HRB NCTO

International Clinical Trials Day Conference

10th May 2022

"HRB NCTO and ECRIN Update"

Michèle Cunnane, Interim Manager NCTO

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HRB Funded Clinical Research Infrastructure Ireland

HRB Funding Calls 2020/2021:

- Clinical Research Facility/Centres – CRF/Cs
- Clinical Trial Networks – 7 CTN's
- Cancer Trials in Ireland – CTI Network and Cancer Groups
- HRB-Trial Methodology Research Network - TMRN
- National PPI Ignite Network
- **National Clinical Trials Office - NCTO**

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HRB National Clinical Trials Office

Hosted by University College Cork

Co-funded by HRB, EI and UCC

CRF/Cs Directors, co-applicants

Partnership of the CRF/C's

Collaborating with CTN's and Academic Investigator

Supporting both Academic and Commercial Clinical Research

HRB Health Research Board

ENTERPRISE IRELAND where innovation means business

UCC University College Cork, Ireland Coláiste na hOllscoile Corcaigh

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Meet the NCTO Team

Ms Michèle Cunnane
Interim Manager

Dr Ruben Keane
Quality & Regulatory Affairs Manager

Ms Olive O'Driscoll
Clinical Industry Liaison Officer

Mr Niall Hore
ECRIN EuCO

Ms Evelyn Crowley
Data Analyst

Mr Eoghan Cooke
Comms Officer

Ms Jean Foley
Trial Platform Lead

Support provided by UCC:

- Legal Officer
- Executive Assistant
- HR support

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NCTO Strategic Objectives *in summary*

INCREASE

Number of multicentre clinical trials through signposting and promotion

Number of International Sponsors

Number of Academic Multinational Clinical Trials lead by or using Irish trial sites by engaging with ECRIN

Number of MedTech companies conducting Clinical Investigations

IMPROVE

The functionality of CRF/C's by central provision and support of selected services:

(a) National Study Feasibility Programme
(b) CRF Manager System
(c) Mutually agreed, appropriate, quality standards
(d) Pharmacovigilance capabilities
(e) National Budget Template

IDENTIFY

Identify and address systematic barriers, opportunities and developments

- Stakeholder and Management Committee
- CTN PI and Managers Meetings
- Participating in external committee's and working groups

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HRB NCTO Services

NCTO Office:

Signposting

Promotion

Advisory & Consultancy

On-line Services www.NCTO.ie

Study Feasibility

NCTO Network:

Study Start-up

Recruitment Tracking

Regulatory & Ethics

Quality Assurance

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HRB NCTO Working Groups

Host:

Quality

Study Feasibility & Start-up

Budget Costing

MedTech

Pharmacovigilance

Participate:

Clinical Research Subgroup of the Higher Education Research Contracts Subgroup

Public & Patient Involvement

Health Research Data Protection Network

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NCTO Quality Working Group

NCTO Team Lead: Dr Ruben Keane, Quality and Regulatory Affairs Manager
Email: ruben.keane@ucc.ie

- **QWG Annual Workplan 2023 –** Agreed; delivery and implementation work ongoing
- **NCTO QWG meetings** – Quarterly & ongoing communication in between
- **Hot Topics 2023**
  - **Implementation of the Clinical Trial Regulation** - moving existing trials to CTIS + new CT Applications via CTIS
  - **Sharing Inspection Findings and Best Practice**
- **Annual Compliance Meeting** between NCTO QWG and HPRA - October 2022
- NCTO and **NREC meeting –** 1st Meeting occurred in April 2023; Quarterly meetings planned.

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NCTO QWG Mutual Recognition Scheme Update

What is the NCTO Mutual Recognition scheme?

- A programme of work undertaken by the NCTO QWG to develop, agree and implement **minimum standards for quality systems** across the HRB funded Clinical Research Facilities/ Centres in Ireland

- The mutual recognition scheme provides assurance to sponsors/potential sponsors of clinical trials and clinical studies that they can carry out **multicentre trials in Ireland** using sites which have **equivalent quality standards** which meet international best practice requirements

- Underwent major overhaul in 2021/2022. New iteration is based on **UK CTU registration process**

- 3 CRF/Cs have completed the process and been awarded letter of MR .
  - 1 in process
  - 1 CRF/C decided to postpone MR as they are merging QMS from 3 existing institutions
  - 1 non HRB funded CRF/C exploring option of voluntarily undergoing the MR

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NCTO Pharmacovigilance Working Group

NCTO Team Lead: Dr Ruben Keane, Quality and Regulatory Affairs Manager
Email: ruben.keane@ucc.ie

- PvWG annual workplan agreed for 2023 with delivery and implementation work ongoing

- **Hot Topics**:
  - Device Vigilance and MDR/IVDR implementation

- Annual **PV activity report** for 2022 completed and submitted to HRB.

NCTO QWG and PvWG Engagement

NCTO QWG and PvWG are represented on:

- UK CRF Network Quality working group - **Mandy Jackson, RCSI CRC & Emma Deenihan, CRF-University of Galway**
- UK Clinical Research Coordination Registration committee - **Ruben Keane, NCTO** - external QA expert
- UK CRF Network Training working group **– Deirdre Hyland RCSI CRC**
- HSE REC Reform Working group - **Ruben Keane, NCTO**
- EU Accelerated Clinical Trials (ACT) Initiative – ***Shane Feeney CRF-SJH**
- Health Research Data Protection Network (HRDPN) - **Ruben Keane, NCTO**
- ECRIN Pv Working group **– Brenda Molloy UCD** nominated , however the ECRIN QWG and PvWG are inactive at present

*SF has just taken up a secondment to the **European Medicines Agency** in Amsterdam

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National Study Feasibility Programme

NCTO Team Lead: Ms Michèle Cunnane

NCTO Trial Platform Lead: Ms Jean Foley

- National Programme that covers **All Therapeutic Areas**
- HRB NCTO Trial Platform Lead works **in conjugation** with the Feasibility Coordinators in the **CRF/Cs, CTNs** etc.
- Oncology - **Collaboration** with **Cancer Trials Ireland**
- **Master Confidential Disclosure Agreement** (mCDA) are established with Applicant
- **CONTACT INFO**: trials-feasibility@ucc.ie

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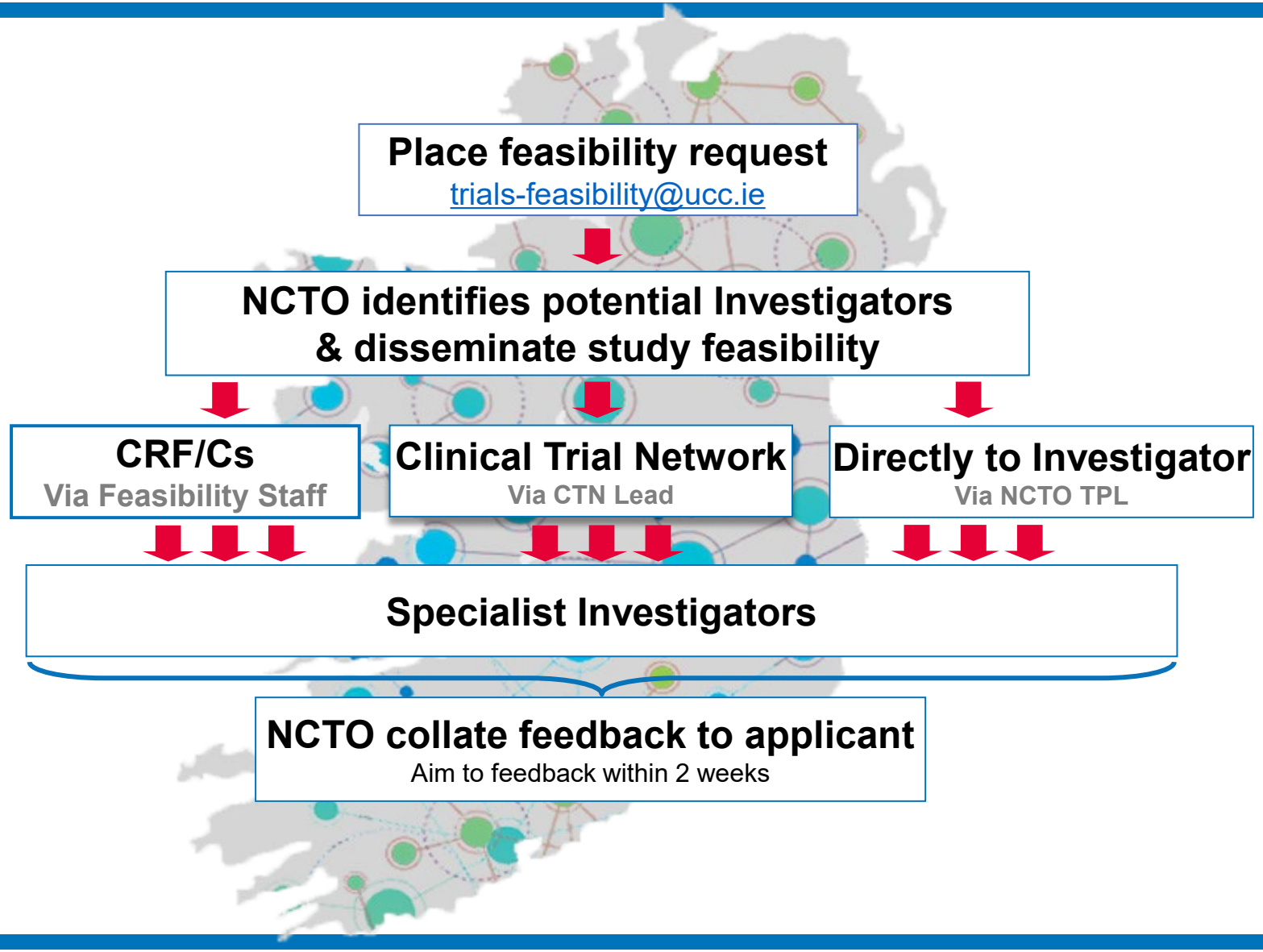
HRB NCTO National Study Feasibility Programme



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NCTO Study Feasibility & Start-Up Working Group

NCTO Team Lead: Ms Michèle Cunnane, NCTO Trial Platform Lead

- Annual workplan agreed with delivery and implementation work ongoing

Investigator & Site Selection

Study Progress Monitoring & Reporting

Study Start-Up & First Patient First Visit Timelines

Promotion & Membership of HRB NCTO

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NCTO Budget Working Group

NCTO Team Lead: Ms Michèle Cunnane, NCTO Trial Platform Lead

- Annual workplan agreed with delivery and implementation work planned for 2023

Clinical Trial Costs for Standardisation

Phase 1 Site Costs Budget Template

Phase 2 Templates - sponsor services

Site Forum

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CRFManager

NCTO Team Lead: Evelyn Crowley **Email:** crf-manager@ucc.ie

CRFManager®

- CRF Manager is a web-based resource management system which facilitates the administration of clinical research studies and research facility management.
- Developed by the University of Edinburgh in 2005, it is widely used throughout the UK & Ireland.
- Currently, CRF Manager is utilised by 7 large University-affiliated Clinical Research Facilities across Ireland.
- The system enables the research facilities to organise and manage staffing and participant scheduling, record study data, track resource utilisation and allocation and report on study activity.

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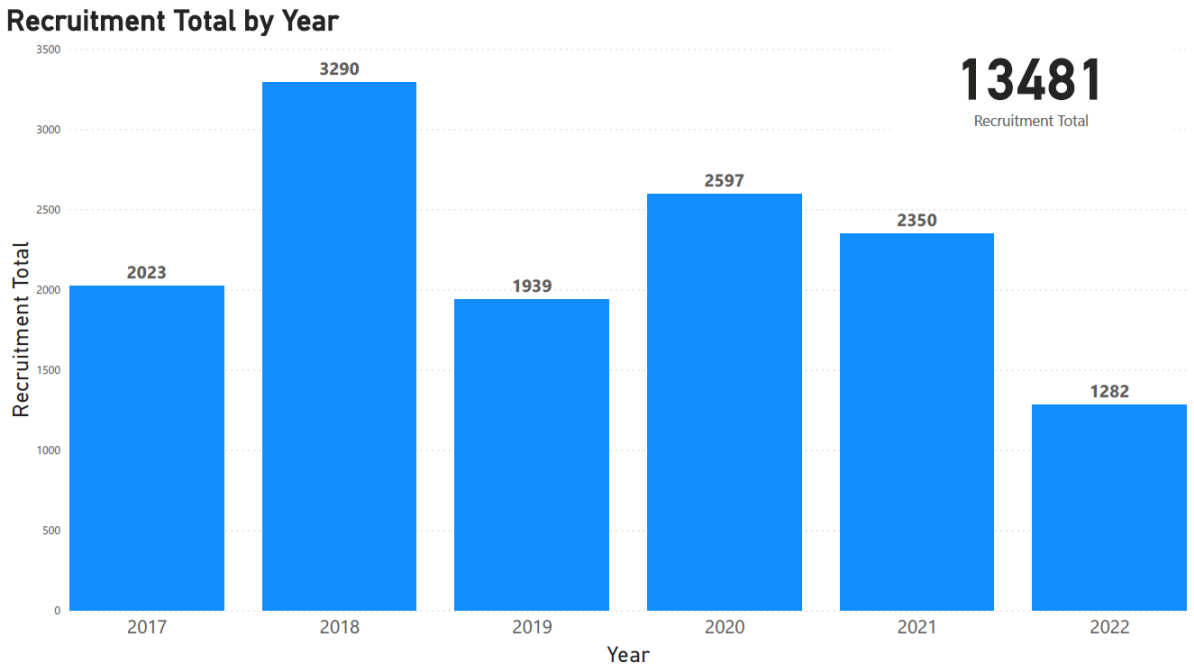
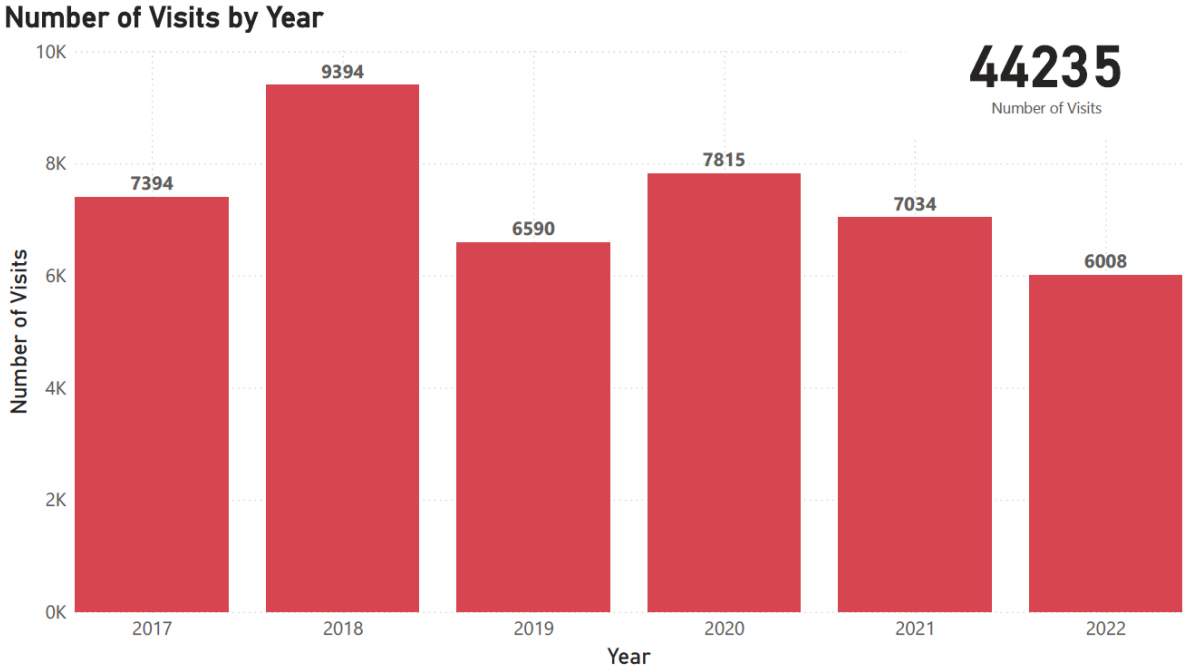
CRFManager





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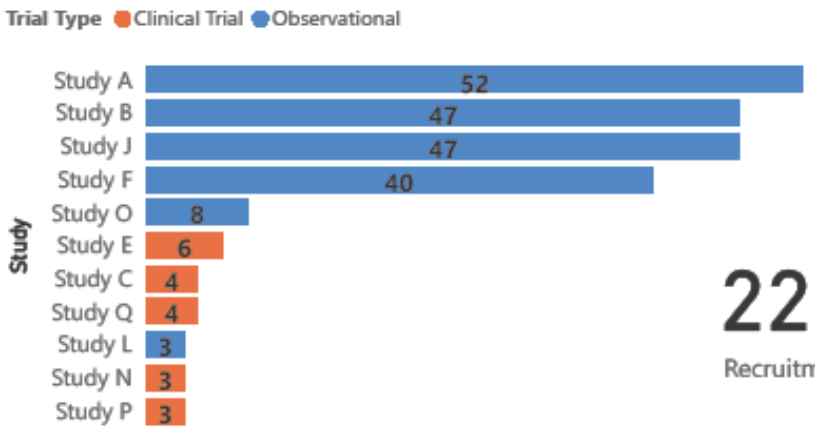
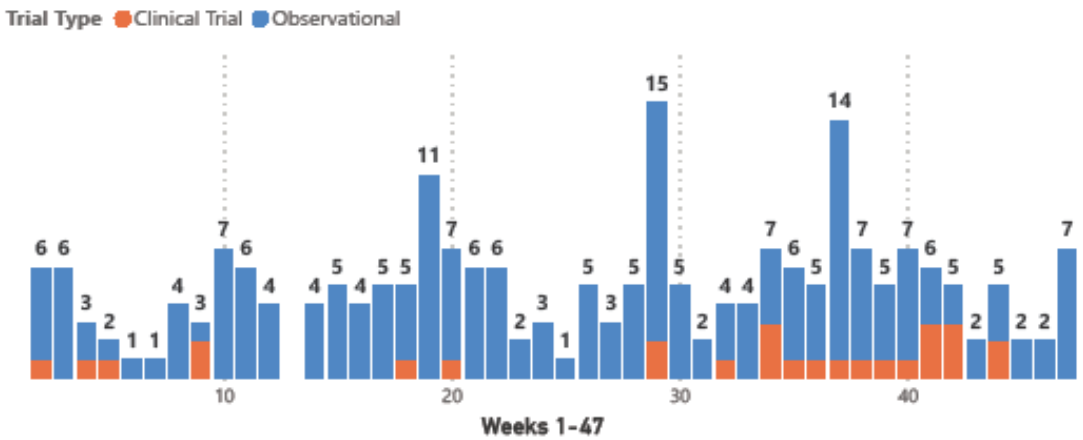
Patient Recruitment and Visits Weeks 1-47 2022

Number of Recruited Patients by Study Weeks 1-47

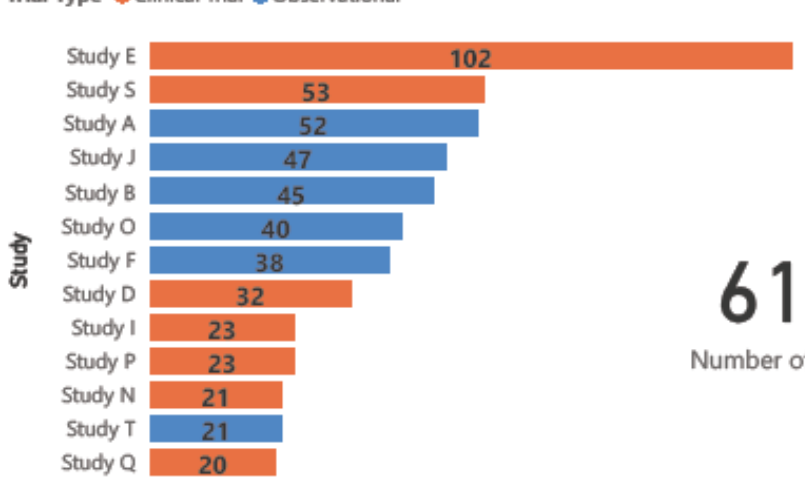


225
Recruitment

Number of Recruited Patients by Week

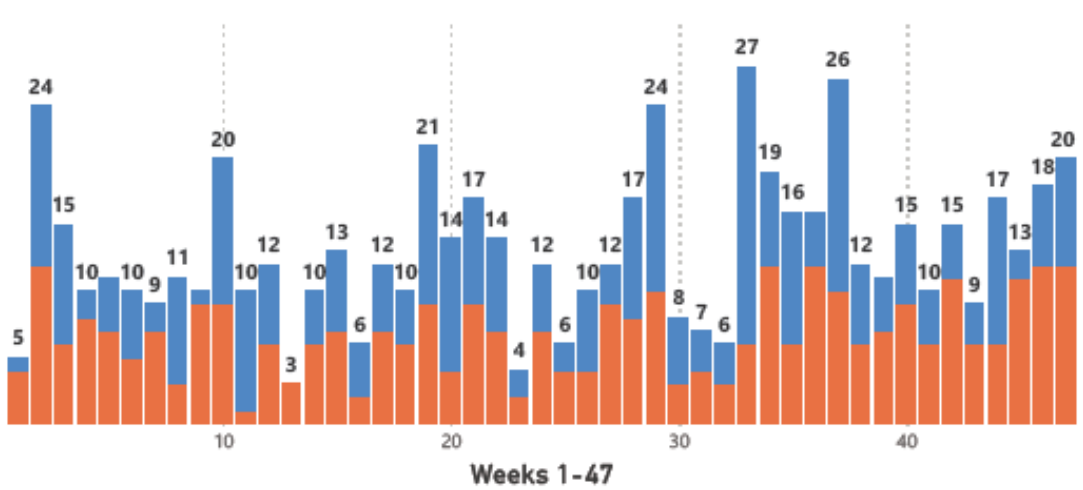


Number of Patient Visits by Study Weeks 1-47



617
Number of Visits

Number of Patient Visits by Week



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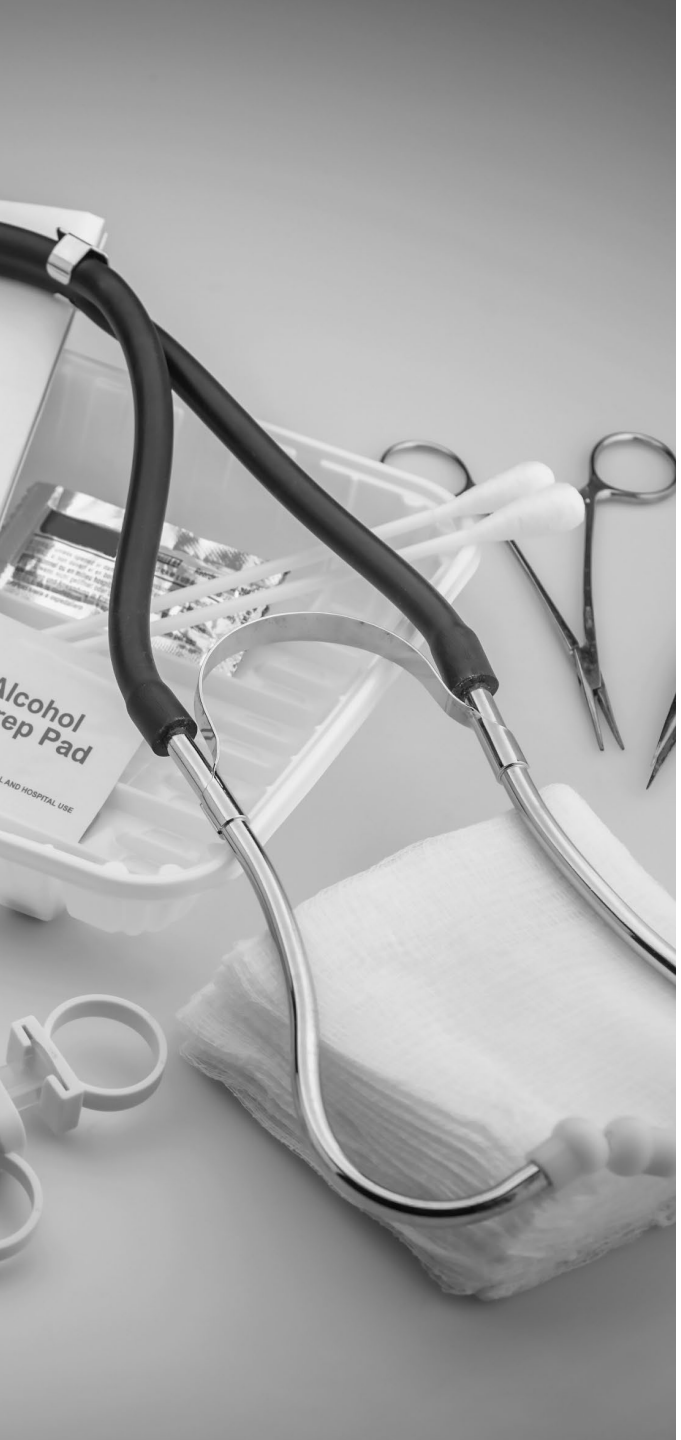

NCTO CILO: Clinical Industry Liaison Officer - MedTech

NCTO CILO: Ms Olive O'Driscoll, email: OliveOdriscoll@ucc.ie

Enterprise Ireland funded role to support MedTech Clinical Research

- Provide **Education and Outreach** services
- Identify and **evaluate strategic capabilities** of infrastructure in Ireland
- **Advise and signpost** support on regulatory requirements
- Support infrastructure for **international market access**
- Work closely with other MedTech supporting research organisations e.g. **Health Innovation Hub Ireland**, HIHI
- Provide **policy and benchmarking advice** to key stakeholders

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NCTO CILO Plan

- **Understand Needs**
  - MedTech company/entrepreneur engagements
  - CRF areas of expertise
  - HIHI
  - Growth opportunities
- **Connect with Key Stakeholders**
  - HPRA, NREC-MD, Enterprise Ireland, Irish MedTech Association etc
- **Education and Outreach**
  - Toolkit
  - MDR and IVDR
- **MedTech Working Group**
- **Policy Input & Change**
- **Increase Clinical Investigations in Ireland**

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European Clinical Research Infrastructure Network

ECRIN's mission is to support the conduct of multinational clinical trials across Europe

- Distributed research infrastructure | 12 countries | 350 million EU citizens | 120 Clinical Trial Units | 70 clinical trials supported | 40 International Infrastructure projects
- ISO 9001:2015 certified for its core services

ECRIN activities

- **Coordinated support to multinational trial management:**
  - Collaboration on trial planning and design
  - Operational trial management services
- **Development of tools, methods and partnerships**

ECRIN Member Countries
ECRIN Observer Countries

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European Clinical Research Infrastructure Network

- **HRB NCTO - National Scientific Partner** for Ireland
- Host **ECRIN European Correspondent** for Ireland
- Access to ECRIN supported **EU funded Clinical Trials and Infrastructure Development projects**
- Access to **ECRIN services** in Europe:
  - proposal development
  - study preparation
  - study implementation

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Irish Involvement in ECRIN/EU projects

- **Irish CRF/C is managing clinical sites in the UK**

ImmunAID necessity RLink macustar

- **Ireland is participating country with clinical sites**

TREOCAPA a c4c study TENSION DISCOVERY IDEA FAST

EU-COVAT-1 AGED

VACCELERATE

- **Trials with an Irish Sponsor**

EU-COVAT-2 BOOSTAVAC

VACCELERATE

ETAPA Trial

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ICTD International Clinical Trials Day
23 May 2023

ecrin

Decentralised Clinical Trials

Challenges & opportunities

23 May 2023

REGISTER NOW

Join us in Warsaw or online

#ICTD2023

Register to attend at https://ecrin.org/ictd-2023

www.ecrin.org

MEDICAL RESEARCH AGENCY

POLCRIN
POLISH CLINICAL RESEARCH INFRASTRUCTURE NETWORK

HRB NCTO Website

www.ncto.ie

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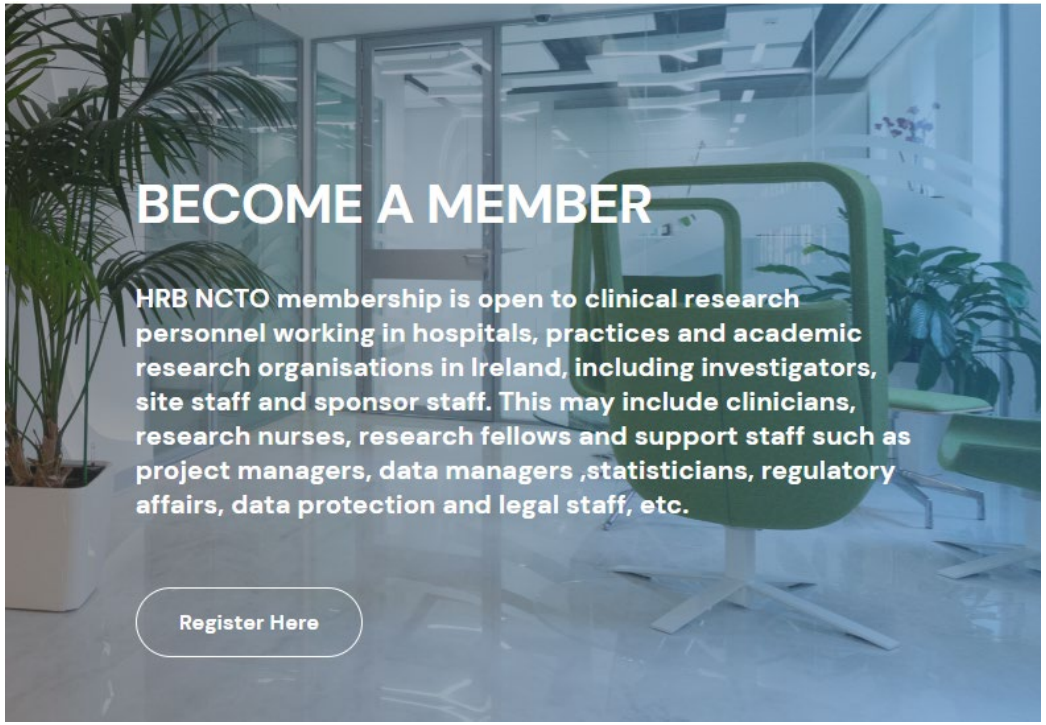
HRB NCTO Membership



Category 1. HRB NCTO Standard Membership

Become a HRB NCTO member to connect with the HRB NCTO national integrated clinical research network. On application, you will be asked to provide your contact information so you can be kept informed of HRB NCTO activities and you will receive HRB NCTO newsletters periodically. Members can also avail of our services, including a range of advisory activities and supports. Your curriculum vitae is not required on application.

Category 2. HRB NCTO Investigator Membership

Investigator members get all of the benefits of a HRB NCTO standard member and are also eligible to participate in the HRB NCTO National Study Feasibility Programme. Investigator members will be informed of the latest research opportunities as they arise and can complete study feasibility assessments for studies of interest to them. On application, you will be asked to provide your contact information, your area(s) of clinical interest and your curriculum vitae, which will allow us to confirm your eligibility and quickly identify research of potential interest to you.

For more information: www.ncto.ie/hrb-ncto-membership/

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ICTD Conference Support

We would like to thank the HRB for its continued support of NCTO and in relation to today's event.

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ICTD Conference Support

We would like to thank RCSI for their support and hosting of our ICTD Conference today.

RCSI UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

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ICTD Conference Support

We would like to thank the following companies for their support for this conference.

This support is not linked in any way with product promotion and there was no company involvement in development of the agenda for this meeting.

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Thank you

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