Australian Teletrial Program
Access to clinical trials, closer to home

Australian Teletrial Program

Sponsor Information Pack

Version 1.2 December 05 2023

This pack includes:

- Teletrials explanation and how to use the model
- Sponsor Guidance & Checklist
- Study Protocol Guidance
- Participant Information Sheet and Consent Form Tools
- Regional Clinical Trial Coordinating Centre Teams
- Other resources and information

Australian Teletrial Model

Primary site

- Specialists
- Clinical trial coordinators
- Specialist pharmacy, nursing and allied health clinicians
- Administration support officers

Teletrial Cluster

Patients are consented, recruited and managed at satellite sites in partnership between clinicians from satellite and primary sites.

Satellite site

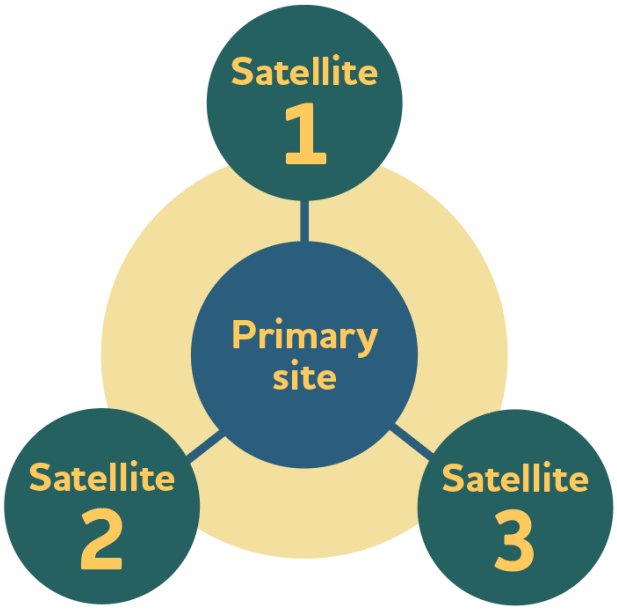
- Patients and families
- Medical officers
- Nursing, pharmacy and allied health clinicians
- With/without trial coordinators

Sabesan & Zalcberg. EJCC, 2016

A teletrial is a group of clinical trial sites that work together to conduct a clinical trial under the supervision of a Primary Site and its Principal Investigator.

Through telecommunication between the Primary Site and Satellite Site/s, the model enables the delivery of aspects of a clinical trial closer to home for patients, particularly in regional, rural, and remote locations. A Principal Investigator supervises Associate Investigator/s to conduct a clinical trial at a Satellite Site, which is geographically distant from the Principal Investigator's Primary Site.

The Principal Investigator remains responsible for the trial and any satellite sites that comprise the cluster. A cluster is a group of two or more sites undertaking the same study.



How to use the model

Teletrial Suitability

The Sponsor must agree to run the trial as a teletrial. Teletrials are a type of de-centralised clinical trial. Sponsors decide which sites stand alone and which can form a cluster with Primary and Satellite Sites. Consider if the clinical trial is suitable for the teletrial model, including what trial aspects or activities can be delegated to a Satellite Site. Some changes that are required to undertake a teletrial include:

- Consent processes and teletrial wording in participant information sheets
- Managing the Investigational Medicinal Product (IMP)
- logistics of pathology, imaging, and other trial-related tests
- study windows and trial timelines to accommodate rural and remote sites

Teletrial Supervision Plan

Trial participants may have trial visits at both the Primary and Satellite Sites, as determined during site feasibility and based on site trial experience and service capability. Satellite Sites undertake agreed clinical trial activities delegated to them by the Primary Site. The teletrial supervision plan specifies the delegated and shared responsibilities for activities at each site. Supervision Plan templates are available on the Medicines Australia website.

Research Agreement and Teletrial Subcontract

The Clinical Trial Research Agreement is the head agreement between the Sponsor and Primary Site institution. The teletrial subcontract formalises the relationship between the Primary Site and the Satellite Site. It describes the obligations and responsibilities for delegated activities of the clinical trial (as outlined in the supervision plan and delegation log). The teletrial subcontract also passes on contractual arrangements from the head agreement to the Satellite Sites, including covering pass-through costs. The Teletrial Subcontract template is available on the Medicines Australia website.

Indemnity and Insurance

For commercially sponsored clinical trials, the Sponsor is required to provide the Primary Site and each of the Satellite Sites with a Medicines Australia Standard Indemnity. Some collaborative groups may also provide a standard indemnity but they are not required to do so.

Where indemnity is not provided by the Sponsor, each participating site (Primary or Satellite) must hold their own insurances to conduct the trial at their site.

Teletrial Regulation

The Sponsor is responsible for ensuring the clinical trial is approved as a Teletrial, including changes to the protocol (if applicable), Participant Information Sheet/s and addition of Satellite Sites:

- Clinical Trial Notification
- Clinical Trial Research Agreement (Schedules 1 and 2 as relevant)
- Human Research Ethics Committee approval

Research governance authorisation is sought by the Principal Investigator and site Associate Investigators (with support from their Regional Clinical Trial Coordinating Centre as available).

Resources

Sponsor Guidance & Checklist

- Sponsor Checklist provides easy-to-follow steps on evaluating potential sites and establishing a teletrial
- Sponsor Q&A Steps to establish the Tele-Trial Model

Study Protocol Guidance

- IMP Management in Tele-Trials
- Teletrials Primary Site IMP Handling SOP
- Remote consent process in Tele-Trials

Participant Information Sheet and Consent Form (PICF) Tools

- Stand Alone Teletrial Participant Information Sheet and Consent Form
- Guidance for the use of optional Teletrial Wording in PICF templates

Regional Clinical Trials Coordinating Centre (RCCC) Teams

Under the Australian Teletrial Program, Regional Clinical Trial Coordinating Centre teams now operate to provide state-based support and expert advice to Sponsors, Sites, Human Research Ethics Committees, and Research Governance Officers. RCCCs offer operational support, funding, assistance and coordination of cluster establishment and study start-up activities, as well as education and training.

Contact your local RCCC team:

- Queensland (click here for information about Teletrials in Queensland)
- Victoria (click here for information about Teletrials in Victoria)
- Tasmania
- South Australia (click here for information about clinical trials in South Australia)
- Northern Territory (click here for information about Teletrials in Northern Territory)
- Western Australia

More information

Australian Teletrial Program

Medicines Australia

VCCC Teletrial Toolkit

The National Teletrials Compendium