



Health Research Board

NCTO

National Clinical Trials Office

Dr Fionnuala Keane, Manager NCTO

HRB National Clinical Trials Office



- Hosted by University College Cork
- Co-funded by HRB, EI and UCC
- Prof Joe Eustace, Director & PI
- 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

NCTO Strategic Objectives *in summary:*

1. Increase the number of **multicentre clinical trials**
2. Increase the number of **International Sponsors**
3. Improve the functionality of CRF/C's by **central provision** of supports and **services** such as
 1. **National Study Feasibility Programme**
 2. **CRF Manager System**
 3. **Mutually agreed, appropriate, minimal quality standards**
 4. **Pharmacovigilance capabilities**
 5. **National Budget Template**
4. Identify and **address systematic barriers to clinical research**
5. Act as the National Scientific partner to **ECRIN**
6. Increase number of **MedTech companies** conducting **Clinical Investigations**

HRB NCTO Services and Activities



Signposting



Promotion



**Advisory
& Consultancy**



**On-line
Services**



**Study
Feasibility**



**Study
Start-up**



**Recruitment
Tracking**



**Regulatory
& Ethics**



**Audit &
Monitoring**



**Quality
Assurance**

HRB NCTO Working Groups

Leading:



**Quality
Working Group**



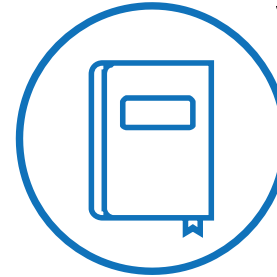
**Study Feasibility
& Start-up
Working Group**



**Budget Costing
Working Group**



**MedTech Working
Group**



**Pharmacovigilance
Working Group**

Participating in:



**Legal Working
Group**

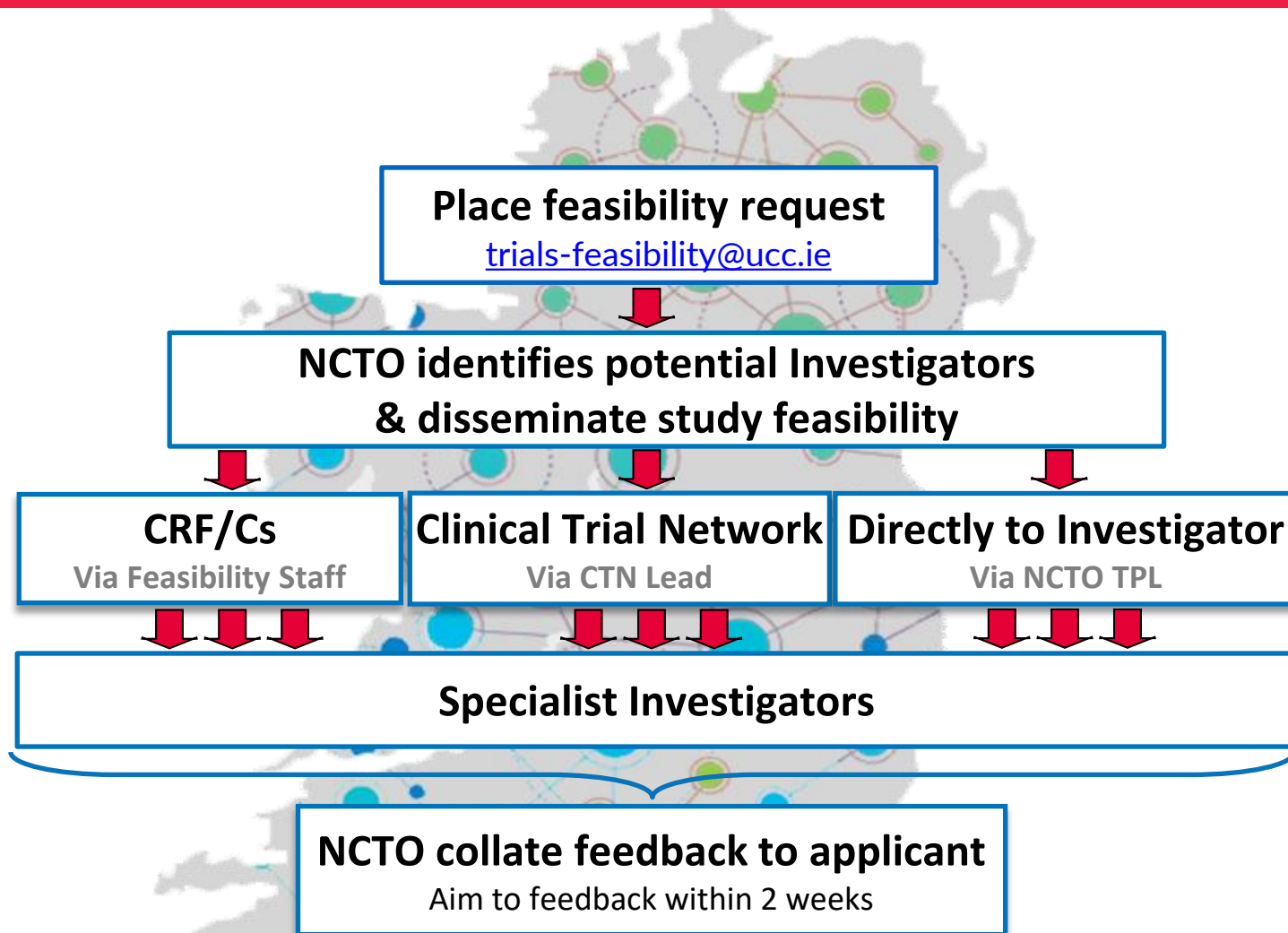


**Public & Patient
Involvement
Working Group**



**Health Research
Data Protection
Network**

HRB NCTO National Study Feasibility Programme



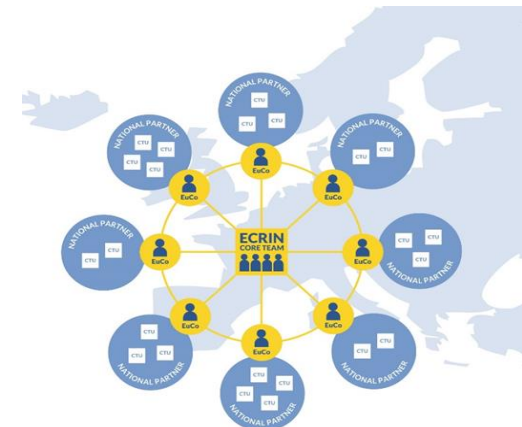
CILO: Clinical Industry Liaison Officer - MedTech

The Aim of the CILO role is to:

- Provide **Education and Outreach** services to researchers, start-ups and established companies in the Medical Technology sector
- Identify and **evaluate strategic capabilities** of clinical infrastructure for Medical Technology investigations in Ireland
- **Advise and signpost** support to Irish researchers, start-up and established companies on regulatory requirements
- Support infrastructure for **international market access** in the Medical Technology sectors
- Work closely with other MedTech supporting research organisations such as the **Health Innovation Hub Ireland, HHI**
- Provide **policy and benchmarking advice** to key clinical research stakeholders and industry stakeholders

European Clinical Research Infrastructure Network

- NCTO Network is the National Scientific Partner for Ireland
- NCTO hosts ECRIN European Correspondents for Ireland
- Ireland can participate in EU funded Clinical Trials and Infrastructure Development Projects through ECRIN
- Irish researchers can benefit from a range of ECRIN services for multinational clinical research such as:
 - proposal development
 - study preparation
 - study implementation



Meet the NCTO Team



Prof Joe Eustace,
PI and Director



Dr Ruben Keane,
Quality and
Regulatory Affairs
Manager



**Dr Stephen
Heaphy,**
Data Scientist



**Ms Michele
Cunnane,**
Trial Platform Lead



**Dr Fionnuala
Keane,**
NCTO Manager

Support provided by UCC:

- Legal Officer
- Executive Assistant
- HR support

Posts yet to be appointed:

- Clinical Industry Liaison Officer
- ECRIN European Correspondent



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Thank you

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