insurance | | Audits / Inspections | Clinical Study Report Submission |
| Contracts | | | |

CLINICAL RESEARCH ACTIVITY

A total of 189 active protocols were undertaken during the year, including 47 newly initiated studies. This study start up rate of almost 1 per week across the UCD CRC demonstrates both the impact of the Centre and the culture of investigation at the associated hospitals.

Of the ongoing projects, 121 are clinical trials with 68 being translational studies, biobanks, registries and other studies. Importantly, the activities involve a large volume of academic initiated studies; of the total 189 active studies, 104 are academic-initiated and 85 are industry-sponsored.

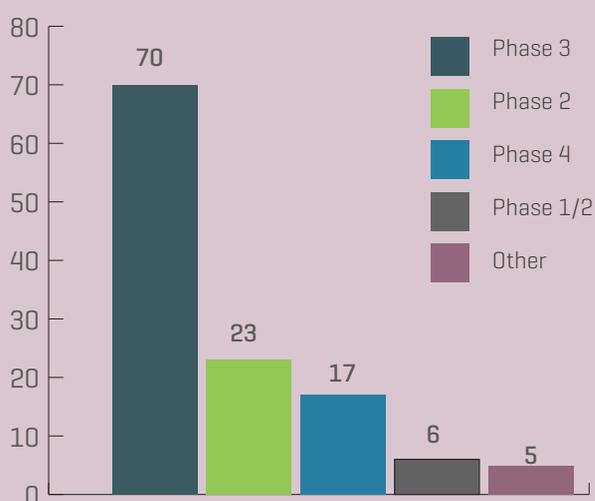
The clinical trial activity is mainly focused on early- to mid-phase trials:

- » 26 Phase 2
- » 70 Phase 3
- » 17 Phase 4

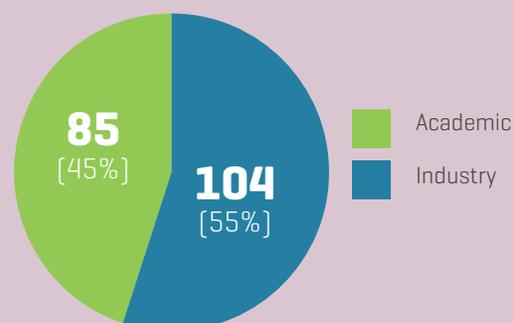
These investigations in aggregate accounted for over 6,500 patient contacts across the CRC sites during the year (including 3,750 contacts in clinical trials and 1,570 in observational studies).

Studies active during 2015/16 were managed by 60 Investigators, with an average of 2.9 studies per investigator.

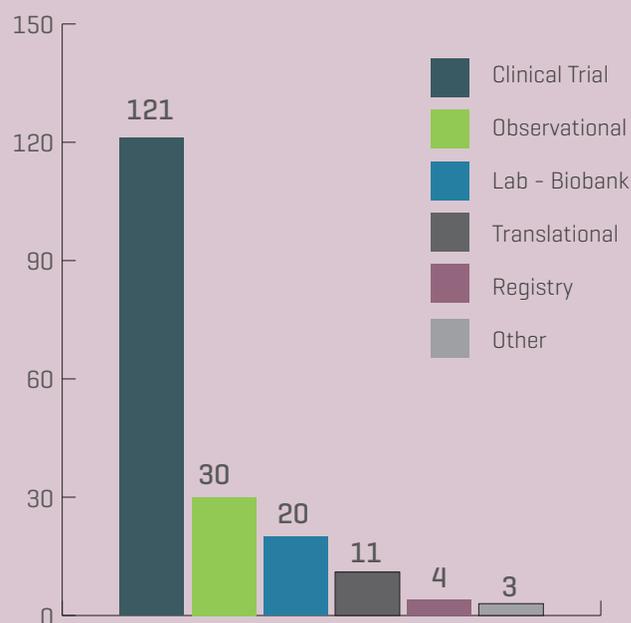
Number of Clinical Trials by Phase



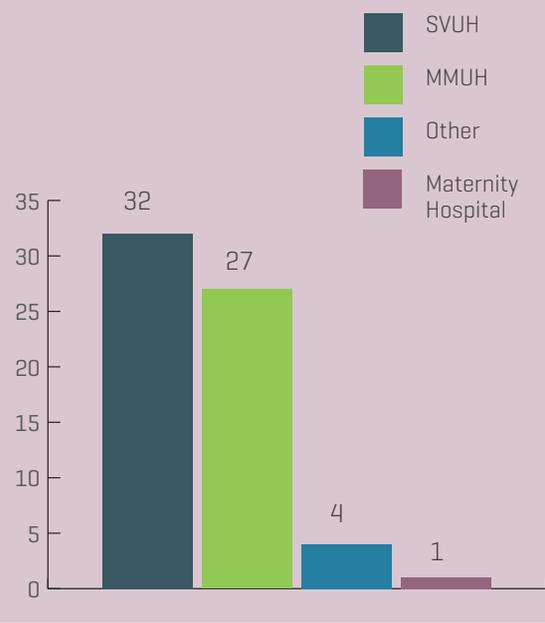
Number of Studies by Origin



Number of Studies by Type



Number of Investigators by Site



CLINICAL RESEARCH

LEADING INVESTIGATOR INITIATED TRIALS

Through the UCD CRC, UCD is committed to providing support for investigators to conduct investigator initiated clinical trials. Full study supports are available including sponsorship. In 2015/16, UCD were sponsor for 15 investigator initiated clinical trials, funded via industry, public agencies and charities. By creating detailed support systems, the UCD CRC facilitates Investigators to leverage major funding awards and to lead emerging clinical trial networks.

Sponsored studies include:

| Study | Clinical Discipline | PI | Sites | Funding | Current Status |
|---------------|---------------------|----------------------|-----------------------------|----------------|--|
| NAPRESSIM | Anaesthesia | Alistair Nichol | SVUH | Charity | Recruiting |
| GOAL-ARC | Gastroenterology | Glen Doherty | SVUH, Mater, St James, Cork | Industry | Recruiting |
| DERMMARK | Dermatology | Martin Steinhoff | SVUH, Mater | Funding Agency | HPRA Approved, Ethics approval pending |
| TAISTR | Infectious Disease | Patrick Mallon | Mater | Industry | Approved |
| CONVINCE | Neurology | Peter Kelly | Multiple | Funding Agency | Approved, FPI expected by end of 2016 |
| Vitamin D | Neurology | Micheal Hutchinson | SVUH | Funding Agency | Closed - CSR |
| DINUP | Dermatology | Brian Kirby | SVUH | Industry | Recruiting |
| DIP | Dermatology | Brian Kirby | SVUH | Industry | Closed - awaiting close-out |
| TEST | Obstetrics | Fionnuala MacAuliffe | NMH, Rotunda | Funding Agency | Closed - CSR |
| Letrozole | Endocrinology | Frances Hayes | SVUH, Loughlinstown | Funding Agency | Closed - Completed |
| Fampyra | Neurology | Chris McGuigan | SVUH | Industry | Ongoing |
| Dexamethasone | Paediatrics | Ronan O'Sullivan | OLHSC, Crumlin | Charity | Completed |
| Sickle Cell | Paediatrics | Ronan O'Sullivan | OLHSC, Crumlin | Charity | Completed |
| SKA | Paediatrics | Colm O'Donnell | OLHSC, Crumlin | Charity | Recruiting |
| GLP-1 | Endocrinology | Carel le Roux | SVUH, Loughlinstown | Funding Agency | Completed |



CASE STUDY:

ENABLING CLINICAL RESEARCH ACROSS THE IRELAND EAST HOSPITAL GROUP: TEST STUDY

The UCD CRC provided supports, including study sponsorship, for the “TEST” study [An Open-Label Randomized-Controlled Trial of Early Screening Test For Pre-Eclampsia and Growth restriction]. Based at the National Maternity Hospital and led by Prof Fionnuala McAuliffe, the study was initiated in 2014 and completed in 2016. Services and support provided by the CRC included sponsor study oversight, Pharmacovigilance SAE reporting oversight, Regulatory Authority liaison, study close-out and archiving of study documents.

QUALITY ASSURANCE IN CLINICAL RESEARCH

The UCD CRC is committed to ensuring that all studies involving human subjects will be carried out in a way which protects the interests of the subjects, whilst ensuring that healthcare is continuously improved. This commitment has been further expanded during the 2015/16 academic year:

1. The UCD CRC Operations Committee reviewed, updated and approved a full catalogue of SOPs at the end of 2015. Currently there are 70 SOPs covering all aspects of CRC activity.
2. All existing and new staff at both SVUH and MMUH completed the new orientation process initiated in May 2016 which included documenting and collecting individual GCP training certification, CVs, Training Records and sign-off on all UCD CRC Policies & SOP compliance.
3. The UCD CRC played a major role in preparation for and participation in the JCI international Survey at St Vincent’s University Hospital.

CRC PROCEDURES AND INFRASTRUCTURE UNDER REVIEW: JCI SURVEY

As a part of a reaccreditation process of St Vincent’s University Hospital, external surveyors of Joint Commission International [JCI] conducted a rigorous survey of the facilities at UCD CRC as well as detailed review of randomly selected clinical trials conducted at the site in September 2016. Following the survey the UCD CRC received positive feedback from the surveyor on the governance and conduct of all research and laboratory activities.

CONTRIBUTIONS TO THE UCD STRATEGY FOR RESEARCH, INNOVATION & IMPACT:

OBJECTIVES:

- 1 Increase the quality, quantity and impact of our research, scholarship and innovation
- 3 Consolidate and strengthen our disciplines
- 4 Conduct strong interdisciplinary research and education in areas of national and global need
- 6 Build our engagement locally, nationally and internationally

60

PEOPLE INITIATED THROUGH THE CRC INDUCTION PROGRAMME

70

STANDARD OPERATING PROCEDURES IN USE



SCIENTIFIC SERVICES

OVERVIEW

The UCD CRC provides a range of core scientific services, which directly support its extensive portfolio of clinical research. Scientific services activities cover both the provision of state-of-the-art facilities, as well as technical support and biomarker expertise.

ACTIVITY FOR THE YEAR 2015-2016:

- » Over 40 ongoing biobank collections and registries at SVUH and MMUH, with over 1,300 samples collected this year
- » Three new biobank collection initiatives started in 2016
- » Support for a number of projects requiring PBMC preparation. Over 300 PBMC (Peripheral Blood Mononuclear Cells) sample preparations
- » Design and provision of patient kits and collection SOPs for all the biobank collection, registries and Investigator-initiated trials with over 3,000 kits provided to clinics. The CRC has extensive experience in developing sampling plans, protocols and patient kits which facilitate collection and tracking of samples to the highest standards

40

BIOBANKS

1,300

BIOBANKED SAMPLES

300

PBMC PREPARATIONS

3,000

PATIENT KITS

UCD-ABBOTT BIOMARKER LAB

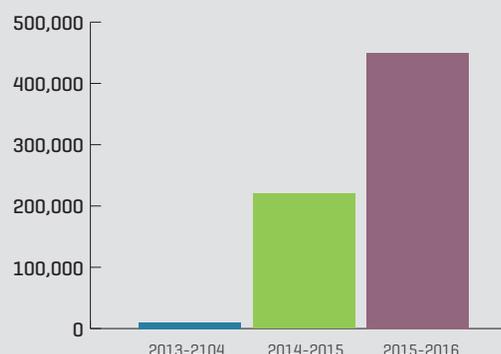
The CRC Biomarker facility is a biomarker testing laboratory located at the CRC facility at St Vincent's University Hospital. Founded through a collaboration between UCD-CRC and Abbott Diagnostics, the CRC Biomarker lab has supported testing for a wide range of international and local studies since its inception. The Lab houses two state-of-the-art high-throughput analysers including an Architect ci4100 biochemical testing platform, which offers a wide test menu covering both clinical chemistry and immunoassay testing. In 2016 an Architect i2000SR immunoassay analyser has been installed that offers an increased throughput of assays per hour (up to 200 samples). In addition in 2016 the Biomarker facility has implemented ELISA based testing for a number of specific research projects, including all the automated apparatus for plate washing and reading. The direct funding to the UCD CRC over the last three years has increased over 100% year-on-year with a total of €464,050 in direct income in 2015/16. In addition, indirect funding of over €500,000 was leveraged in the form of reagent kits.

This growth in activity brings total funding from Abbott since the inception of the partnership to €700,000 in direct funding, over €800,000 indirect funding and €1m instrument costs, representing an overall investment of €2.5m.

Abbott funding & investment into the UCD-Abbott Biomarker Lab since inception:

| | |
|-------------------------|-------------------|
| Direct Funding | €700,000 |
| Indirect Funding | €800,000 |
| Instruments | €1,000,000 |
| TOTAL INVESTMENT | €2,500,000 |

CRC Biomarker Lab Direct Funding 2013-2016





UCD-Abbott Core Biomarker Lab - studies undertaken during 2015/16:

| Study AA 2015-2016 | Samples | Analytes | Tests | Status |
|--------------------------|---------|---|--------|-------------|
| Heart failure | 266 | hsTnl, Gal-3 | 452 | Completed |
| Nutrition | 30 | C-peptide, CRP, GluC, Insulin, Tryglicerids | 150 | Completed |
| AKINESIS Plasma | 4,097 | Tnl, BNP, Galectin, NGAL | 16,388 | Completed * |
| TAVR SERUM | 393 | GDF-15, hsCRP, hsTnL, Gal-3, Pre-Albumin | 1,965 | Completed |
| TAVR PLASMA | 396 | hsCRP, Cystatin C, GGT, Bilirubin, Albumin, BNP, Insulin. | 2,772 | Completed |
| OPTIMISE | 823 | NGAL, Creatinine [3 timepoints] | 1,646 | Completed |
| TBI Study [7 studies] | 670 | ApoA1, hsCRP, hsTnL, Sodium, Creatinine, Urea Nitrogen, S100, NSE, MBP, Free BDNF, Total BDNF, Tau, P-Tau | 7,718 | Ongoing |

* published study J Am Coll Cardiol. 2016 Sep 27;68(13): 1420-31

As demonstrated in the table above, the level of activity through the biomarker laboratory has been significant during the academic year, with 7 new projects undertaken, encompassing 6,675 samples and involving 31,091 total tests.

HIGH-QUALITY, HIGH-THROUGHPUT SAMPLE ANALYSIS AT THE UCD-ABBOTT CORE LAB: THE TBI STUDY

During 2016 testing commenced on 7 cohorts in order to assess known and experimental biomarkers of Traumatic Brain Injury (TBI). The contract, the largest yet undertaken through the UCD-Abbott Core Biomarker Laboratory and valued at €421,000, requires testing of 3,106 samples. During the 2015/16 academic year 7,718 tests were undertaken on 670 samples, with testing due to continue until early 2017.

CONTRIBUTIONS TO THE UCD STRATEGY FOR RESEARCH, INNOVATION & IMPACT:

OBJECTIVES:

- 1 Increase the quality, quantity and impact of our research, scholarship and innovation
- 3 Consolidate and strengthen our disciplines
- 6 Build our engagement locally, nationally and internationally

EDUCATION

The UCD School of Medicine, through the UCD CRC, is committed to ensuring that novel interventions are developed and diffused into routine healthcare practice. Recognising the importance of excellent human capital in the conduct of clinical research, the CRC offers a suite of taught programmes to train the researchers of the future. This training is critical to ensuring that the next generation of research leaders are appropriately skilled to continue to advance human medicine.

“ The modules cover pertinent topics in clinical research including good clinical practice, data management, clinical trial development and critical appraisal of the literature. The modules offer a didactic and practical experience including biorepositories and novel technology development. The course is delivered by active investigators and in general the students exit with strong methodological and technical skills. ”

Prof. Ravi Mehta, UCSD – External Course Review 2015

PROGRAMMES

The CRC education programmes are specifically designed to address areas of need including:

- » **MSc in Clinical and Translational Research**
Designed to train the prospective investigators of the future
- » **MSc in Translational Research**
[jointly-delivered with Shenzhen University, China]; Designed to develop international expertise
- » **Graduate Certificate in Clinical Research**
Designed to train high performing staff with skills and knowledge relevant to the clinical research industry
- » **Online Graduate Certificate in Clinical Research**
Designed to meet the staff development needs of the multinational CRO and pharmaceutical sectors.

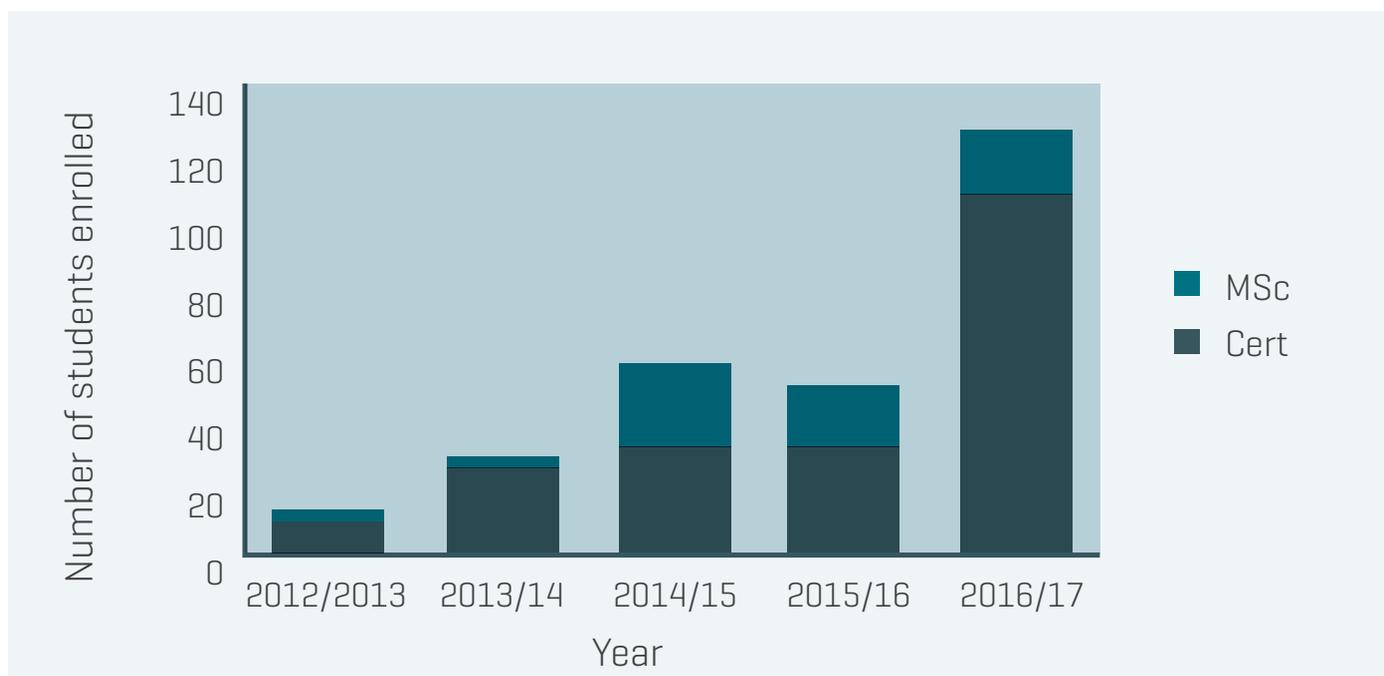
| | MSc [PT] Yr 1 | MSc [PT] Yr 2 | Graduate Cert | MSc [FT] |
|-------------------|--|--|---|---|
| Semester 1 | Principles & Practices of Clinical & Translational Research Data Management & Biostatistics | Clinical Trials Clinical Trial Management | Clinical Trials Clinical Trial Management Data Management & Biostatistics | Clinical Trials Principles & Practices of Clinical & Translational Research Data Management & Biostatistics |
| Semester 2 | Clinical Protocol Development Principles of Laboratory Medicine | Clinical Research Project | Clinical Trials Clinical Trial Management Data Management & Biostatistics | Clinical Protocol Development Clinical Trial Management Principles of Laboratory Medicine |
| Semester 3 | | | | Clinical Research Project |

STUDENTS

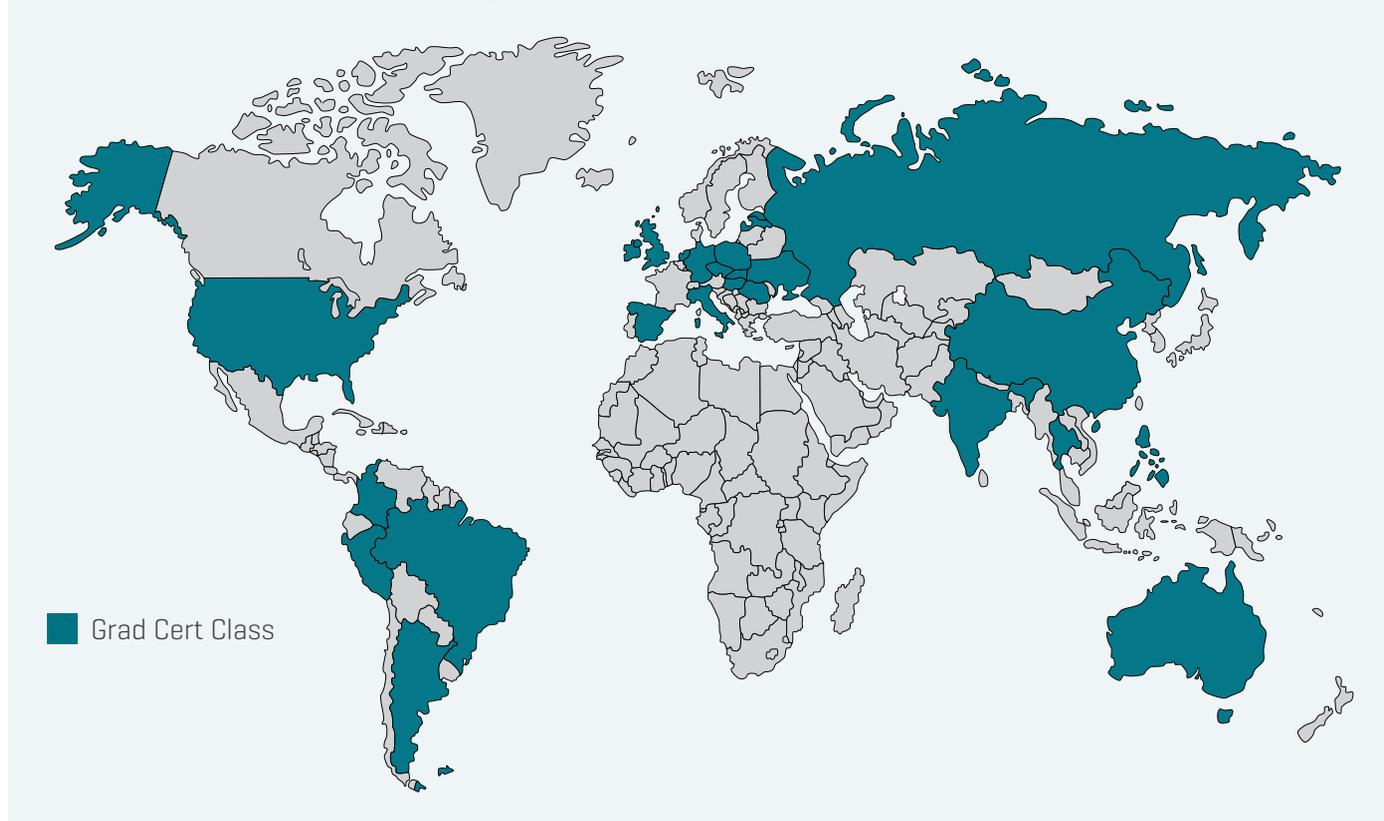
2015/16 has seen a significant growth in student numbers and a year-on-year increase in total student numbers [see below]. 110 students enrolled on our graduate programmes in the 2015/16 academic year, a doubling on the previous academic year.

This increase arises from demand and unmet needs from both students and industry, as is evident from the initiation of two new majors in the last year, a full time MSc (X789) and an online Graduate Certificate (X787). The online Graduate Certificate has been developed to meet the requirements of clinical research

organisations to provide up to date training to staff, whilst earning a qualification from a leading university to enable staff up-skilling, retention and development. The e-learning delivery methodology used for this course reflects the global nature of the student body. The online Graduate Certificate is delivered over 22 weeks to classes which currently comprise of employees from ICON Plc. Delivery of this programme utilises innovative Virtual Learning Environment teaching modalities such as recorded lectures, storyboards, videos, online tutorials, weekly quizzes and assignment based learning and assessment.



Global student enrolment into cohort 1 of the online Graduate Certificate





Conferring Ceremony of the first class of the UCD-Shenzhen MSc Clinical Research

The MSc programme with Shenzhen University has also continued during 2015/16, with the first class graduating in September 2016.

ENSURING QUALITY

The University Strategy (2015-2020) includes a **“commitment to educational excellence through a strong student-focused, research-led, educational experience”**. The CRC education team took part in the curriculum review and enhancement process to ensure that the programmes offered through the CRC deliver educational excellence. The process confirmed that the curriculum strongly encompasses the integration of research into all teaching through a comprehensive programme of hands-on practical experience complementing classroom based learning as well as the skills and knowledge to appraise, evaluate and enhance clinical research.

“ The UCD Graduate programme in clinical research is a highly innovative way of providing training to graduates in science and medicine. It allows them access to employment in Biopharma and in clinical research organisations. The highly immersive approach in which students are given extensive experience, works extremely well. We at ICON Clinical Research have been very pleased to host an important part of the immersion experience at our Global HQ in Dublin. The programme rapidly brings participants to a situation in which they are highly attractive to employers and it dramatically shortens their training time once employed. We at ICON have employed a high proportion of the graduates from this programme and look forward to continuing to do so. We believe that it gives us and indeed Ireland a significant competitive advantage as well as serving our graduates well. ”

Prof Brendan Buckley, Chief Medical Officer, ICON Plc

INNOVATION ENABLING EDUCATIONAL CONTENT DELIVERY: THE ONLINE GRADUATE CERTIFICATE IN CLINICAL RESEARCH

In May 2016 the CRC welcomed the first cohort of students onto the Online Graduate Certificate. 38 students from 19 countries, undertook the course and accessed learning materials, including presentations, videos, articles and quizzes, through the blackboard platform. Utilising course content developed by the CRC education team, and also drawing on lectures and content provided from Clinical Investigators from across UCD School of Medicine and the Ireland East Hospital Group, the programme is both academically rigorous and industry-relevant. Designed to run twice per year to enroll staff onto the programme, the programme is a demonstration of the capability of the CRC to deliver relevant and innovative educational programmes to industry on an international basis.

CONTRIBUTIONS TO THE UCD STRATEGY FOR RESEARCH, INNOVATION & IMPACT:

OBJECTIVES:

- 2 Provide an education experience that defines international best practice
- 4 Conduct strong interdisciplinary research and education in areas of national and global need
- 6 Build our engagement locally, nationally and internationally

NETWORKS AND PARTNERSHIPS



Recognising the importance of external relationship development, the CRC has played a significant role in sustaining and developing major partnerships with other academic institutions and with commercial partners. The CRC's expertise is well-recognised as an indispensable resource by investigators at all affiliated clinical sites, industry and academic partners, funders and other collaborators throughout Ireland and internationally.

UCD CRC has made a major contribution to the national collaborative research agenda through participation in a multitude of MMI-centred projects and programmes. The growth in the range of services and supports offered by the CRC during 2015-16 has been mirrored by the number of key strategic networks and partnerships that have commenced in the period.

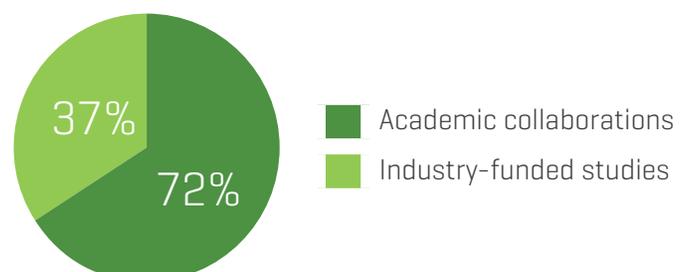
NETWORK SUPPORTS

The CRC offers a range of supports to clinical research networks and groups, with many based at the CRC facilities at the MMUH & SVUH. The supports available include:

- » Office and meeting space
- » Laboratory Services
- » Clinical suites
- » HR/recruitment, finance and project management
- » Quality & Regulatory Affairs
- » Data Management & Information Systems

2015/16 ACTIVITY

Studies taking place at the CRC include a broad range of national, international and industry collaborations and speak clearly to the collaborative nature of high quality clinical research.



COLLABORATORS AND SPONSORS OF CURRENT STUDIES INCLUDE:



PROVIDING THE PLATFORM AND SUPPORTS FOR HIGH-IMPACT CLINICAL RESEARCH GROUPS: PROF ALISTAIR NICHOL AND THE IRISH CRITICAL CARE CLINICAL TRIALS GROUP

The CRC facilities at SVUH host Prof Nichol's Irish Critical Care Clinical Trials Group. Following the CRC's role in assisting Prof Nichol with his successful HRB Network Grant funding proposal, the group now utilises both the CRC's physical infrastructure, as well as support in areas such as Quality & Regulatory Affairs and Scientific Services. As well as being hosted by the CRC, Prof Nichol's group have become involved with industry-funded studies through the UCD-Abbott Diagnostics collaboration. As at the end of 2015/16, an Abbott-funded study in collaboration with Prof Nichol's group was under discussion and subject to contract, with others pending.

During the 2015/16 academic year the CRC has been central to the initiation and development of a range of key strategic research groups and networks:

IRISH CRITICAL-CARE CLINICAL TRIALS GROUP €2.5M FUNDING

The HRB Irish Critical-Care Clinical Trials Group (IC-CCTG) is a collaboration involving three quarters of the Irish intensive care capacity and is led by Prof. Alistair Nichol. Following the successful funding of the Group, of which the CRC was an integral part of the application, the IC-CCTG core team is based within the CRC at St Vincent's University Hospital.

IRISH STROKE CLINICAL TRIALS NETWORK €2.3M FUNDING

The HRB Irish Stroke Clinical Trials Network (ISCTN), led by Prof Peter Kelly, will initially involve eight Irish hospitals, six leading universities, and all seven Hospital Groups. With a project team based at the CRC at The Mater Misericordiae University Hospital, the group have utilised CRC supports in Quality & Regulatory Affairs, Finance & Strategy and Data Management.

GOAL-ARC €489K FUNDING

GLM dose Optimisation to Adequate Levels to Achieve Response in Colitis (GOAL-ARC), is a multi-site study led by Prof Glen Doherty and managed from the CRC St Vincent's University Hospital. The CRC at St Vincent's is providing Laboratory Services to the study and has also been central to study initiation, regulatory approvals and project management.

SFI-ABBVIE DERMATOLOGY STUDIES €1.05M FUNDING

Joint funded by SFI and Abbvie, the translational research programme between AbbVie, UCD Charles Institute of Dermatology, Systems Biology Ireland and UCD Clinical Research Centre Led by Prof Martin Steinhoff aims to use a unique combination of clinical sampling techniques, high-throughput screening and systems approaches to facilitate discovery and development of new biomarkers and drugs for HS, AD and PSO.

CLINICAL RESEARCH COORDINATION IRELAND (CRCI)

CRCi became operational in May 2015 as a partnership of five university based Clinical Research Facilities/Centres and their associated hospitals. The CRC Director, Dr Peter Doran is a member of the senior management team of CRCi. It is supported by the Health Research Board, Enterprise Ireland and Molecular Medicine Ireland.

A fully-funded CRCi Coordinator was appointed by the CRC in May 2016. Responsible for coordinating incoming CRCi study proposals, the UCD CRCi Coordinator has spread awareness of the CRCi network throughout the UCD-affiliated clinical sites and has hosted study feasibility assessments with companies including Bayer and Novartis. The first study initiated through this channel is expected to commence in November 2016, at both St Vincent's and the Mater Misericordiae sites.

The CRC typically receives 1-2 CRCi trial enquiries per week. As at the end of the 2015/16 academic year, there were 9 trials under discussion, in the areas of Renal, Rheumatology, Dermatology, Gynaecology, Gastroenterology and Critical Care.

CONTRIBUTIONS TO THE UCD STRATEGY FOR RESEARCH, INNOVATION & IMPACT:

OBJECTIVES:

- 3 Consolidate and strengthen our disciplines
- 4 Conduct strong interdisciplinary research and education in areas of national and global need
- 6 Build our engagement locally, nationally and internationally
- 7 Develop and strengthen our University community

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