



HRB NCTO Newsletter

We are delighted to let you know that the HRB NCTO will host an all day, online event to celebrate **International Clinical Trials Day (ICTD)** on May 12th, 2022.

This year's event will include of a number of guest speakers in the morning focusing on clinical research in Ireland during the Covid 19 Pandemic and the changing clinical research environment of the present time.

You will also hear from the HRB funded Clinical Trial Networks and PPI Ignite and you will receive a status report on the development of the HRB NCTO.

We will have a solution focused expert panel session in the afternoon looking at the challenges in the Irish clinical research system today and how we can work to resolve them.

Registration will open in April but for now please save the date for the NCTO ICTD event on May 12th 2022!



CLINICAL TRIAL REGULATION 536/2014 - TWO MONTHS ON



CTR came into effect on 31 January 2022. The biggest change in the way in which Clinical trials are approved and managed in over 20 years slipped into place with little fanfare. Two months on where are we and what have we learned?

- Many sponsors are taking advantage of the transition period have not moved existing trials over to the new system.
- As of 18 March 2022, fourteen (14) new CT applications had been submitted via CTIS and 221 CT applications were in draft. Applications submitted were from both academic and commercial sponsors.
- CTIS ability to deal with platform trials is limited. New 'arms' of a platform trial have to be entered as a 'new' trial and get a new EudraCT number.
- In keeping with the aim of increased transparency a Clinical trials website has been launched [Clinical Trials in the European Union - EMA](#) .This interface provides a simple tool which can be used by the public, researchers etc. to search for clinical trials.
- In February NREC indicated that it had received a very high volume of substantial amendments. [Status of assessment of clinical trial substantial amendments - NREC](#)

Building on previous collaboration, NUI Galway, the Royal College of Surgeons in Ireland (RCSI), and the Irish College of General Practitioners established the HRB Primary Care CTNI in 2015. Recently refunded by the Health Research Board through to 2026, the vision of the network is to improve individual patient health and health care through the design, conduct and dissemination of high quality, internationally recognised, randomised trials in Irish primary care, which address important and common problems.

Primary care, often provided by a local GP, is the first port of call for most patients when they are sick. More than 20 million GP consultations take place in Ireland each year. 90% of all health problems can be addressed by GPs and primary care services, so it is vital that GPs and other healthcare professionals have firm evidence on which to make informed decisions about which medication or treatment is right for each patient.

The Primary Care CTNI is led by Director Professor Andrew Murphy (Discipline of General Practice, NUI Galway), and Co-Director Professor Susan Smith (Discipline of Public Health and Primary Care, Trinity College Dublin), both also practicing GPs. They are supported by Network Manager Dr Patrick Murphy, Postdoctoral Researcher Ms Laura O'Connor, and Administrator Ms Breda Kelleher who manage day to day activities, lead research, education and training, and facilitate patient and public involvement from the network base in NUI Galway. The core team also maintains relationships with the wider team of primary care practices and individual healthcare professionals, research groups and researchers, and primary care patients and members of the public who make up the network.

A key function of the HRB Primary Care CTNI is to support the many primary care healthcare professionals and practices in Ireland interested in research to take part in clinical trials. More than 170 primary care providers are currently linked into the Primary Care CTNI network of practices, who benefit from the training and development supports on offer as well as being the first to hear about relevant high-quality research led by the network or its collaborators. To date, the Primary Care CTNI has supported more than 30 clinical studies, recruited almost 4,000 patients, leveraged funds of over €19,000,000, and published in the New England Journal of Medicine, the Lancet, and the British Medical Journal.

Over the next 5 years, the Primary Care CTNI aims to continue supporting the creation of high-quality clinical evidence that will improve patient outcomes in Irish primary care through the realisation of 4 objectives:

Objective 1: To maximise the successful delivery of primary care trials in Ireland

Objective 2: To continue to build capacity for world-class clinical trials in Irish primary care

Objective 3: To develop an agenda for Irish primary care clinical trials research

Objective 4: To enhance PPI in primary care research in Ireland by continuing to grow the capacity of the Primary Care CTNI PPI group

<https://primarycaretrials.ie/> info@primarycaretrials.ie, [@pmrycaretrials1](https://twitter.com/pmrycaretrials1)

GENERAL INFORMATION

General Enquiries: ncto@ucc.ie

Feasibility Programme: trials-feasibility@ucc.ie

- ❖ To promote an event or advertise a post/job, email ncto@ucc.ie and we will post on our website
- ❖ Sign up to our mailing list by emailing ncto@ucc.ie
- ❖ Opt out on receiving this newsletter by emailing ncto@ucc.ie