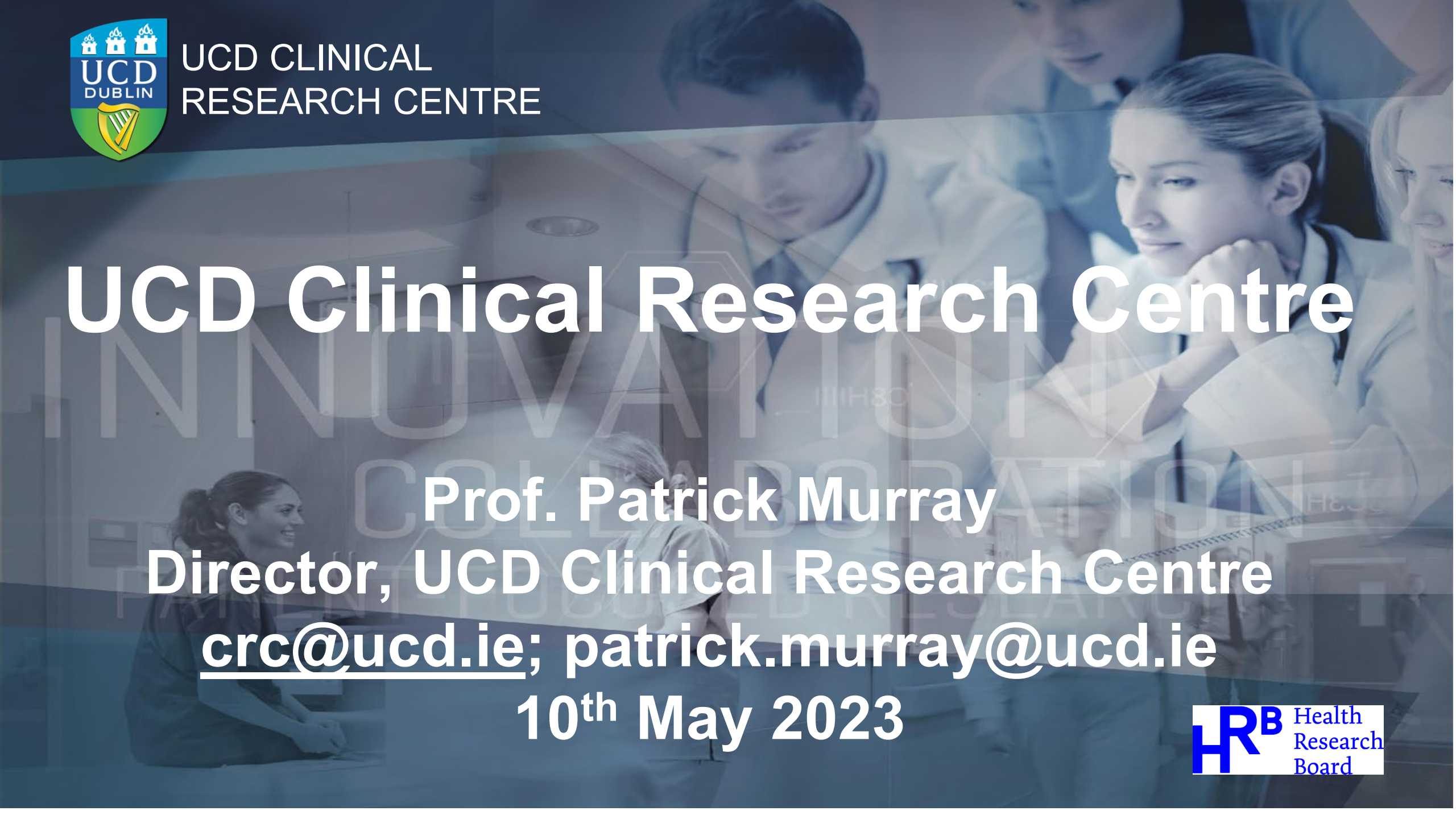

UCD CLINICAL RESEARCH CENTRE

UCD Clinical Research Centre

Prof. Patrick Murray
Director, UCD Clinical Research Centre
crc@ucd.ie; patrick.murray@ucd.ie

10th May 2023

HRB Health Research Board

UCD CLINICAL RESEARCH CENTRE

MISSION & VISION

Mission

To conduct, support and promote high quality clinical research that improves clinical practice and patient outcomes.

Vision

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

HRB Health Research Board

UCD CLINICAL RESEARCH CENTRE

Themes & Strategic *Priorities*

CRC Themes

Strategic Priorities

i. Doubling the numbers of trials by year 5.

ii. Developing our research site network.

iii. Extending into early phase trials.

iv. Aligning the universities research assets for greater impact.

v. Developing a priority partnership with a CRO.

vi. Providing research leadership and oversight

vii. Enhancing the CRC's reputation as a centre for excellence in training the clinical investigators of the future.

viii. Focusing on mechanisms to grow core CRC areas.

HRB Health Research Board

UCD CLINICAL RESEARCH CENTRE

CRC in Numbers

Clinical Research

- 373 Studies
- 62 New Studies
- 177 Clinical Trials

Scientific Services

- 3,177 Patient Samples Bio banked
- 1,623 Samples related to PI Initiated Clinical Trials
- 39,635 Biomarkers tested on 12,319 Patient Samples
- 5,477 Elisa/ Digital Elisa markers on 13,651 Patient samples

Quality & Regulatory Affairs

- 6 DSUR Reports
- >25 HPRA Approvals
- 58 UCD CRC SOPs
- 8 Staff completed Training reports
- 9 Investigator Initiated Trials

Education

- 5 Education Programmes
- 10 Modules
- 151 Students
- 3 Professional Development

Outputs

- 68 PIs across University & Hospitals
- 402 Publications
- 2.91 Field Weighted Citation, 4.08 for International

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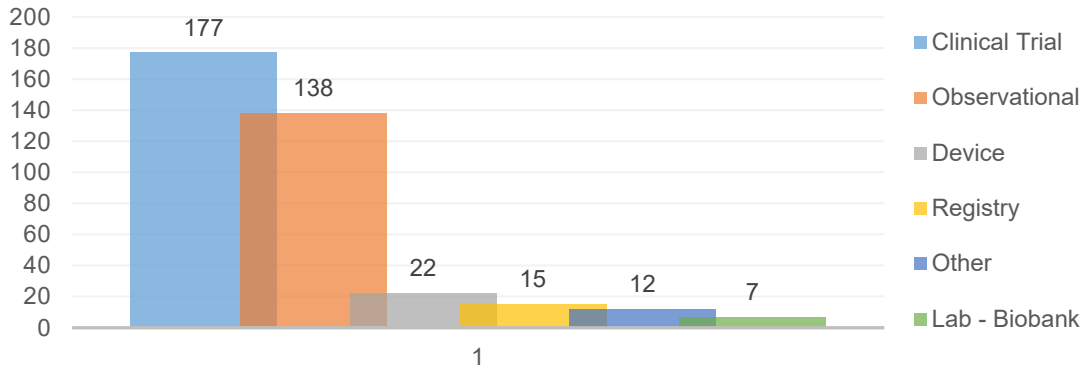
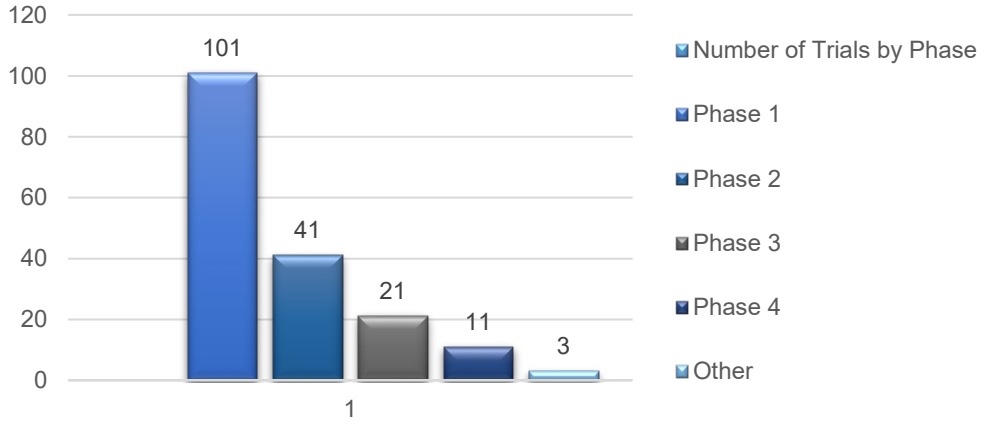
CRC Study Activity 2022

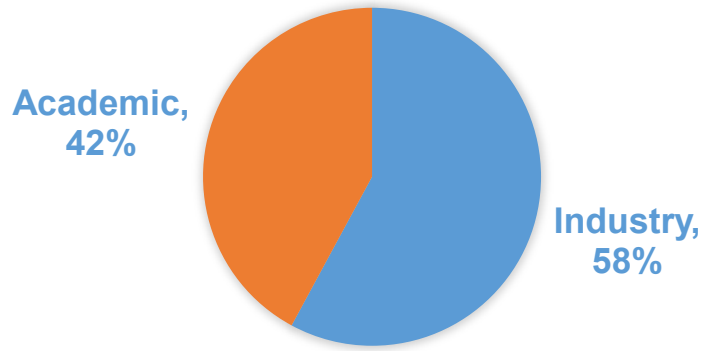
NUMBER OF STUDIES BY TYPE



NUMBER OF TRIALS BY PHASE



NUMBER OF STUDIES BY ORIGIN



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NEW CRC STUDIES

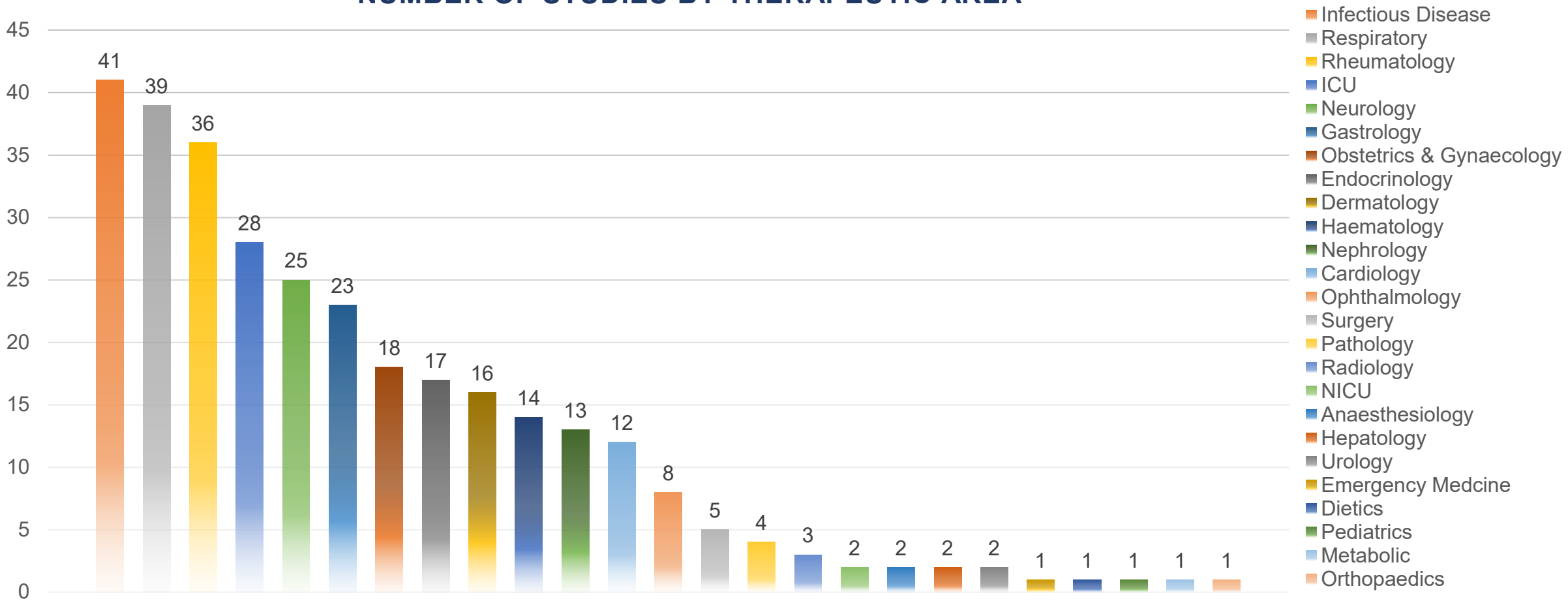
Health Research Board

UCD CLINICAL RESEARCH CENTRE

CRC Study Activity 2022

Health Research Board

NUMBER OF STUDIES BY THERAPEUTIC AREA



UCD CLINICAL RESEARCH CENTRE

HRB – UCD Clinical Trial Networks

- **HRB Infectious Diseases Clinical Trials Network Ireland (ID-CTNI)**
  - ID-CTNI is led by Professor Paddy Mallon, St Vincent's University Hospital and University College Dublin (UCD). The ID-CTNI network is hosted at the UCD Clinical Research Centre and supported by the UCD Centre for Experimental Pathogen Host Research (CEHR).
  - The ID-CTNI network brings together a team with expertise in leading, directing and assisting Infectious Diseases clinical trials and investigations, both investigator and industry led.

- **HRB Rare Disease Clinical Trial Network (RD-CTN)**
  - RD-CTN is led Dr Rachel Crowley and Dr Cormac McCarthy, St Vincent's University Hospital and University College Dublin (UCD).
  - The RD-CTN will allow people with rare disease greater opportunities for participation in the latest research and more access to innovative new therapies that will improve outcomes and transform treatments and care.

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UCD DUBLIN

RDCTN

HRB – UCD Clinical Trial Networks

- **HRB Irish Critical Care Clinical Trials Network – Improving Outcomes After Critical Illness**
  - Is led by Professor Alistair Nichol, St Vincent's University Hospital and University College Dublin (UCD).
  - The ICC-CTN will continue improving the outcomes (survival and recovery) for patients requiring Intensive Care Unit (ICU) treatment in Ireland and building capacity for the conduct of clinical trials in ICU.
    - **Website | https://iccctn.org/**
- **HRB Stroke Clinical Trials Network**
  - The SCTNI is led by Prof Peter Kelly, Mater Misericordiae University Hospital and and University College Dublin (UCD).
  - SCTNI aims to provide Irish patients access to cutting edge new treatments with the potential to prevent strokes, or to improve emergency treatment and recovery after stroke.
    - Website |https://hrb-sctni.ie/

HRB Health Research Board · UCD DUBLIN · Irish Critical Care Clinical Trials Network · SCTNI

CAYA Cancer Cluster

- Programme Management
- Partnerships
- Expanding trial portfolio

MMUH-SVUH-UCD Cancer Cluster

- Integration across sites
- Programme management
- Addressing gaps (phase 1 clinical trials)

OECI Accreditation (SVHG-UCD)

- St Vincent's – UCD
- Programme management
- Expanding research impact

UCD CLINICAL RESEARCH CENTRE

UCD Strategic Theme 3: Building a Healthier World

- CAYA Cancer Cluster
- MMUH-SVUH-UCD Cancer Cluster
- OECI Accreditation SVHG-UCD

- All Ireland Infectious Disease Cohort
- National Irish COVID-19 Biobank (co-host with TCD)
- HRB Infectious Disease Clinical Trials Network

Mission: To compile an expansive, harmonised and integrated biorepository of biological samples and linked sociodemographic and clinical data from participants with COVID-19 and non-infected controls

Host Institutions: TCD and UCD

- Support high quality, impactful research into the causes, progression, diagnostics, treatment and consequences of COVID-19
- Adapt as new knowledge gaps emerge
- Better prepared for future emergencies
- Provide a roadmap for future integration of biobanking for other diseases, e.g. cancer

UCD CLINICAL RESEARCH CENTRE

EPO-TRAUMA

ERYTHROPOIETIN IN TRAUMA

A randomised, double-blind, placebo-controlled trial of erythropoietin alfa vs. placebo in mechanically ventilated critically ill patients following traumatic injury

Co-Chief Investigators: Prof Craig French and Prof Alistair Nichol

Co-Sponsors: Monash University & University College Dublin

Project Managers: Vicki Papanikolaou (ANZ & KSA), Kate Ainscough (EU & Switzerland)

HRB Health Research Board | anzic research centre | MONASH University | Irish Critical Care Clinical Trials Network | UCD DUBLIN | MEDICAL RESEARCH INSTITUTE OF NEW ZEALAND

Traumatic Injury

A Major Public Health Problem

In the year 2000, 5 million people worldwide died from traumatic injuries (WHO, 2002)

3rd

Predicted to become the 3rd leading cause of death and disability by 2030 (WHO, 2000)

~9%

Did not survive after admission to an ICU in Australia and NZ with a trauma diagnosis between 2010 - 2015 (Magee, 2014)

31%

31% of critically ill trauma patients either died or suffered severe disability 6 months after their injury (VSTR)

Rationale

1 STRONG EVIDENCE FOR BENEFIT

- The basic science rationale for EPO's role in tissue protection is extremely strong
- Strong evidence for a potential clinically relevant protective effect in critically ill trauma patients

2 LIMITATIONS OF PREVIOUS RCTS

- Trauma patients were retrospectively or prospectively defined subgroups
- Outcomes of interest were secondary endpoints
- Some were of low quality and did not assess functional outcomes

3 UNCERTAINTY REMAINS AT THE BEDSIDE

Large body of clinical evidence is insufficient to justify routine administration/change in practice

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HRB Health Research Board

EPO-TRAUMA

Aim

To evaluate the effect of epoetin alfa compared to placebo administered to critically ill mechanically ventilated trauma patients on mortality and severe disability at six months

Hypothesis

The administration of epoetin alfa to critically ill trauma patients requiring mechanical ventilation, compared to placebo, reduces mortality and severe disability at six months

Study design

A prospective, multi-centre, double-blind, phase III, randomised controlled trial of 2500 mechanically ventilated ICU patients admitted with a primary trauma diagnosis

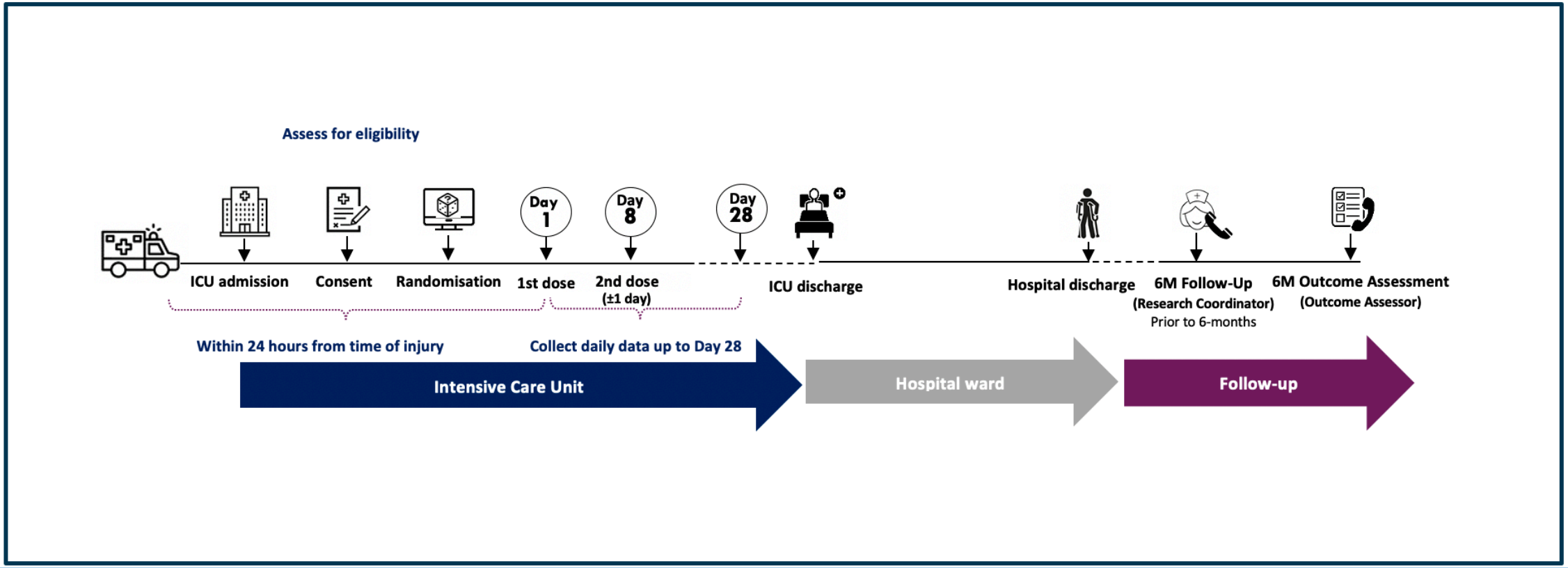
MONASH University

anzic research centre

- France
- Ireland
- Belgium
- Italy
- Germany
- Finland
- Switzerland
- Slovenia
- Kingdom of Saudi Arabia
- Australia
- New Zealand

Participating Countries

Study Flowchart



Study Outcomes

Primary outcome

Combined mortality and disability (defined as a WHODAS 2.0 score ≥ 25%) at six months.

Secondary outcomes

- 6-month Mortality, ICU Mortality, 28-Day Mortality, Hospital Mortality
- Dichotomised GOSE at 6-months (favourable outcome (i.e. GOSE > 4))
- The proportion of patients with composite thrombotic vascular events (DVT, PE, MI, cardiac arrest, CVA) at 6 months

Tertiary outcomes

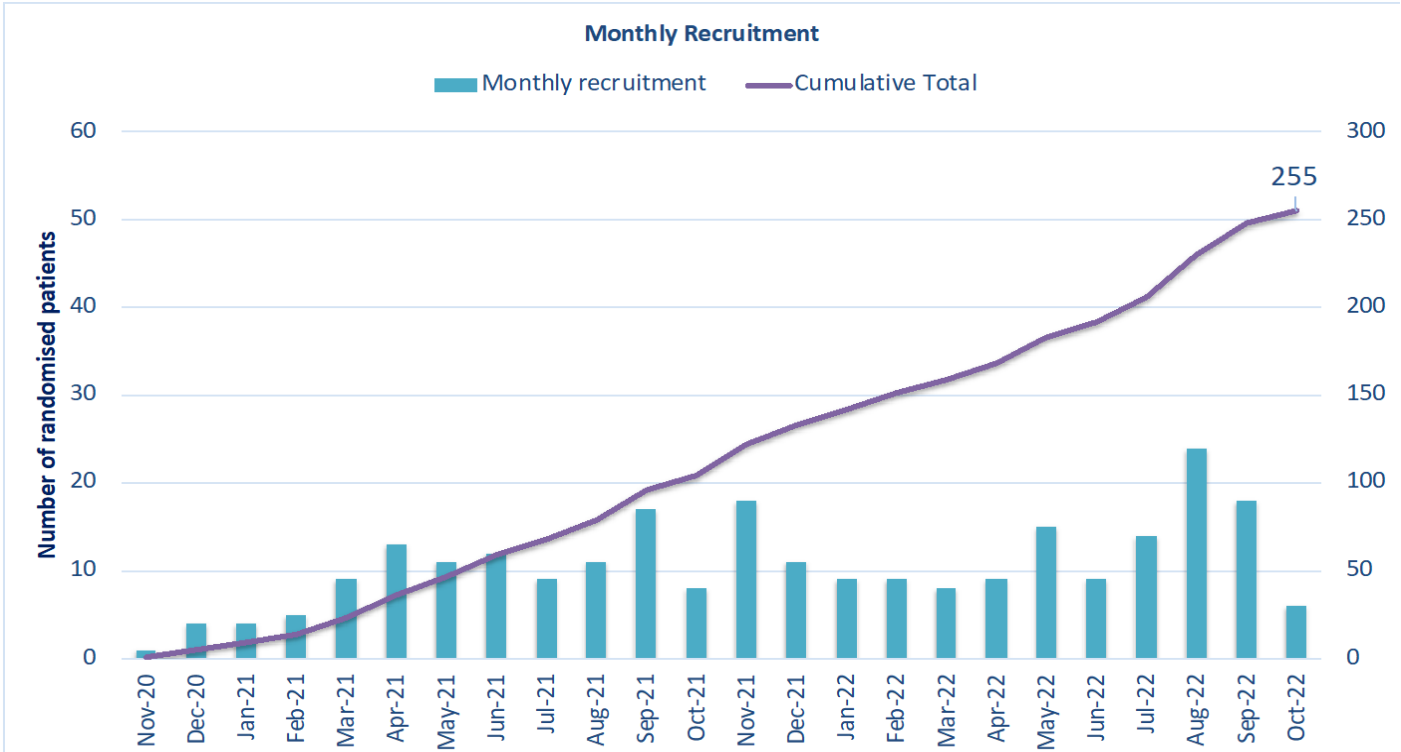
- Total health care costs
- Quality-adjusted life years gained
- Cost per quality-adjusted life year gained

EQ-5D-5L

Progress to date

369/2500 (15%) patients randomised

- 30 active sites:
  - 10 active sites in Europe:
    - 2 active sites in Switzerland
    - 2 active site in Slovenia
    - 3 active sites in Finland
    - 3 active sites in Ireland
  - 20 active sites across Saudi Arabia, Australia & New Zealand
- Approx. 54 international sites planned in total



EPO-TRAUMA Plans for 2023

+ 4 additional EU Countries

- Germany, France, Italy & Belgium:
  - ~ 20 additional sites
    - Germany; 2 confirmed participating sites
    - France; 7 confirmed participating sites
    - Italy; 4 confirmed participating sites
    - Belgium; funding approved; approx. 5 Belgian sites - TBC
- This will bring the total number of EU sites to ~ 30 across 8 countries

If you are an investigator at a trauma centre and would like to get involved or would like more information, please contact the EU project managers.

Coordination & Support

Kate Ainscough, Project Manager (Europe)

Irish Critical Care Clinical Trials Network

University College Dublin (UCD)

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ANZIC Research Centre

Monash University

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Acknowledgements

Management Committee

- A/Prof. Craig French (Co-Chief Investigator)
- Prof. Alistair Nichol (Co-Chief Investigator)
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- Prof. Yaseen Arabi
- Prof. Michael Bailey
- Ms Ann-Marie Baker (Consumer Rep.)
- Ms Deborah Barge (Research Coordinator)
- Prof. Rinaldo Bellomo
- Prof. Jamie Cooper
- Dr. Dashiell Gantner
- Prof Matthias Haenggi
- Dr. Lisa Higgins
- Prof. Carol Hodgson
- Ms Sally Hurford (Project Manager NZ)
- Ms Hannah Keane (Project Manager EU)
- Dr. Colin McArthur
- Ms Vicki Papanikolaou (Project Manager ANZ/KSA)
- Prof. Michael Reade
- Ms Liadain Reid (Project Manager EU) – *on leave*
- Mr Tony Trapani
- Prof. Markus Skrifvars

Funding Partners

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MRF1170001

Health Research Board
DIFA-2018-028

hrc nz
20/366

Endorsements

ANZICS Clinical Trials Group
CTG1617-005

Irish Critical Care Clinical Trials Group

MONASH University

UCD DUBLIN

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Further Information

Trial Registration

- ClinicalTrials.gov identifier (NCT number): NCT04588311
- ANZCTR Registration Number: ACTRN12619001632189p
- EudraCT Number: 2020-003388-24

Study Website

Visit https://www.epotrauma.org/ for up-to-date recruitment and progress

Twitter

Follow us @EPO_Trauma


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