Clinical Trial Notification (CTN)

What is a CTN?

The Therapeutic Goods Administration (TGA) administers two pathways for goods supplied for clinical trials: -

- The Clinical Trials Notification (CTN) and
- Clinical Trials Approval (CTA) schemes.

These provide an avenue through which 'unapproved' therapeutic goods may be lawfully supplied for experimental purposes in humans. Examples include new pharmaceutical drugs or medical devices used in First in Human clinical trials, drugs or devices being repurposed for a different pathology and are therefore used ‘off label’, software designed for clinical interpretation and patient management.

CTN or CTA?

The CTN is a notification only process which requires the completion of an on-line notification form and payment of the required fee, prior to starting to use an “unapproved” therapeutic good, in a clinical trial situation.

The CTA is an approval process using paper-based, postal submission of two forms with supporting preclinical or clinical data, seeking approval to supply “unapproved” therapeutic goods for a clinical trial.

Who is responsible for the CTN?

The Australian clinical trial sponsor is responsible for submitting the CTN or CTA.

The sponsor of a trial can be an individual, company, institution, or clinical research organisation (CRO) which takes on the overall responsibility for the conduct (initiation, management, and/or financing) of a clinical trial. The sponsor of the trial must be a legal Australian entity. An overseas company, person or entity, for the purpose of the Australian legislation, is not the 'sponsor' of the trial in Australia.

Clinical Trial Notification details

Royal Brisbane and Women’s Hospital

Approving authority	Metro North Hospital and Health Service
Name	Professor Michael O’Sullivan
Position	Director of Research and Implementation, Royal Brisbane and Women’s Hospital
Phone number	07 3647 9550
Email	MetroNorthResearch-RGO@health.qld.gov.au

All other sites (TPCH, Redcliffe, Caboolture, STARS, Mental Health)

Approving authority	**Metro North Hospital and Health Service**
Name	Executive Director *(enter the name of the Executive Director)*
Position	Executive Director, *(enter the name of the facility)*
Phone number	07 3647 9550
Email	MetroNorthResearch-RGO@health.qld.gov.au