

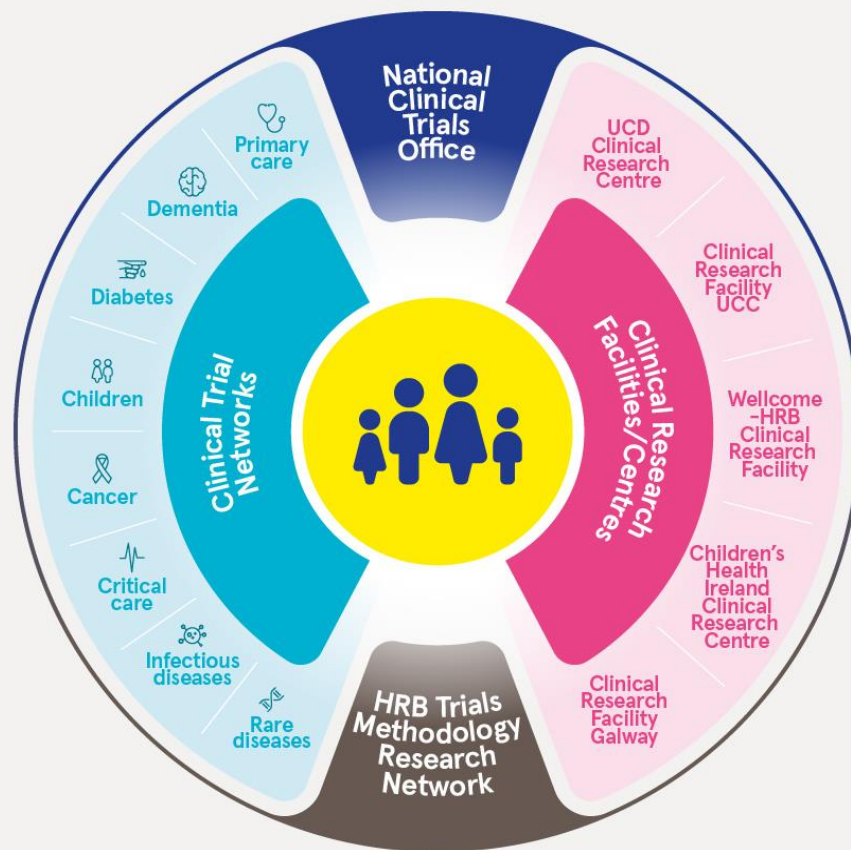


**New Horizons:
Navigating The Road Ahead**
Thursday 10th November 2022

HRB-NCTO update and comments

**Dr Fionnuala Keane, Manager
National Clinical Trials Office, Ireland**

HRB Funded Clinical Research Infrastructure Ireland



HRB Health
Research
Board

HRB Clinical Trials Infrastructure

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



Meet the NCTO Team



**Dr Fionnuala
Keane**
NCTO Manager



Dr Ruben Keane
Quality &
Regulatory Affairs
Manager



**Ms Michèle
Cunnane**
Trial Platform
Lead



**Ms Olive
O'Driscoll**
Clinical Industry
Liaison Officer



Mr Niall Hore
ECRIN EuCO



Ms Evelyn Crowley
Data Analyst



Mr Eoghan Cooke
Comms Officer

Support provided by UCC:

- Legal Officer
- Executive Assistant
- HR support

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 through **stakeholder engagement**

HRB NCTO Services

NCTO Office:



**Signposting &
Promotion**



**Advisory
& Consultancy**
*IMP, MedTech,
Academic, Commercial*



**Study
Feasibility**



**CRF Manager
Support**



**National
Scientific
Partner**



**Useful
Resources**
www.NCTO.ie

NCTO Network:



Study Start-up



**Recruitment
Tracking**



**Quality
Assurance**
*Mutual Recognition of Quality
Management Systems*



**Regulatory
& Ethics**



Health Research Board
NCTO
National Clinical Trials Office

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**



**HSE Research
Governance
Implementation**



**Health Research
Data Protection
Network**



Health Research Board
NCTO
National Clinical Trials Office



NCTO Strategic Objectives – *NCTO Activity update 2022*



INCREASE



IMPROVE



IDENTIFY



Health Research Board
NCTO
National Clinical Trials Office

NCTO activity update 2022

- **Business Development:**
 - **18 companies have submitted feasibilities to date in 2022**
 - **Recent feedback from Companies – key issues:** DPIA's, contract sign off, access to scanning services for trials, pharmacy agreements
- **ECRIN Activities:**
 - **ECRIN studies with Irish participation clinical sites**
 - 4 trials with Ireland as a participating country with clinical sites
 - 4 trials with an Irish CRF managing clinical sites in the UK
 - 2 Trials with Irish Sponsor: BOOSTAVAC and ETAPA (both Sponsored by UCD)
 - **ECRIN Data Centre Certification Programme, Independent Certification Board (ICB): Padmaja Javkar from CRFG** approved by ECRIN to join this board
 - NCTO participating in **ECRIN Performance Task Force**
- **CILO** role:
 - **17 Companies/clients** supported to date since appointment in April 2022



INCREASE

NCTO activity update 2022

- **Study Feasibility Programme**, service being provided for oncology and non-oncology feasibilities; 2022 YTD – **Total 67 -Target for year 35; 24 Oncology & 43 Non Oncology** feasibilities
- **CRF Manager Support** – Ongoing – **155 queries** dealt with Jan to June 2022
- **Quality Working Group**, Mutual Recognition Scheme for Quality Management Systems – **full revision of programme completed** – currently being rollout across CRF/C's
- **HPRA Compliance meeting scheduled for 24 Nov 2022** – CRF/C's QRAMS and NCTO Team members attending “in person” meeting in the HPRA
- **Working Group Meetings** held and activities ongoing:
 - Budget and Costing – 12th July
 - PhV – 12th Oct
 - QWG – 12th Sept
 - Study Feasibility – 6th Sept



IMPROVE

NCTO activity update 2022

- **Co-applicant Committee meetings**
 - Every 2 months
- **Stakeholder and Management Committee**
 - 4 meetings per year
 - **Key topics discussed:**
 - IPHA Standard Clinical Trial Agreement
 - Data Protection
 - Standard DPIA template
 - Overview of the “HRDPN Practical Guide on Data Protection for Health Researchers” (available on <https://ncto.ie/useful-resources/>)
 - HSE National R&D update
- **Clinical Trial Network PI’s and Managers meeting**
 - 4 meetings per year
 - Last meeting held 21 September in collaboration with the **TMRN**
- **International Advisory Committee**
 - 1st meeting 9th Nov



IDENTIFY

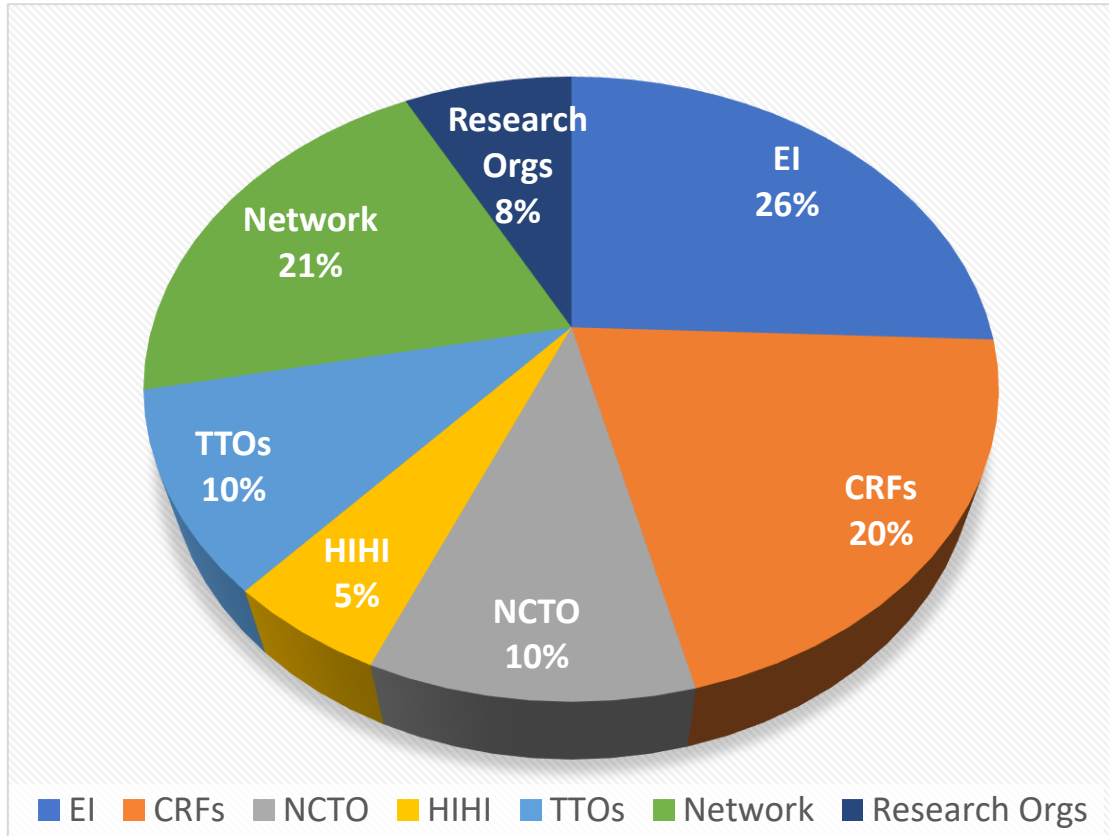
Clinical Industry Liaison Officer - MedTech (CILO)

- Increase high quality clinical investigations in Ireland:
 - Understand **needs** of Sponsors, Stakeholders and CRFs
 - Identify and evaluate strategic capabilities of **infrastructure** in Ireland
 - Advise and **signpost** e.g. HPRA, NREC, MDR
 - Work closely with **key med tech research** organisations e.g. HIHI
 - **Education** and outreach e.g. toolkit
 - **Med tech working group** – 1st meeting 8th Sept
 - **Policy and benchmarking** advice

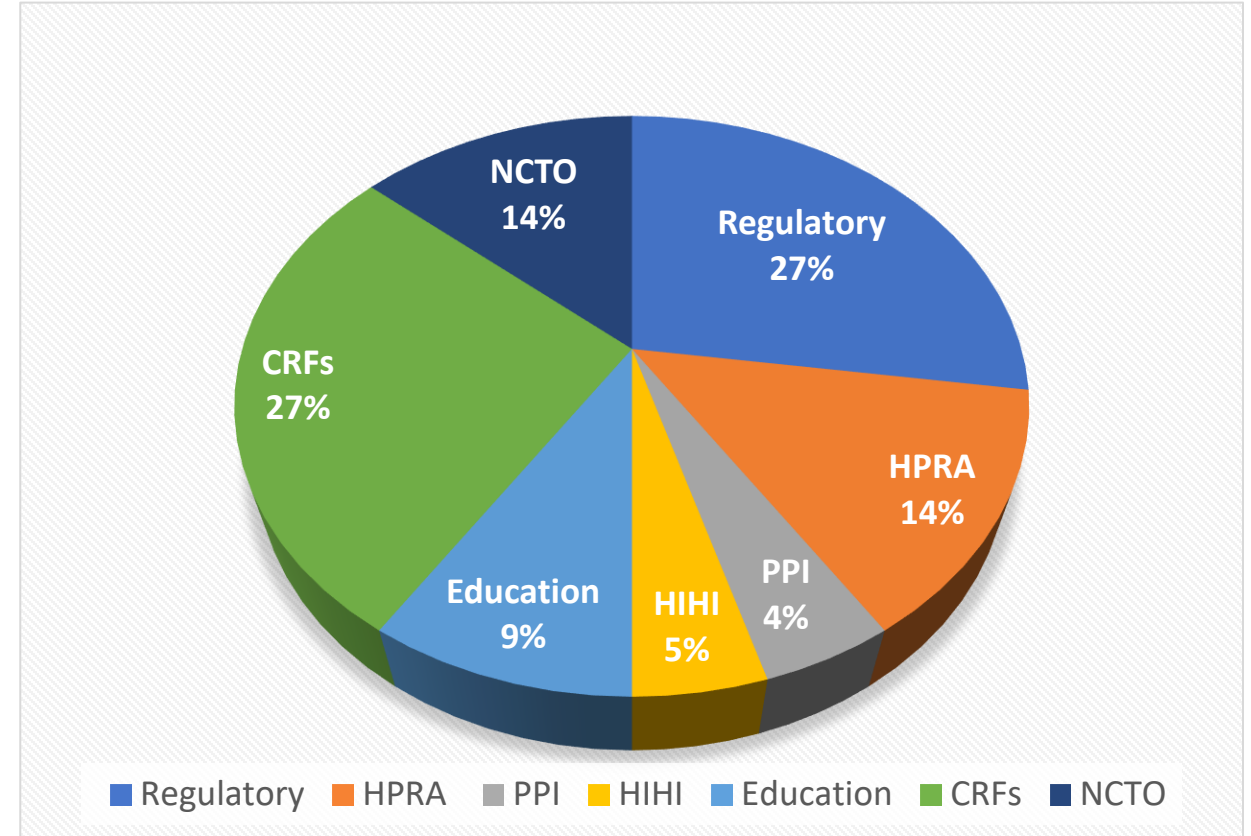


CILO ENGAGEMENTS

CLIENTS REFERRED TO CILO BY



CILO SIGNPOSTING/ADVICE



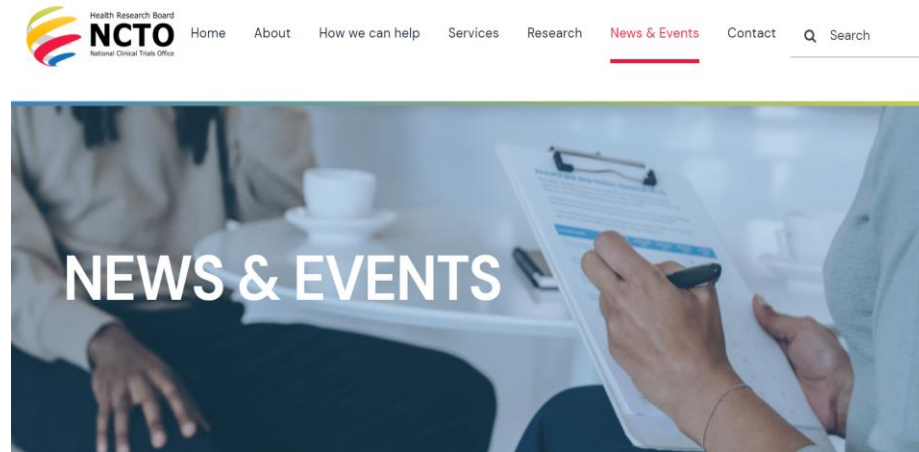


New NCTO Website!

Launched Oct 27th

www.ncto.ie

Feedback welcome!!



SAVE THE DATE

NCTO End Of Year Meeting

- **7th December:** from 10am-1pm, via Zoom
 - NCTO update and Working Group review
 - Clinical Trial presentation from each CRF/C
 - Meeting open to all NCTO Working Group members and those working in the CRF/C's





Thank you

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www.ncto.ie