

# RCSI-Clinical Research Centre

Professor Mark Sherlock

Consultant Endocrinologist, Beaumont Hospital  
Professor of Medicine, RCSI  
Director RCSI-Clinical Research Centre



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# RCSI-Clinical Research Centre (RCSI-CRC)



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# Clinical Research at RCSI and Beaumont Hospital

World Rankings



**Top 2%**

Research



**No. 1**  
Citation Rate in Ireland

Researchers



**165**  
Clinical Investigators

Research Publications and citations



**1,538**

Peer reviewed research publications

**20,424**

International Collaboration



**679**

A further 1,013 were national collaborations

Funding



**€25m**

Funding secured over previous 5 years

**€11m**

Invested in extension of the RCSI Education and Research building at Beaumont Hospital



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# Supporting Excellence with Established & Emerging Investigators



Prof G. McElvaney



Prof N. Delanty



Prof A. Hill



Prof R. Costello



Prof P. Conlon



Prof D. Williams



Prof M. Cannon



Prof D. Cotter



Prof C. Thompson



Prof D. McNamara



Prof S. Glavey



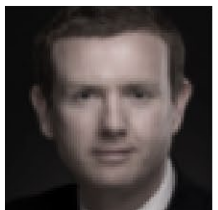
Prof G. Curley



Prof K. Hurley



Prof M. O'Reilly



Prof C. O'Seaghda



Prof J. Ryan



Prof J. Burke



Prof M. Javadpour



Prof B. Hennessy

The NEW ENGLAND JOURNAL of MEDICINE

NOVEMBER 8, 2015

**A CFTR Potentiator in Patients with Cystic Fibrosis and the G551D Variant**

Background: Cystic fibrosis is a genetic disease caused by mutations in the CFTR gene. The G551D variant is the most common mutation in patients with cystic fibrosis who are homozygous for the G551D variant. Ivacaftor is a CFTR potentiator that is approved for patients with the G551D variant.

**RESULTS:** In this study, we evaluated the efficacy and safety of ivacaftor in patients with the G551D variant. The study was a randomized, double-blind, placebo-controlled trial. The primary endpoint was the change from baseline in the percentage of sweat chloride excretion.

**CONCLUSIONS:** Ivacaftor significantly improved the percentage of sweat chloride excretion in patients with the G551D variant. The study was well tolerated, and no serious adverse events were reported.

THE LANCET

NOVEMBER 14, 2015

**Intravenous augmentation treatment and patient deficiency (RAPID): a randomised controlled trial**

Background: Intravenous augmentation treatment (RAPID) is a novel treatment for patients with acute ischaemic stroke. The study was a randomised, double-blind, placebo-controlled trial.

**RESULTS:** In this study, we evaluated the efficacy and safety of RAPID in patients with acute ischaemic stroke. The study was a randomised, double-blind, placebo-controlled trial.

**CONCLUSIONS:** RAPID significantly improved functional outcomes in patients with acute ischaemic stroke. The study was well tolerated, and no serious adverse events were reported.



**A randomised controlled trial of a novel inhaler device for patients with severe asthma**

Background: A novel inhaler device (the 'AeroChamber') has been developed for patients with severe asthma. The study was a randomised, double-blind, placebo-controlled trial.

**RESULTS:** In this study, we evaluated the efficacy and safety of the AeroChamber in patients with severe asthma. The study was a randomised, double-blind, placebo-controlled trial.

**CONCLUSIONS:** The AeroChamber significantly improved lung function in patients with severe asthma. The study was well tolerated, and no serious adverse events were reported.

**Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke**

Background: Rapid endovascular treatment (RET) is a novel treatment for patients with acute ischaemic stroke. The study was a randomised, double-blind, placebo-controlled trial.

**RESULTS:** In this study, we evaluated the efficacy and safety of RET in patients with acute ischaemic stroke. The study was a randomised, double-blind, placebo-controlled trial.

**CONCLUSIONS:** RET significantly improved functional outcomes in patients with acute ischaemic stroke. The study was well tolerated, and no serious adverse events were reported.

THE LANCET

NOVEMBER 14, 2015

**Efficacy and safety of nerinetide for the treatment of acute ischaemic stroke (ESCAPE-NA): a multicentre, double-blind, randomised controlled trial**

Background: Nerinetide is a novel treatment for patients with acute ischaemic stroke. The study was a randomised, double-blind, placebo-controlled trial.

**RESULTS:** In this study, we evaluated the efficacy and safety of nerinetide in patients with acute ischaemic stroke. The study was a randomised, double-blind, placebo-controlled trial.



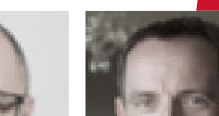
Prof J. Donnelly



Prof F. Breathnach



Prof A. El-Khuffash



Prof F. Malone



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# What is unique and successful about Beaumont/ Rotunda Hospitals and RCSI?



**RCSI HOSPITAL GROUP**  
GRÚPA OSPIDÉAL RCSI



7 Hospitals



2,192 Beds



Serving 1.1 Million People



Serving the Country

## Beaumont Hospital



National Cancer Centre  
National Centre for CF and AATD  
National Neuroscience Centre  
National Renal Transplantation Centre  
National ENT/Head and Neck Surgery  
National Pituitary Centre  
Regional/ National Adrenal Centre  
National Cochlear Implantation  
Regional Gastroenterology Centre  
Regional Rheumatology Centre

## Rotunda Hospital



Maternity Services  
Maternal Fetal Medicine  
Neonatal Care  
Gynaecology Care



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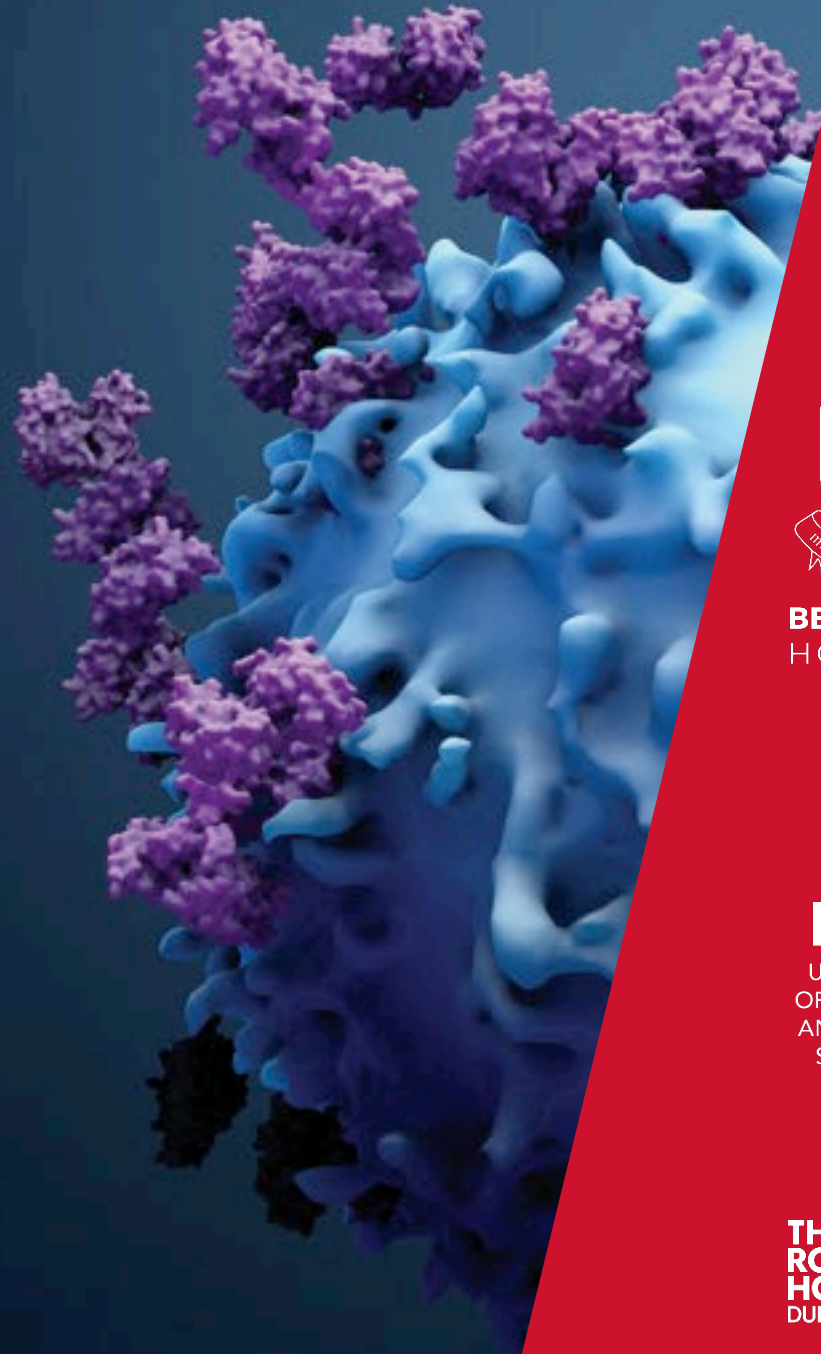


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## Beaumont RCSI Cancer Centre OEI Accreditation

- Research and clinical trials is a key metric
- Synergistic working Between RCSI-CRC and Cancer Clinical Trials Unit



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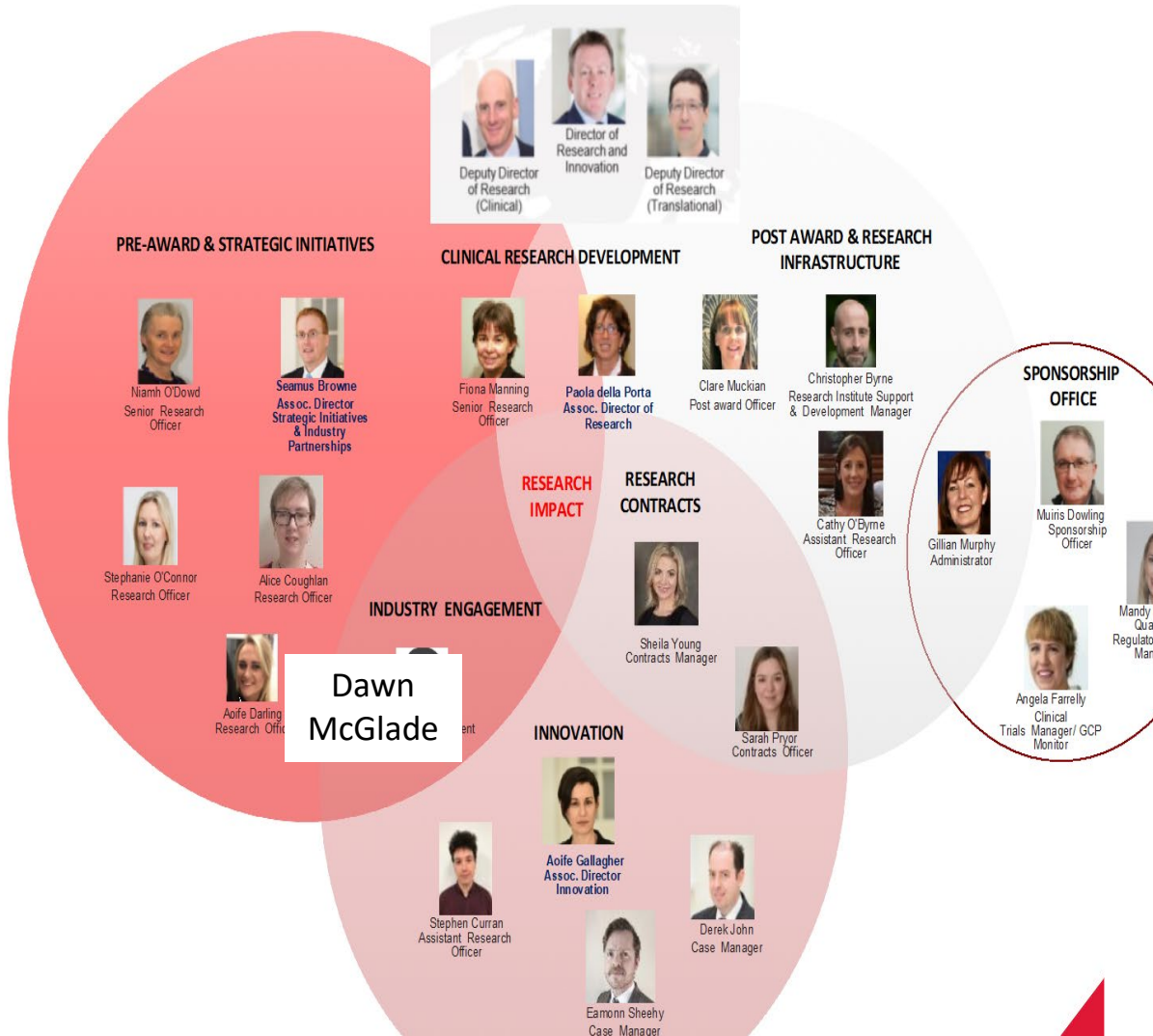


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# RCSI-CRC Close Collaborations with RCSI-SSG for Translational Research



## Resources and facilities

RCSI's research activities are sustained by an integrated research infrastructure consisting of a network of centres and core facilities.

These facilities support genomics analysis, peptide synthesis and labelling, solid phase chemistry, proteomics, molecular, live cellular and human imaging, clinical research and biobanking.

### Clinical Research Centre

Located at Beaumont Hospital, the Clinical Research Centre was the country's first purpose-built clinical research centre.

### Data Science Centre

Providing support for researchers in areas such as biostatistics, bioinformatics, epidemiology and data management.

### Research ethics

Ensuring RCSI adheres to the highest standards of conduct in research.

### Molecular and cellular imaging

Focusing on live cell imaging applications and supporting users from different fields in biomedical research.

### Biobank

Providing tissue samples and DNA extraction for RCSI researchers.

### Automated Biopolymer and Biomaterial Synthesis Facility

Providing synthetic peptides and polymers for medical materials and devices.



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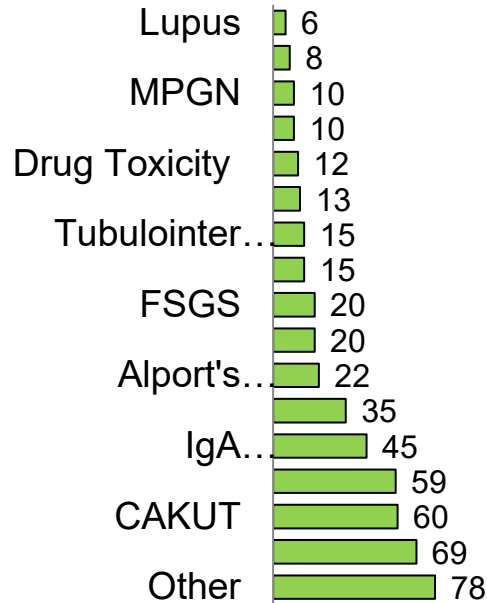
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# Irish Kidney Gene Project

## Professor Peter Conlon

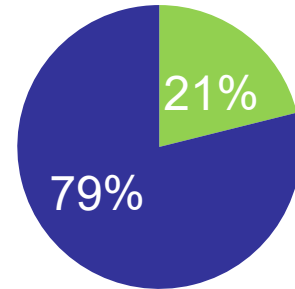


### Aetiology Kidney Disease in Non-PCKD Positive Family History



### Aetiology of Kidney Disease in the Positive Family History Cohort

■ PCKD ■ Non PCKD



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# Neurovascular Stroke Studies

## ESCAPE Study

Professor David Williams and Professor John Thornton

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

### Randomized Assessment of Rapid Endovascular Treatment of Ischemic Stroke

M. Goyal, A.M. Demchuk, B.K. Menon, M. Eesa, J.L. Rempel, J. Thornton, D. Roy, T.G. Jovin, R.A. Willinsky, B.L. Sapkota, D. Dowlathshahi, D.F. Frei, N.R. Kamal, W.J. Montanera, A.Y. Poppe, K.J. Ryckborst, F.L. Silver, A. Shuaib, D. Tampieri, D. Williams, O.Y. Bang, B.W. Baxter, P.A. Burns, H. Choe, J.-H. Heo, C.A. Holmstedt, B. Jankowitz, M. Kelly, G. Linares, J.L. Mandzia, J. Shankar, S.-I. Sohn, R.H. Swartz, P.A. Barber, S.B. Coutts, E.E. Smith, W.F. Morrish, A. Weill, S. Subramaniam, A.P. Mitha, J.H. Wong, M.W. Lowerison, T.T. Sajobi, and M.D. Hill for the ESCAPE Trial Investigators\*

ABSTRACT

- 4180 citations
- 258,104 Page Views
- Beaumont CRC was the Largest Recruiter of Patients outside Canada
- Led to a 'seachange' in the management of ischaemic stroke
- ESCAPE recruitment model led to SCTNI



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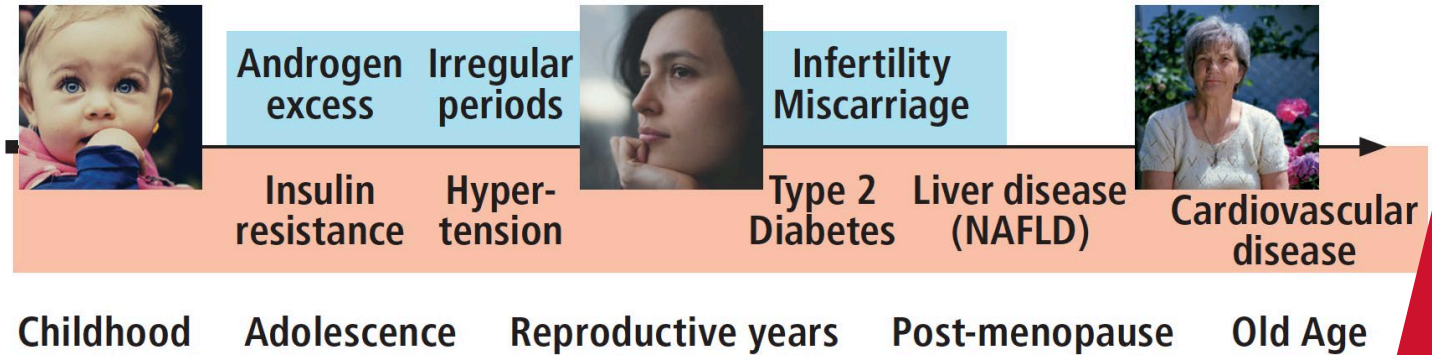
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# Polycystic ovary syndrome

## Professor Michael O'Reilly



### Polycystic ovary syndrome - a life's journey



- 3-fold increased risk of **type 2 diabetes mellitus**
- 2-fold increased risk of **non-alcoholic fatty liver disease**
- 2-fold increased risk of **cardiovascular disease**

**HR<sup>B</sup>** Health Research Board

*'PCOS guidelines are informed by low-to-moderate quality evidence'*

**11OXO-Diabetes**

Prof. Michael O'Reilly

HRB Emerging Clinician Scientist Award 2020



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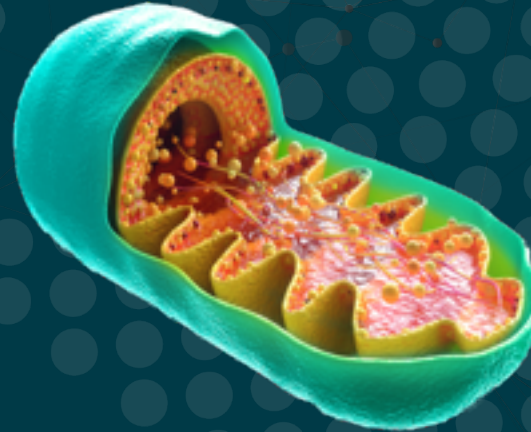
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# Mechanistic Research in PCOS leading to clinical trials



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**HR<sup>B</sup>** Health  
Research  
Board

**11OXO-Diabetes**

Prof. Michael O'Reilly

HRB Emerging Clinician Scientist Award 2020

# Infectious Disease Research

## Dr Eoughan De Barra and Prof Sam McConkey



All Ireland Infectious Diseases Cohort  
RCSI >900 enrolled in biobank



European Clinical Research Alliance for Infectious Diseases

Active recruitment Boostavac COVID vaccine study

Key member for future adaptive trial platforms across EU



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# WHO COVID-19 Solidarity Therapeutics Trial

## RCSI-CRC largest recruiter Nationally



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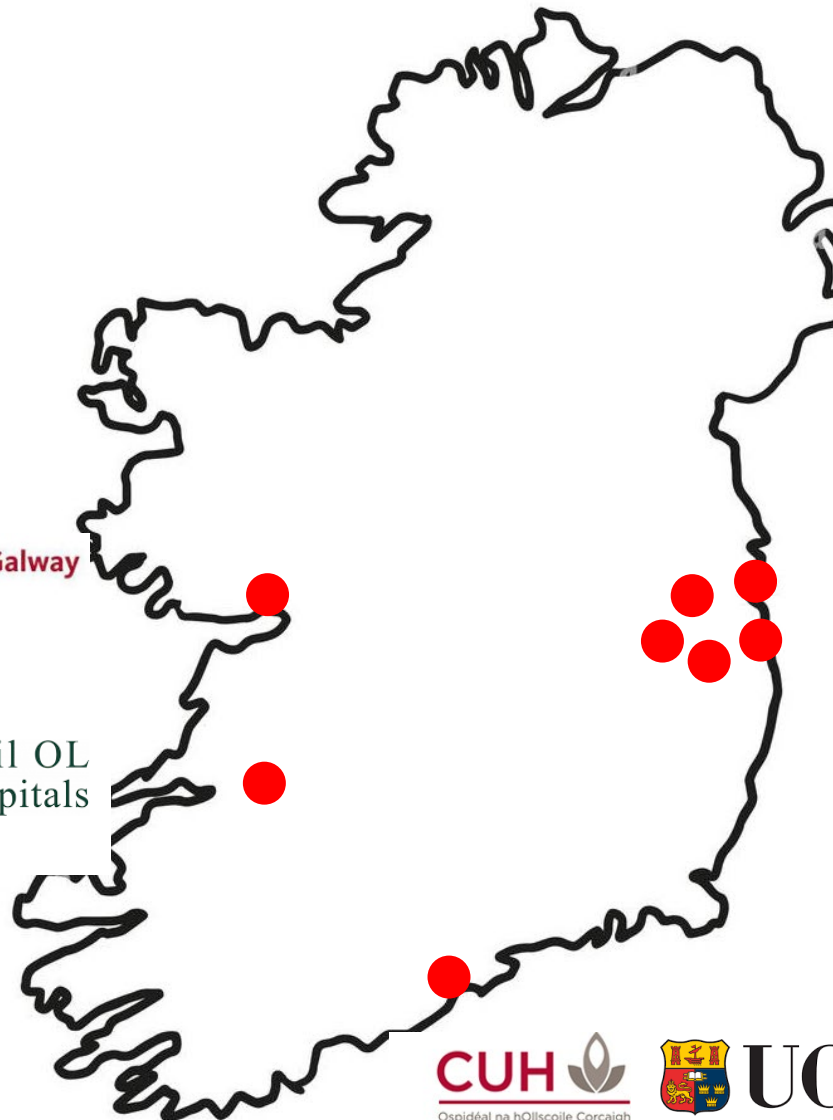
An Roinn Sláinte  
Department of Health



Health Research Board  
**NCTO**  
National Clinical Trials Office



**University Hospital Galway**  
Ospidéal na h-Ollscoile, Gaillimh  
GALWAY UNIVERSITY HOSPITALS



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The **NEW ENGLAND**  
JOURNAL of MEDICINE

ESTABLISHED IN 1812      FEBRUARY 11, 2021      VOL. 384 NO. 6

Repurposed Antiviral Drugs for Covid-19 — Interim WHO Solidarity Trial Results

WHO Solidarity Trial Consortium\*

# Infectious Disease Studies



Ongoing site for EU wide adaptive platform COVID and potentially other viral infections



Largest Irish recruiter to Pharma sponsored injectable HIV medicines trial. Positive findings now market approved.



Largest Irish recruiter to Pharma sponsored HIV medicine phase IV trial



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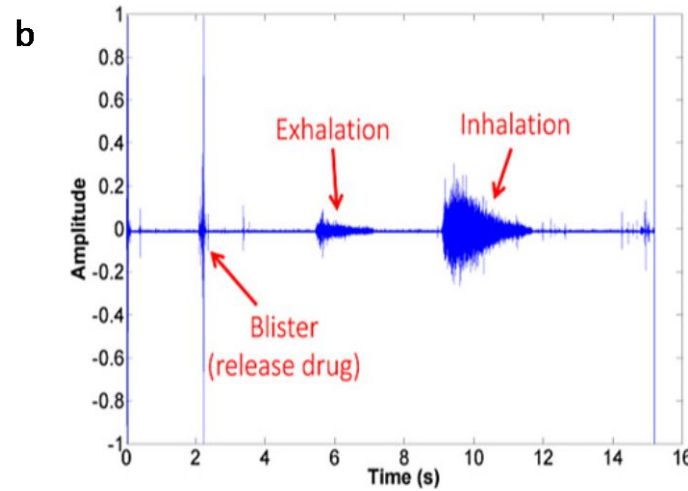
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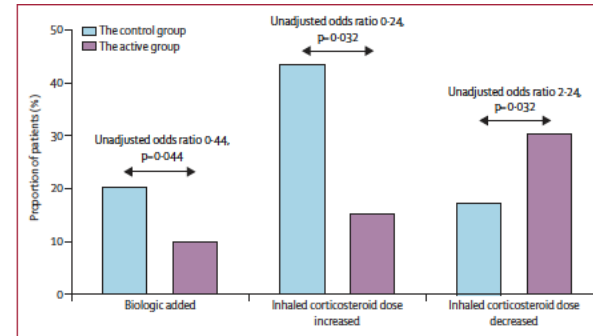
# Professor Richard Costello

## Technology and Asthma Control (INCA studies)



Use of digital measurement of medication adherence and lung function to guide the management of uncontrolled asthma (INCA Sun): a multicentre, single-blinded, randomised clinical trial

Elaine Mac Hale\*, Garrett Greene\*, Christopher Mulvey\*, Matshediso C Mokoka\*, Job F M van Boven, Breda Cushen, Imran Sulaiman, Vincent Brennan, Patrick J Kerr, Richard B Reilly, Cian Hughes, Brian D Kent, David J Jackson, Marcus Butler, Ian Counihan, James Hayes, John Faul, Martin Kelly, Rory Convery, Alexandra M Nanzer Kelly, J Mark Fitzgerald, Desmond M Murphy, Liam G Heaney, Richard W Costello on behalf of the INCA Research Team†



**Figure 3:** Proportion of patients randomly assigned who were referred for add-on biological therapy. At 32 weeks, patients were referred for add-on biological therapy (n=22 control; n=11 active); or over the treatment adjusted period, patients had inhaled corticosteroid dose increased from FP 500 µg once per day to 1000 µg once per day (3 [16%] of 19 active patients and 11 [44%] of 25 control patients), or reduced from FP 1000 µg once per day to 500 µg once per day (26 [31%] of 83 active patients and 13 [18%] of 73 control patients). The odds ratios for each of the changes in the active group, compared with the control group having these medication changes are per protocol analysis. FP-fluticasone propionate.

# Professor Gerry McElvaney

## Cystic Fibrosis and alpha 1 antitrypsin research

### ORIGINAL ARTICLE

#### **Trikafta Rescues CFTR and Lowers Monocyte P2X7R-induced Inflammation**

The NEW ENGLAND JOURNAL of MEDICINE

Claudie Gabillard-L  
Anne-Marie Lyons<sup>2</sup>

<sup>1</sup>The Irish Centre of Genetic Lung Disease,  
Royal College of Surgeons in Ireland,  
St James's Hospital, Dublin, Ireland

ORCID IDs: 0000-0002-4000-0002-4  
0000-0002-1922-0447 (E)

ORIGINAL ARTICLE

#### **Triple Therapy for Cystic Fibrosis *Phe508del*-Gating and *-Residual Function* Genotypes**

P.J. Barry, M.A. Mall, A. Álvarez, C. Colombo, K.M. de Winter-de Groot, I. Fajac, K.A. McBennett, E.F. McKone, B.W. E. Tullis, N. Ahluwalia, L.S. Jun, S.M. D. Waltz, F. Xuan, Y. Zhar  
for the VX18-44

Check for updates

### ORIGINAL ARTICLE

#### **Clarifying the Role of Alpha-1 Antitrypsin Deficiency**

Alessandro N. Franciosi<sup>1,2</sup>  
Cedric Gunaratnam<sup>1,2</sup>, Ed

<sup>1</sup>Irish Centre for Genetic Lung Disease,  
Department of Medicine and <sup>2</sup>Department  
of Medicine and <sup>4</sup>Division of Pulmonary and

ORCID IDs: 0000-0002-4241-87



CrossMark

on<sup>2</sup>,

Centre,  
nt



EDITORIAL  
ERS CLINICAL RESEARCH COLLABORATIONS

#### **The European Alpha-1 Research Collaboration (EARCO): a new ERS Clinical Research Collaboration to promote research in alpha-1 antitrypsin deficiency**

Marc Miravittles<sup>1</sup>, Joanna Chorostowska-Wynimko<sup>2</sup>, Ilaria Ferrarotti<sup>3</sup>,  
Noel G. McElvaney<sup>4</sup>, Karen O'Hara<sup>5,6</sup>, Jan Stolk<sup>7</sup>, Robert A. Stockley<sup>8</sup>,  
Alice Turner<sup>9</sup>, Marion Wilkens<sup>6,10</sup> and Timm Greulich<sup>11</sup> on behalf of the  
EARCO Clinical Research Collaboration<sup>12</sup>

Clarke<sup>5</sup>,

Department  
Medicine

).



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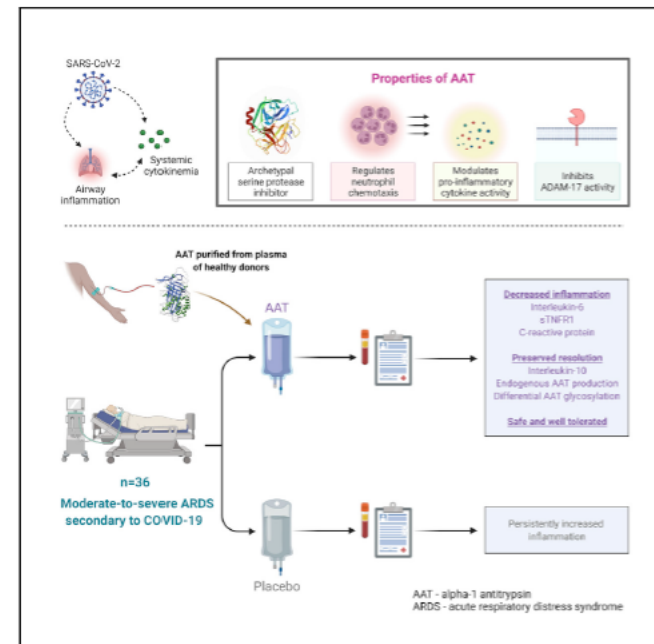
# Investigator initiated Double blind, placebo controlled RCT in COVID Professor Ger Curley and Professor Gerry McElvaney

Med

CellPress

## Clinical Advances

A randomized, double-blind, placebo-controlled trial of intravenous alpha-1 antitrypsin for ARDS secondary to COVID-19



Oliver J. McElvaney, Natalie L. McEvoy, Fiona Boland, ..., Ignacio Martin-Loeches, Noel G. McElvaney, Gerard F. Curley

olivermcelvaney@rcsi.ie (O.J.M.)  
gmcelvaney@rcsi.ie (N.G.M.)

### Highlights

Patients with COVID-19-associated ARDS were randomized to receive IV AAT or placebo

Patients receiving IV AAT had decreased IL-6, sTNFR1, and CRP at 1 week

Differential glycosylation of endogenous AAT was preserved in the treatment group

Treatment with IV AAT was safe and well tolerated



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# Department of Gastroenterology & Hepatology

## Professor Karen Boland and Professor John Ryan

### Inflammatory Bowel Disease

- **M14-533:** A Phase 3 Multicenter, Long Term Extension Study to Evaluate the Safety and Efficacy of upadacitinib in Subjects with Ulcerative Colitis (UC)
- **Celgene RPC01-3201:** A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Oral Ozanimod as Induction Therapy for Moderately to Severely Active Crohn's Disease
- **RPC01-3204:** Open label extension study of ozanimod in Crohn's disease



### Hepatology

- **NUT-3/NAS:** Efficacy and safety of norursodeoxycholic acid in NASH
- **NN9931-4553:** The Effect of semaglutide in Subjects with Non-Cirrhotic Non-Alcoholic Steatohepatitis



### Interventional Endoscopy

- **Archimedes:** To assess utility of bio-degradable bile duct stent
- **Sure Study:** Multi-centre prospective study to assess performance of single use duodenoscopes
- **Impact of bariatric endoscopy on NAFLD (IBENA study)**



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# Pulmonary Fibrosis in Ireland

## Professor Killian Hurley

**Aim 1.** Determine the yield of genomic diagnostics in FPF



Patients from our National Referral Network

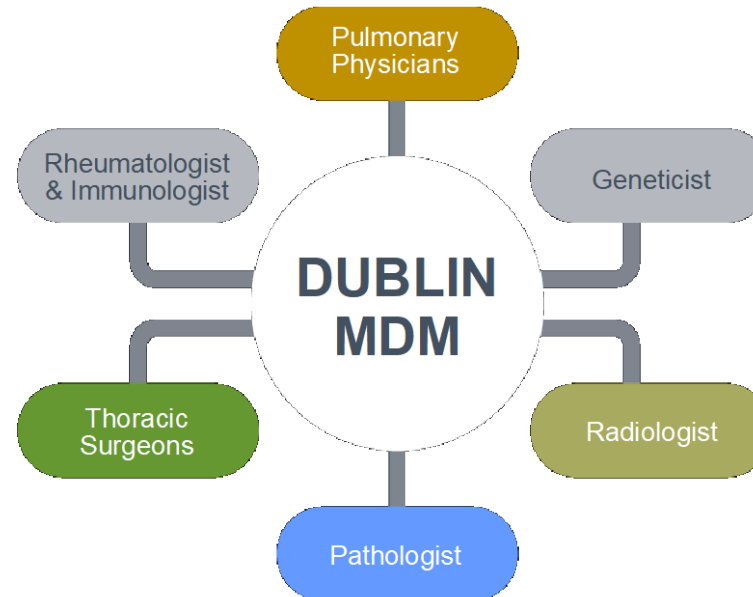


Evaluate Patients with familial and 'sporadic' ILD

- National Referral Pathway
- Estimate prevalence
- Genotype/phenotype relationships
- Patient samples for disease modelling

### Collaborators in All Hospital Groups

- Dr. Killian Hurley (PI); Dr Katherine O'Reilly; Dr. Michelle Murray
- Profs. Michael Keane, Cormack McCarthy
- Prof. Seamas Donnelly
- Dr. Michael Henry
- Dr. Aidan O'Brien
- Prof. Anthony O'Regan



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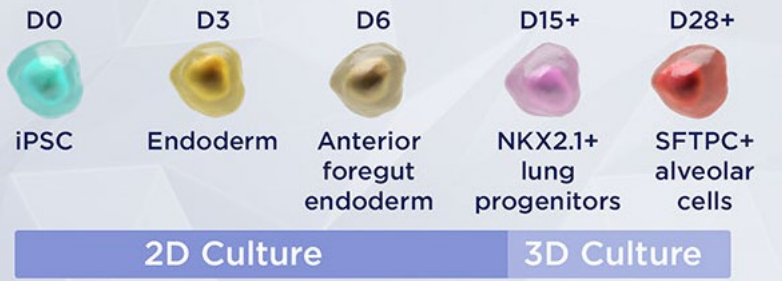
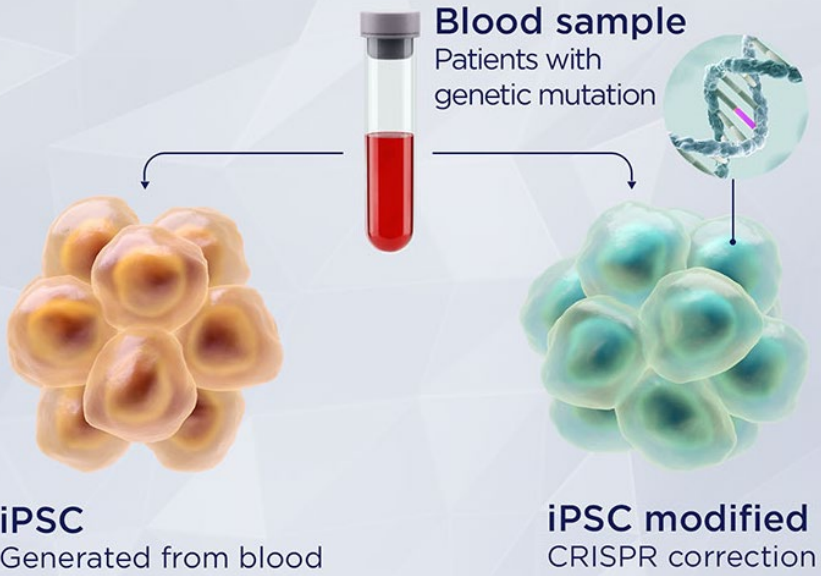


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# Model familial pulmonary fibrosis using patient-derived iPSC lung organoids.



Type 2 alveolar epithelial cells Spheroids (iAT2)



ERC Starting Grant



European Research Council  
Established by the European Commission



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# Rotunda Hospital Clinical Research and Trials



www.nature.com/jp

Journal of Perinatology

## ARTICLE

### The use of milrinone in neonates with persistent pulmonary hypertension of the newborn - a randomised controlled trial pilot study (MINT 1)

Aff EL-Khuffash<sup>1,2,3</sup>, Patrick J. McNamara<sup>3</sup>, Colm Breatnach<sup>1</sup>, Neidin Bussmann<sup>1</sup>, Aisling Smith<sup>1</sup>, Oliver Feeney<sup>4</sup>, Elizabeth Tully<sup>4</sup>, Joanna Griffin<sup>4</sup>, Willem P. de Boode<sup>5</sup>, Brian Cleary<sup>6,7</sup>, Orla Franklin<sup>8</sup> and Eugene Dempsey<sup>9,10</sup>

Check for updates

## Original research



OPEN ACCESS

### Hypotension in Preterm Infants (HIP) randomised trial

Eugene M Dempsey<sup>1</sup>, Keith J Barrington<sup>2</sup>, Neil Marlow<sup>3</sup>, Colm Patrick Finbarr O'Donnell<sup>4</sup>, Jan Miletin<sup>5</sup>, Gunnar Nauelaers<sup>6</sup>, Po-Yin Cheung<sup>7</sup>, John David Corcoran<sup>8</sup>, Afif Faisal EL-Khuffash<sup>8</sup>, Geraldine B Boylan<sup>1</sup>, Vicki Livingstone<sup>1</sup>, Gerard Pons<sup>9</sup>, Jozef Macko<sup>10</sup>, David Van Laere<sup>11</sup>, Hana Wiedermannova<sup>12</sup>, Zbyněk Straňák<sup>13</sup>, On behalf of the HIP consortium

Open access

Research

### BMJ Open Trial of feasibility and acceptability of routine low-dose aspirin versus Early Screening Test indicated aspirin for pre-eclampsia prevention (TEST study): a multicentre randomised controlled trial

Fionnuala Mone<sup>1</sup>, Cecilia Mulcahy<sup>1</sup>, Peter McParland<sup>1</sup>, Fionnuala Breathnach<sup>2</sup>, Paul Downey<sup>3</sup>, Dorothy McCormack<sup>4</sup>, Marie Culliton<sup>3</sup>, Alice Stanton<sup>5</sup>, Fiona Cody<sup>2</sup>, John J Morrison<sup>6</sup>, Sean Daly<sup>7</sup>, John Higgins<sup>8</sup>, Amanda Cotter<sup>9</sup>, Alyson Hunter<sup>10</sup>, Elizabeth C Tully<sup>2</sup>, Patrick Dicker<sup>2</sup>, Zarko Alfirevic<sup>11</sup>, Fergal D Malone<sup>2</sup>, Fionnuala M McAuliffe<sup>1</sup>



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# CLINICAL RESEARCH COURSES

## Good Clinical Practice (GCP): IMP Trials

In-person or online

- Introduction to Drug Development & Clinical Research
- Clinical Research Governance & GCP Principles
- Investigator Responsibilities
- Safety Reporting, Essential Documents & Regulatory Inspection

## Good Clinical Practice in Medical Device Research

In-person or online

- Introduction to Clinical Research and GCP Principles
- Medical Devices: Types & Classification; Legislation; Clinical Evaluation
- Planning and Conducting a Clinical Investigation
- Safety Reporting, Monitoring & Audit

## Clinical Research Coordination and Management

Online

- Study Set-up and Administration: Feasibility to Site Initiation
- Study Organisation and Management
- Patient Recruitment, Informed Consent & Study Visits
- Quality, Safety & Regulatory Issues



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# Thank you

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**Email:**

**[Director of RCSI-CRC: Marksherlock@rcsi.com](mailto:Marksherlock@rcsi.com)**

**[Director of Operations RCSI-CRC: FionnualaKeane@rcsi.com](mailto:FionnualaKeane@rcsi.com)**