

UNIVERSITY OF MEDICINE

COLLABORATING WITH INDUSTRY TO IMPROVE HUMAN HEALTH

Pictured (L-R) are Professor Tracy Robson, Head of School of Pharmacy and Biomolecular Sciences, RCSI; Professor Tim Harrison, Vice President Discovery Chemistry, Almac Discovery and Dr Graham Cotton, Head of Protein Therapeutics, Almac Discovery.

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### WELCOME FROM RCSI



**Prof. Fergal J O'Brien** Deputy Vice Chancellor for Research & Innovation

At RCSI, we have a dynamic research culture with global reach and celebrate a historic legacy of over 230 years of clinical innovation as well as unrivalled expertise in surgical training and practice. We have built a sustainable environment for growth and innovation as evidenced by our recent investments in the RCSI Strategic Academic Recruitment Programme (StAR), which has broadened our Principal Investigator base, 26 York Street, Europe's most advanced clinical healthcare simulation facility and Project Connect, the forthcoming 12,000m<sup>2</sup> education and research building on St Stephen's Green. We are proud to be ranked number one in the world for SDG3 'Good Health and Well-being' in THE University Impact Rankings 2023, and among the top 300 universities worldwide in the THE World University Rankings (2024). We are driven by our ambition to continue delivering highly impactful research that improves human health, as illustrated by the impact of our publications in the leading global scientific journals and the continued successful translation of research from the bench to bedside in partnership with industry.

Partnering with industry and the commercialisation of our research outputs through spinout companies and licensing is an integral part of our research strategy. Such partnerships and activities are vitally important to delivering on our mission to improve human health and patient outcomes on a global scale.

We look forward to discussing how we can collaborate with your organisation.



Dr Aoife Gallagher, Head of Innovation

Since its establishment in late 2014, the Innovation Team in RCSI's Office of Research and Innovation (ORI) has forged a reputation for professionalism, flexibility and expediency in our approach to research commercialisation and engagement with industry.

In recognition of the importance of industry engagement, we have a dedicated team to support industry partnerships and consultancy engagements, led by Dr. Seamus Browne, Head of Strategic Initiatives & Industry Partnerships.

As outlined in the coming pages, there are many ways that industry can work with us. Through our experience and knowledge, we can expedite the identification of appropriate funding supports for industry-RCSI collaborations leading to efficient project set-up, implementation and knowledge transfer. We encourage industry partners aligned with RCSI's strengths in our established and emerging clusters of research excellence, to contact us and see how engaging with our researchers and clinical partners can add value to your business. 1,663

PubMed indexed articles PUBLISHED IN 2022

> <u>non future</u> non neuro

SFI funded

Research Centres

### **ABOUT RCSI**





**32%** SUCCESS RATE OF RCSI-LED HORIZON EUROPE RESEARCH PROPOSALS

# INNOVATION

**70%** of research PIs innovation active

### 8% of research expenditure from industry sources

Enabled Innovation funding of

for spin-out company formation in latest AKTS (normalised)







TIMES HIGHER EDUCATION WORLD UNIVERSITY RANKINGS 2023



Comm Fund SUCCESS RATE 100%

### **RCSI'S RESEARCH FOCUS AREAS**

Founded by Royal Charter in 1784 as the national surgical training body, today RCSI University of Medicine and Health Sciences is an innovative, independent, world-leading international university with a mission to "educate, nurture and discover for the benefit of human health". Headquartered in Dublin with global reach through its overseas, medical Universities in Bahrain, Malaysia, and Dubai, RCSI is first in the world for 'Good Health and Well-being' and listed in the top 300 Global Universities in the Times Higher Education (THE) World University Rankings 2024. RCSI is compliant with the EU's Horizontal Principles of Equality and Non-Discrimination, has retained the EU's HR Excellence in Research award and holds an Athena SWAN Bronze award in recognition of its positive gender practices.

As articulated in our new Institutional Strategy 2023-2028-*Innovating for a Healthier Future*, RCSI research covers a wide range of health science disciplines, with a specific focus on seven key research themes:

- Cancer
- Biomaterials, Medical devices & Pharmaceutical Sciences
- Neurological & Psychiatric Disorders
- Surgical Science & Practice
- Population Health & Health Services
- Respiratory & Critical Care
- Vascular Biology & Cardiology

Our research activities focus on driving scientific breakthroughs and innovations that allow us to respond to changing health needs and contribute to the development of medicines, devices, technologies and system changes that improve patient wellbeing. Our researchers are based in state-of-the-art facilities in RCSI's city centre campus (St. Stephen's Green), RCSI's new Translational Research Institute incorporating the Clinical Research Centre (CRC) at Beaumont Hospital and in our affiliated hospital partners including the Rotunda Hospital, Connolly Hospital (host to a new €22M RCSI funded facility) and the Mater Private Hospital. RCSI's city centre expansion project, Connect, will extend and improve facilities for research and innovation and include public engagement space.

RCSI is a founding partner in four SFI Research Centres (RCSI-led FutureNeuro, AMBER, CURAM and SSPC), which link scientists in academia and industry to solve critical problems. RCSI continually invests in hiring the highest quality, innovation active PIs through its Strategic Academic Recruitment Programme (StAR), commercialising intellectual property arising from its research programmes, and driving collaboration with industry is embedded in our Institutional Strategy as a specific action.

### ESTABLISHED RESEARCH CLUSTERS



Biomaterials, Medical Devices and Pharmaceutical Sciences



Cancer



Neurological and Psychiatric Disorders



Vascular Biology and Cardiology





Surgical Science and Practice

## Trans-Cluster Research Themes

Genomics & Personalised Medicine ~ Digital Medicine & Healthcare Data ~ Infection, Immunity and Inflammation

Emerging Areas of Excellence						
Simulation and Healthcare Professional Education	Nursing and	d Midwifery	Gynaecology and Perina	/, Obestetrics atal Health	Peadia Child	tric and Health
Endocrinology		Physiotherapy and Positive Health		Nephrology and Gastroenterology		

### INDUSTRY ENGAGEMENT AT RCSI

At RCSI, we believe meaningful engagement, collaboration and partnership with industry is an essential component to achieving our research mission. We are deeply committed to working with industry, both multinational corporations (MNCs) and small and medium-sized enterprises (SMEs) in the areas of Cancer, Biomaterials, Medical devices & Pharmaceutical sciences, Neurological & Psychiatric Disorders, Surgical Science & Practice, Population Health & Health Services, Respiratory & Critical Care, and Vascular Biology & Cardiology through the following mechanisms:

#### Industry informed

- Research informed by industry but directed by academia
- No company funding required
- No company pre-emptive rights to project results

#### Industry collaborative

- Research directed collaboratively by industry and academia
- Company typically pays a proportion of project costs
- Option to licence project results

#### **Industry directed**

- Research directed by company
- Company pays full cost of project
- Possible for company to own project results

As a higher education institute with an exclusive focus on human health, RCSI can offer unique opportunities for industry that include:

- Access to well-defined translational research programmes, internationally recognised research teams, clinical expertise and networks and state-ofthe-art biomedical and clinical research infrastructure.
- A professional industry relationship management team to ensure ease of, benefit from, and co-ordination of engagement with RCSI researchers.
- Access to RCSI's expertise and knowledge of appropriate National and European funding programmes to co-fund your project.
- An efficient, agile approach to negotiation of contracts with industry due to our size and status.
- Access to an array of therapeutics, diagnostics and medical device technologies available for commercial exploitation.



### WHY PARTNER WITH RCSI?

#### Collaborate for success with RCSI

RCSI's Office of Research and Innovation (ORI) facilitates engagements between industry and the RCSI research community.

#### RCSI provides your company with access to:

- World class research capability willing to focus on your challenges
- New intellectual property assets
- State of the art surgical simulation, medical training facilities and research infrastructure
- Significant leveraged research funding opportunities
- Clinical expertise and network of clinicians in the RCSI hospital group
- Clinical research infrastructure
- Bespoke training programmes for company staff

If you are interested in informing, collaborating or directing research at RCSI, please contact us to discuss how we can partner with your organisation to drive innovation and significantly enhance your competitive advantage.

















### **3 WAYS TO ENGAGE WITH RCSI**

ENGAGEMENT MECHANISM	DESCRIPTION	COMPANY SIZE	TYPICAL PROJECT SIZE
100% Industry Funded Research Programmes	Allows your company to work with RCSI to address a specific research question where expeditious project set-up is critical.	SME or Large	Directed by industry Partner
Enterprise Ireland Innovation Partnership Programme	El encourages Irish-based companies to work with Irish research institutes to access expertise and resources to undertake research towards the development of new and improved products and processes	Any client of El, IDA or ÚnG	20% cash contribution from industry partner
SFI Strategic Partnership Programme	Supports standalone collaborative research initiatives of scale between your company and RCSI that can demonstrate strong potential for delivering economic and social impact.	Companies with sufficient financial capacity	>€800K
SFI Research Centre Targeted Projects, Rolling Spoke Programme	Provides a mechanism for your company to engage in new collaborative research projects involving RCSI researchers and existing SFI research centres.	SME or Large	Minimum cash contribution of 50% of the Spoke Budget
RCSI Strategic Industry Partnership Seed	Aims to nurture new research collaborations between RCSI researchers and industry partners. RCSI contribution is 25-50K matched €for€ from industry.	SME or Large	€25-€50K from industry partner
Fund			

	ENGAGEMENT MECHANISM	DESCRIPTION	COMPANY SIZE	TYPICAL PROJECT SIZE
AND EXPERIISE	IRC Postgraduate and Postdoctoral Enterprise Partnership Award	Develops partnerships between your company and RCSI research groups through co-supervised MSc, PhD and Postdoctoral projects.	SME or Large	Postgraduate: €9,500 per annum Postdoctoral: Yr 1: €17,224 Yr 2: €17,502
	IRC Employment- based Postgraduate Award	Provides support for an employee in your company to pursue a MSc or a PhD degree at RCSI while remaining as an employee in your organisation.	SME or Large	€9,500 per annum for 1-4yrs
	SFI Industry Fellowship Programme	Facilitates (a) embedding RCSI researchers in your company; or (b) your company embedding company personnel in RCSI.	SME or Large	SFI funding 25-80% of total project costs to a max of €100K direct costs
	Consultancy	Bespoke consultancy provided by a recognised expert in her/his field. IP is owned by the company.	SME or Large	Consultancy Hourly rate

0 S I S	ENGAGEMENT MECHANISM	DESCRIPTION	COMPANY SIZE	TYPICAL PROJECT SIZE
SI ASSE	Access to RCSI Research Facilities	Companies may have an interest in performing company directed research using RCSI's facilities and equipment. Facilities can be hired or accessed via a research services agreement as a cost-effective alternative to investment in expensive equipment.	HPSU, SME or Large	On application
AS	IP Assets, Research Tools and Materials	Technologies for license, and transfer of research tools & materials such as reagents, cell lines, plasmids, chemical compounds and vectors via a Material Transfer Agreement.	HPSU, SME or Large	On Application

### **OUR INDUSTRY ENGAGEMENT PROCESS**



### **CASE STUDIES**

RCSI has partnered with a wide range of companies to address a number of healthcare challenges resulting in improved diagnostics, therapeutics, devices, enhanced healthcare delivery, clinical practice and healthcare professional education. Models of engagement vary and are tailored to meet the company's requirements as illustrated in the following case studies.

















### **INTEGRA LIFESCIENCES**

#### Title:

Advanced Biomaterials for Peripheral Nerve Repair

#### Engagement Type:

SFI Research Centre Co- Funded Research Project

#### Industry Partner:

Integra LifeSciences is a world leader in medical technology, offering innovative solutions in orthopedic surgery, neurosurgery, and reconstructive and general surgery. Integra are experts in the development of innovative collagen-based regenerative biomaterials -they aspire to be a worldwide leader in neurosurgery & reconstructive surgery, delivering outstanding customer experience to positively impact the lives of millions of patients and families.

#### Challenge:

Peripheral nerve injury remains a major clinical problem, affecting more than 1 million patients worldwide annually. The collaboration between RCSI and Integra, through the SFI funded AMBER (Advanced Materials and Bioengineering Research) Centre, has developed novel biomaterial solutions to repair damaged nerves and alleviate associated loss of motor or sensory function. These new biomaterials have the potential to significantly enhance functional recovery and quality of life, improving outcomes while also eliminating the need for secondary surgeries.

#### **RCSI Value Added:**

The RCSI Tissue Engineering Research Group (TERG) is one of the largest advanced biomaterials and tissue engineering/regenerative medicine research groups in Ireland. The TERG multi-disciplinary group brings together bioengineers, chemists, pharmacists, molecular biologists, and clinicians to develop advanced biomaterials for bone, cartilage, cardiovascular, respiratory, neural, skin, tissue repair and corneal regeneration. Led by Prof. Fergal O'Brien, this collaboration enabled Integra LifeSciences to access international expertise in biomaterials and pre-clinical models in TERG.

The technologies developed by TERG have proven highly effective in repairing damaged nerves in pre-clinical trials and resulted in the generation of patentable IP and commercialisation of the technologies by Integra.

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**Dr Simon Archibald** Vice President and Chief Scientist Integra LifeSciences





TILLOTTS PHARMA

#### Title:

"The interaction with

Professor Fitzpatrick

therapeutic area of C. diff. infections

and the environment

stewardship programs

Europe. Together with

educational activities

targeted at HCPs to

raise awareness of

the need to follow

and productive."

AG

Dr Christian Weidenfeller Global Head of Medical Affairs.

AMS programs. The interaction with the

RCSI was fast, efficient,

Anti-Infectives, Tillotts Pharma

Professor Fitzpatrick, we were able to engage in

helped to better

understand the

of antimicrobial

in Ireland and in

To Better Understand How The New European CDI Treatment Guidelines May Impact Clinical Practice, Diagnostics, Treatment Options And Epidemiology of CDI Infections.

#### **Engagement Type:**

Consultancy

#### Industry Partner:

Tillotts Pharma is a fast-growing international specialty pharma company located in Switzerland, employing over 300 employees worldwide. Their product portfolio is focussed on gastrointestinal diseases including IBD, ulcerative colitis and Crohn's disease.

#### Challenges:

Tillotts Pharma had recently acquired the rights to DIFICLIR™, a recommended treatment option for patients suffering from CDI, a serious and sometimes life-threatening infection of the colon. They were interested in consulting with Prof. Fitzpatrick on her opinion on how the new European CDI treatment guidelines may impact clinical practice, and around the diagnostics, treatment options and epidemiology of CDI infections.

#### **RCSI Value Added:**

Professor Fidelma Fitzpatrick is the Head of Department of Clinical Microbiology, RCSI, and Consultant Microbiologist, in Beaumont Hospital. In addition, she is elected Chair of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Study Group for Clostridioides difficile, and a member of the Community Antimicrobial Prescribing Committee, HSE Antimicrobial Resistance Infection Control (AMRIC) and National Healthcare-associated infection (HAI) Hospital Point Prevalence Steering Group, Health Protection Surveillance Centre (HPSC). As the first National clinical lead for the prevention of HAI and antimicrobial resistance (AMR), she established the national clinical programme, led the national public information campaign on antibiotics, national hand hygiene and antimicrobial stewardship campaigns and oversaw the establishment of the National AMR Intersectoral Coordinating Committee between the Dept of Health and Dept of Agriculture. As Consultant Microbiologist in the HPSC she established C. difficile surveillance in Ireland, chaired a number of national guideline committees, was the European Centres for Disease Control and Prevention (ECDC) national HAI focal point and coordinated the first national HAI prevalence studies in both hospitals and long-term care facilities.



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### SPECTRAL MD, INC.

Title:

Wound Assessment Using Spectral Imaging (WAUSI)

**Engagement Type:** Company Fully Funded Project

#### Industry Partner:

Spectral MD, Inc., a wholly owned subsidiary of Spectral AI, Inc. (Nasdaq: MDAI), is a US company developing imaging technology that provides clinicians with faster and more accurate treatment decisions in wound care. The company's DeepView<sup>®</sup> wound imaging system, uses AI and multispectral imaging to provide clinicians with immediate wound healing prediction information that is not visible to the human eye.

#### Challenge:

Diabetic foot ulcers affect millions of patients globally each year and have the potential to require multiple treatments, develop gangrene and lead to amputation. They also come at an extreme costs and burden to the healthcare system. Early and accurate diagnosis is key to improving healing rates and overall outcomes, dramatically enhance patient quality of life.

Spectral MD engaged in a collaborative research project with the RCSI Skin Wounds and Trauma (SWaT) Research Centre. The project helped identify the potential use of Spectral's DeepView<sup>®</sup> AI technology in the diagnosis of diabetic foot ulcers.

#### **RCSI Value Add:**

The RCSI Skin Wounds and Trauma (SWaT) Research Centre is leading cutting-edge research in the field of wound healing and tissue repair, with a specific emphasis on pressure ulcer prevention and management. Specialising in the evaluation and regulated clinical investigations of novel medical devices, the SWaT Research Centre is a hub for industry partners seeking to evolve – and bring to market – wound care prevention and treatment devices.

"We are delighted to partner with such a world-renowned institution. Working in partnership with RCSI's Skin Wounds and Trauma Research Centre and Office of Research and Innovation, we have successfully navigated the development of this relationship that harnesses our collective expertise."

Wensheng Fan CEO of Spectral MD, Inc.



Strong partnerships with clinical and academic institutions, close relationships with patients and patient advocacy groups, SWaT woundcare KOL Network, make the Centre the ideal partner for companies working on outcome-focused healthcare, and the translation of scientific evidence into contemporary clinical decision-making and practice.

The project team for this collaboration included Prof. Declan Patton (PI), Prof. Zena Moore (Co-PI), Chief Clinical Investigator Prof. John McDermott and Clinical Sub Investigator Prof. Seamus Sreenan, both from Connolly Hospital.



### NUALTRA

#### Title:

Sarcopenia as a Prognostic Indicator in Patients with Cirrhosis and Potential for Amino Acid Supplementation as an Immuno-Metabolic Intervention.

#### **Engagement Type:**

Enterprise Ireland Innovation Partnership Programme

#### **Industry Partner:**

Founded in 2012 by registered dietitian Paul Gough, Nualtra is a medical nutrition company with the goal of creating 'Better Value, Better lives' for patients and health care professionals by delivering great-tasting, affordable Oral Nutritional Supplements (ONS). Nualtra is the fastest-growing medical nutrition company in the UK and Ireland for the past 7 years.

In 2020, Nualtra was acquired by Ajinomoto Co. Inc., a Japanese multinational food and biotechnology corporation that operates in 36 countries and employs an estimated 34,198 people.

#### Challenge:

Patients with end-stage liver fibrosis or cirrhosis are at high risk of disease-related malnutrition. However, even with dietetic support and dietary adjustments, the symptoms and signs associated with their liver disease including ascites means that compliance with standard nutrition supplements can be challenging due to poor tolerance. It is known that patients with liver disease can have significant muscle loss which is itself associated with frailty and loss of independence and is linked with disease-related malnutrition. The project evolved through identification of a need to assess the impact of a low-volume, well tolerated supplement for this patient population which can target effects of sarcopenia and ideally reduce the life-limiting complications of cirrhosis. This project addresses some of these issues by testing a low volume branched chain amino acid (BCAA) supplement. The nature and volume of the supplement means that tolerance in patients with decompensated cirrhosis and ascites will be less challenging and will allow patients to continue with their own or dietitian-advised diet while providing an additional support for muscle development and potentially reduce progression of sarcopenia.

🛇 nualtra

"Nualtra are delighted to be working alongside RCSI and Prof. Karen Boland to conduct and complete research on novel nutrition products in an effort to improve the lives of patients living with liver cirrhosis. Prof. Karen Boland is the principal investigator based in Beaumont Hospital in Dublin and has a passion for improving the nutritional status of patients. It has also been an honour to learn from her expertise as the study progresses.

Ajinomoto are one of the world leaders in R&D activities in the production of high grade amino acids and it is a very exciting time to be able to bring this research and innovation to the world of medical nutrition."

Paul Gough Company Founder

#### **RCSI Value Added:**

This project facilitated a novel collaboration between immune-metabolic specialists at RCSI and Prof Karen Boland at the Department of Gastroenterology, Beaumont Hospital, to develop novel expertise in analysis of muscle mass and the development and assessment of interventions for an underserved patient population with poor prognosis. Prof. Boland has led a number of research studies focussing on unmet needs and patient related outcomes in populations profoundly impacted by disease-related malnutrition including anorexia nervosa, cirrhosis, and inflammatory bowel disease.

This partnership with Nualtra provided an opportunity to develop evidence-based data studying the potential benefits of a low volume supplement to a large population of patients with complications of liver disease.



Pictured with Ajinomoto CEO and President Taro Fujie are Prof. Karen Boland (PI), Prof. Fergal O'Brien, Dr Seamus Browne and Dawn McGlade (RCSI Office of Research and Innovation), Mark Hill, Paul Gough and members of the Nualtra UK&I team.

### F. HOFFMANN-LA ROCHE

#### Title:

nental Disorders



MicroRNA Biology in Neurodevelopmental Disorders and Pediatric Epilepsies.

#### Engagement Type:

Fully Funded Industry Project in SFI FutureNeuro Centre, Hosted at RCSI

#### **Industry Partner:**

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology, and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

#### Challenge:

Epilepsy is the most prevalent serious neurological condition in childhood, affecting up to 1% of children. Despite the wide range of treatments available today, 30% of people with epilepsy continue to have seizures. As a result, there is a major need for new therapies that will target seizures in a different way to existing drugs. The opportunities presented by a better understanding of epilepsy at a genetic and molecular level offer great hope for the future, especially for those with rare and severe forms of treatment resistant epilepsy.

#### **RCSI Value Added:**

Prof. David Henshall and his FutureNeuro research group have made pioneering contributions on the role of microRNAs in epilepsy. MicroRNAs offer the unique advantage of gene network-targeting capability to achieve disease modification in epilepsy; targeting multiple pathways as opposed to current epilepsy drugs which act on a single receptor or channel. The partnership builds on recent breakthroughs at RCSI in understanding how gene activity is controlled in the brain. Through this collaboration, the team looked for unusual gene expression patterns in brain tissue and cell models of childhood epilepsies, focusing on the genome's so-called 'dark matter' – stretches of DNA which do not code for proteins but work as molecular switches to activate or inhibit protein production. This large scale, multi-annual collaboration between Roche and RCSI has resulted in new patent filings, commercialisation agreements and facilitated access, for both parties, to resources, technologies and expertise that would otherwise not have been available.

"The research collaboration with Prof. David Henshall at the Royal College of Surgeons in Ireland (RCSI) has identified valuable links between the neurodevelopmental disorders Dravet Syndrome, Angelman Syndrome and Rett syndrome and the regulation of miRNAs. The work has further improved the biological understanding of the role of miRNAs in pediatric epilepsia, and potential future treatments using antagomirs."

**Dr. Jesper Worm** Principle Scientist, Roche Innovation.





"RCSI played a key role in building the DTIF consortium and through providing access to the clinical centres of excellence at Beaumont Hospital, they have helped to accelerate the path to market for our technology."

Eamonn Costello CEO patientMpower

### patientMpower/SIXTY CONSORTIUM

#### Title:

Haemodialysis Outcomes & Patient Empowerment (HOPE), an AI enabled software medical device & wearable device that will empower kidney dialysis patients to self- manage & provide clinicians with insights to improve care.

#### **Engagement Type:**

Disruptive Technology Innovation Fund

#### **Industry Partners:**

patientMpower is a digital healthcare company providing virtual care solutions for people living with chronic illnesses.

Sixty is developing a wearable device to measure hydration and heart rate through the principle of optical spectrometry.

#### Challenge:

Dialysis is associated with poor outcomes for patients and is a considerable financial burden for the healthcare system, costing the HSE approximately €142 million every year. Current practices in administering dialysis are key underlying drivers of this situation. The HOPE project aims to replace the current subjective, trial-and-error system for monitoring and managing dialysis patients outside the clinic with patientMpower's objective machine learning algorithm and patient-centred suite of apps and software. By combining this artificial intelligence platform with Sixty's wearable hydration monitor technology, patients will be able to administer dialysis at home while being continuously monitored by healthcare professionals, who could intervene when necessary.

#### **RCSI Value Added:**

The RCSI/industry consortium on the HOPE DTIF Project comprised two Irish SMEs (patientMpower and Sixty) and RCSI clinicians from the Kidney Centre at Beaumont Hospital. RCSI led the consortium and provided grant application and post-award support. RCSI clinicians at Beaumont Hospital Kidney Centre provided deep domain expertise in the management of patients with chronic kidney disease that was critical to the development and clinical validation of the digital platform and wearable device.







### **INFLECTION BIOSCIENCES**

#### Title:

Developing New Breast Cancer Therapies

#### Engagement type:

Enterprise Ireland Innovation Voucher

#### Industry partner:

Inflection Biosciences, based in Dublin and London, is developing small molecule therapeutics for the treatment of cancer. The company's pipeline of highly innovative cancer treatments comprises IBL-202, IBL-300 selected from a series of unique dual mechanism kinase inhibitors and the IBL-100 series (selective pan-PIM kinase inhibitors), are currently in pre-clinical stages of development. Inflection Biosciences was named 'Start-up Company of the Year' at the 2014 Irish Pharma Awards.

#### Challenge:

Inflection Biosciences approached RCSI for assistance in the identification of specific breast cancer patients who may be likely to respond to the company's therapeutic pipeline.

#### **RCSI** value-add:

In depth knowledge of current treatment strategies for drug resistant breast cancer and the ability to perform pre-clinical assessment of new compounds targeting that indication.

where current breast cancer treatments were failing in the clinic and their passion and capability to assess new cancer therapeutics in treating these resistant patient groups. The results from our initial collaboration have identified breast cancer patients who are more

"We approached

Hennessy and his

team at RCSI due to their understanding of

Professor Bryan

innovative therapeutic approach." Darren Cunningham Chief Executive Officer

likely to respond to our

Chief Executive Officer Inflection Biosciences



Pictured (L-R): Professor Bryan Hennessy, Senior Clinical Lecturer at RCSI, Consultant Medical Oncologist in Beaumont Hospital, Dublin and Our Lady of Lourdes Hospital, Drogheda and Adjunct Professor in the Division of Cancer Medicine at MD Anderson Cancer Centre (MDACC); Darren Cunningham, Chief Executive Officer at Inflection Biosciences, and Dr Michael O'Neill, Director of Research and Development at Inflection Biosciences.

### RCSI: PLAYING A LEADING ROLE IN NATIONAL RESEARCH CENTRES OF SCALE



#### **FutureNeuro**

FutureNeuro is a RCSI hosted SFI Research Centre focused on addressing the socio-economic burden caused by chronic and rare neurological diseases. In an internationally unique manner, FutureNeuro links innovative neurotherapeutics development with genomic and biomarker-based patient stratification, a national eHealth infrastructure and a nationwide clinical network. The Centre connects national and multinational industry with key academics and clinicians in RCSI, Trinity College Dublin, Dublin City University, NUI Galway and University College Dublin. Building initially on internationally recognised pre-clinical and clinical research into epilepsy and motor neurone disease, the FutureNeuro Centre is a scalable platform that aims to expand quickly to focus on other chronic and rare neurological diseases.



#### CÚRAM Centre

for Research in Medical Devices RCSI is a founding partner in the SEI Research Centre CÚRAM. The CÚRAM centre is focused on improving health outcomes for patients by developing innovative implantable medical devices that can respond to the body's environment and deliver therapeutic agents, such as drugs, exactly where needed. CÚRAM's outputs will particularly benefit patients with chronic diseases such as heart disease, diabetes and musculoskeletal diseases.



AMBER -

Advanced Materials and **BioEngineering Research** Since its foundation in 2013, the SFI Research Centre AMBER has become an internationally recognised centre of excellence for materials research. The AMBER Centre brings together leading researchers from RCSI's Tissue Engineering Research Group, the Trinity Centre for Bioengineering (TCBE) and the Trinity Centre for Research on Adaptive Nanostructures and Nanodevices (CRANN) as well as researchers in materials chemistry from UCC and has a strong focus on supporting industry partnerships.



#### Irish Centre for Vascular Biology

Hosted by RCSI, the Irish Centre for Vascular Biology (ICVB) comprises an integrated network of research groups across Irish hospitals and universities actively engaged in research in the field of vascular biology. Health Sciences. The CVRI The Centre's mission is to combine and harness the expertise of these individual groups, thereby establishing a single, internationally recognised, national centre of excellence in vascular biology research. In addition to leveraging existing Irish research expertise, the ICVB is building new partnerships with the major stakeholders involved in vascular research, including healthcare providers, patients and industry partners, with the goal of formulating and applying novel, interdisciplinary methods to the study of vascular biology.



#### CVRI

The Cardiovascular Research Institute Dublin (CVRI) is a research institute in the Mater Private Hospital Dublin and Mater Private Cork. It is also a collaboration with the RCSL University of Medicine and Dublin is affiliated with the Heart and Vascular Centre in the Mater Private, which is home to the largest group of specialist and subspecialist Cardiology Consultants in Ireland. The CVRI Dublin is led by Professor Robert Byrne, a recognized expert in the field of Cardiovascular Medicine and Research.

### **IP COMMERCIALISATION**

RCSI has a broad portfolio of patented technologies available for licensing relevant to the medical device, therapeutics, diagnostic and healthcare delivery sectors. We have established an experienced, pro-business team in our Office of Research and Innovation to support the licensing of RCSI IP to both established and spin-out companies. We welcome interest from companies who would like to explore licensing and partnering opportunities around our available technologies. For further information on our current portfolio please click **here**.







Therapeutics



Devices



Digital Health

### SPIN-OUT COMPANY FORMATION

We encourage experienced entrepreneurs and investors to talk to us about the creation of RCSI spin-out companies that may have the potential to develop into High-Potential Start-up Companies based on RCSI IP or aligned with RCSI's research focus. Ireland has several government funding schemes to support entrepreneurs seeking to create High-Potential Start-ups based on IP from higher education institutes including the Enterprise Ireland Business Partner Programme. RCSI's Office of Research and Innovation can advise entrepreneurs on accessing these funding schemes and explain how RCSI can support spinout company formation and the technology transfer process. Please contact us if you are interested in investing in or leading early-stage companies.

### BUILDING AN RCSI STARTUP COMPANY



### **S3 CONNECTED HEALTH**

#### Title:

Enodatis Digital Clinical Support Tool

#### **Engagement Type:**

Technology Licence

#### **Industry Partner:**

S3 Connected Health provide digital health solutions that help manage chronic conditions and enable patients to take control of their health. They specialise in the design and creation of cloud-based digital therapy management solutions and connected medical devices with partners in Pharma and MedTech. Using behavioural analysis, patient journey mapping and data-driven insights, they strive to truly understand the needs of patients, clinicians, and providers and support the move towards outcome-based healthcare.

#### Challenge:

In early March 2020, with the first wave of Covid-19 infections in Ireland rapidly swelling, Prof Richard Costello, Professor of Medicine at RCSI and Respiratory Medicine Consultant at Beaumont Hospital was tasked with developing technology enhanced care pathways for Covid-19 patients attending Beaumont Hospital. Carefully observing internationally events and acutely aware of the lack of Electronic Patient Record infrastructure in the Irish Healthcare System, Prof. Costello quickly concluded that an easy-to-use mobile application was required to optimise care of for these patients. The developed technology has application outside of Covid 19 for other patients suffering from respiratory conditions.

#### **RCSI Value Added:**

In an intensely collaborative effort, the clinical and academic researchers worked with medical and technical experts at S3 Connected Health night and day to: (a) develop a risk assessment score, now known as the Covid Critical Care Index (CCCI), to map disease progression and identify those patients most at risk of ICU admission and (b) incorporate CCCI into a web based GDPR compliant app (Enodatis) to enable non-respiratory specialist healthcare professions to triage and treat patients with the virus and monitor whether the patient was improving, stable or deteriorating. Within two weeks, the app was developed and deployed with a HPRA derogation in Beaumont Hospital. Enodatis has been used in six hospitals by 300 doctors with nearly 3500 patients registered on the system. It was CE marked and registered as a Class I Medical Device under MDD just seven weeks after initial meeting.



#### **Jim O'Donoghue** S3 Connected Health's President

"In normal circumstances

clinical support tool from <u>concept to dep</u>loyment.

What is most remarkable

than a fortnight. This was

only possible because of

a truly unique partnership

collaborative team effort

and outstanding

from all involved"

about Enodatis that it came to fruition in less

it would take up to

a year to develop a

"The process we went through negotiating the agreements did more than just produce those documents, it built a high level of trust between our organisation which is great".

James O'Riordan CTO RCSI and S3 Connected Health entered into a number of license agreements to facilitate commercial use by the company of the jointly created technology in different fields and to facilitate future use by the academic co-developing parties. Negotiations were smooth and swiftly completed to enable to technology to be brought to market as quickly as possible. The company went on to win e-health innovation of the year in the 2020 Irish MedTech Awards.



"I was delighted to work with the RCSI ORI Innovation Team on the creation of OncoLize. I found their approach to the licensing and spinout negotiations to be professional, pragmatic, and commercially informed which enabled a mutually beneficial outcome for both the University and the Founders."

Mike de Leeuw, CEO OncoLize

### ONCOLIZE

#### Title:

Commercialising New Treatments for Solid Tumour Cancers.

#### **Engagement Type:**

RCSI Spin-Out Company

#### **Industry Partner:**

Founded by Mike de Leeuw, Prof Helena Kelly and Dr Leo de Leede, OncoLize BV offers the next step in injectable drug depots for better tumour treatment. Oncolize's platform technology aims to improve outcomes for hard-to-treat cancers (such as pancreatic cancer) by localizing drugs to the tumour, with better efficacy, fewer side-effects, and at much lower costs to the national healthcare systems.

#### Challenge:

Surgical resection offers the best survival outcomes for patients with non-metastatic Pancreatic Cancer. Pancreatic Cancer often presents late and requires aggressive neoadjuvant chemotherapy to shrink the tumour back into the range where surgical resection is possible. However, due to its low vascularisation, dense stroma and poor tumour immunogenicity, Pancreatic Cancer is poorly responsive to systemic chemotherapy which limits the efficacy of neo-adjuvant treatments.

#### **RCSI Value Added:**

RCSI researcher and OncoLize co-founder Prof Helena Kelly developed the ChemoGel technology, a thermoresponsive hydrogel for direct intra-tumoural administration of chemotherapy for solid tumours which became the foundational IP for the spin-out which subsequently closed a \$1.7m seed funding round in 2023.





Pictured (I-r, front row) Dr Ian Nicoud, Libertatis Ergo Holding; Dr Aoife Gallagher, Head of Innovation, RCSI; Prof. Helena Kelly, OncoLize co-founder and CSO, School of Pharmacy and Biomolecular Sciences, RCSI; Mike de Leeuw, OncoLize founder and CEO; (back row) Dr Luuk Hawinkels, Leiden University Medical Centre; Dr Leo de Leede, OncoLize co-founder; Prof. Fergal O' Brien, Deputy Vice Chancellor for Research and Innovation, RCSI; and Rob Mayfield, Libertatis Ergo Holding.

### **RCSI CLINICAL RESEARCH FACILITY**



Professor Mark Sherlock Professor of Medicine/Consultant Endocrinologist; Director RCSI Clinical Research Facility

The RCSI Clinical Research Centre (RCSI CRC) provides state-of-the-art facilities and expertise to enable investigators to conduct clinical research to the highest standards.

The centre is located on the Beaumont Hospital campus in Dublin, which is Ireland's second largest hospital; the main teaching hospital and academic partner for RCSI. It is the national and regional centre for many specialties including neurosurgery, neurology, renal transplantation, rare lung diseases, pituitary and adrenal endocrinology, gastroenterology and infectious diseases. The close proximity between the hospital and RCSI CRC allows for synergy with clinicians to deliver seamless translational research and impactful clinical trials. RCSI CRC provides physician investigators with a unique facility and a comprehensive range of support systems for clinical research with the capability to conduct research in all therapeutic areas. The RCSI CRC team can provide assistance to investigators and study sponsors in study feasibility, contract and budget negotiation and study coordination throughout the life cycle of a clinical trial/investigation.

The outputs from the centre have been recognised in high-impact journals such as The New England Journal of Medicine, The Lancet, and other highly cited clinical papers, resulting in practice changing outcomes for patients. The centre provides examination rooms, inpatient and outpatient beds, procedure rooms and ancillary services required for the delivery of world-class patient focused research.



Key areas of support to the physician investigators include a management structure to oversee and perform clinical trials and provide support in regulatory compliance. The research nurse team has extensive experience in working with ethical and regulatory requirements and is optimally positioned to deal with the flexibility required to respond to the rapidly changing demands of a dynamic research environment.

The centre takes a leading role in supporting research nurse education and development, from the provision of postgraduate educational opportunities to the establishment and ongoing support of the Irish Research Nurses and Midwives Network (IRNM). RCSI CRC is the leading provider of good clinical practice (GCP) training, not only for investigational medicinal product (IMP) trials, but also GCP in medical device research and sponsor responsibilities. The provision of train-the-trainer courses for other centres has allowed these institutions to adapt RCSI CRC courses for their own use locally. The centre also provides continuing education for research nurses and midwives and other healthcare disciplines in the coordination and management of clinical research.

National and international networking and collaboration are fundamental to research quality and growth, and RCSI CRC is committed to active engagement with research partners. The centre is an active member of the HRB National Clinical Trials Office Network (HRB-NCTO) participating in the NCTO Co-Applicant Committee, Stakeholder and Management Committee and national working groups, including quality, costing, feasibility and start-up and Medtech. Core RCSI CRC staff are active members of national/international working groups and committees, including IRNM, UK/Ireland branch of the International Association of Clinical Research Nurses (IACRN), UK Clinical Research Facilities Network (UKCRF) workstreams and the European Clinical Research Infrastructure Network (ECRIN).



Today, the RCSI-CRF supports research in a broad spectrum of clinical areas and has developed particular expertise in core clinical areas which align with the strengths of the clinical services provided in Beaumont and Rotunda Hospitals including:

#### 1. Respiratory and Critical Care Medicine

- » National Centre for Cystic Fibrosis, Alpha-1-Antitrypsin Deficiency.
- » Asthma and COPD (Chronic Obstructive Pulmonary Disease) studies
- » Large critical care department including a dedicated neuro-critical care department

#### 2. Kidney disease

» National Centre for Renal Transplantation, Renal Replacement Therapy & Rare Kidney Disease.

#### **3. Clinical Neurosciences**

- » National Neurosurgical Centre
- » Stroke/National Thrombectomy Service
- » National Epilepsy Surgery Service and clinical centre for SFI Research Centre FutureNeuro
- » Motor Neuron Disease & MS

#### 4. Endocrinology

- » National Pituitary Centre, National Lead for ENDO-ERN
- » Regional/ supra-regional Centre for Adrenal disease
- » Thyroid disease
- » Reproductive Endocrinology

#### 5. Gastroenterology

- » Centre for Inflammatory Bowel Disease
- » Advanced Endoscopy and Upper GI Surgery
- » Liver disease
- » Colorectal surgery

#### 6. Maternal and Fetal Medicine

» Host for Mother and Baby Clinical Trials unit

#### 7. Haematology and Oncology

- Full Medical Oncology and Radiation Oncology services (via St Luke's Radiotherapy centre co-located on Beaumont Hospital site)
- » Regional/National centre for Breast Cancer, Primary Brain Tumours, Gastrointestinal/Adrenal Tumours, Myeloma/Lymphoma and Lung Cancer

#### 8. Infectious diseases

- » COVID related clinical trials
- » HIV related clinical trials

#### RCSI-CRF facilities include:

- » Day ward Accommodating four patients
- » Consultation rooms Patient consultations and study visits
- » Samples room Processing of blood and biological samples, storage of biological samples (refrigerator, -20° and -80° freezers).
- » Dedicated research office space
- » Pharmacy space for safe and monitored storage of Investigational Medicinal Products (IMPS)
- » A dedicated and experienced core research nursing staff funded by RCSI, together with a recently established Sponsorship Office, currently delivers RCSI-CRF services.

#### Additional Expertise;

- » Biostatistics support via RCSI Data Sciences Centre
- » Data management
- » Study Feasibility/Activation Support
- » Study Quality/Safety and Regulation
- » Clinical Research Education Programs
- » CRC Operations
- » Efficient Contracting Process
- » Assistance with protocol development



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Taighde Éireann Research Ireland



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