Frequently Asked Questions

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**What is the Australian Teletrial Program?**

The Australian Teletrial Program (ATP) is funded by a five year grant from the Commonwealth’s Medical Research Future Fund (MRFF) - *Enabling Infrastructure for Rural, Regional and Remote Clinical Trials* initiative.

The program will deliver a scaled-up version of the Australasian Teletrial Model that was tested during a pilot phase between 2017 and 2020.

Queensland Health is the program lead and is working with jurisdictional partners to implement the Australian Teletrial Model nationally.

**What is a Teletrial?**

A teletrial uses telehealth technology to communicate between the Primary Site and Satellite Site/s and enable delivery of aspects of a clinical trial as defined in the Supervision Plan. This technology supports a Principal Investigator to supervise Associate Investigator/s to conduct a clinical trial at a Satellite Site which is geographically remote from the Principal Investigator’s Primary Site. The Principal Investigator remains responsible for the trial.

A detailed Supervision Plan is required, in addition to a Delegation Log required by ICH GCP for all Satellite Sites regardless of experience. Trial participants may have trial visits at both the Primary and Satellite Sites, as determined by the Protocol and Supervision Plan.

The conduct of the trial is detailed under the ‘head agreement’, (Clinical Trial Research Agreement/Clinical Trial Agreement between the Sponsor and the Principal Investigator’s Institution) and a Sub-Contract between the Primary Site and the Satellite Site Institutions (see Teletrial Sub-Contract).

Definition from [*National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia.*](https://www.health.gov.au/resources/publications/national-standard-operating-procedures-for-clinical-trials)

**What is the vision for the ATP?**

The Australian Teletrial Program will improve access to and participation in clinical trials for rural, regional and remote Australians.

**Who can participate in the ATP?**

The ATP is open to all researchers conducting a phase I, II or III clinical trial (or equivalent classification for device and biological trials) under the Australian Teletrial Model (ATM). The program includes clinical trials undertaken in the public, private and academic health sectors.

**Which clinical trials are suitable to be conducted as a Teletrial?**

Not all trials may be suitable to be conducted as a teletrial. Each trial must be evaluated to assess its suitability to conducted under the teletrial model. Trials which require specialised equipment, intense monitoring of participants, complex preparation or administration of the investigation product and complex pathology sample collection and processing may not be appropriate as a teletrial.

However, if one visit (as per protocol / schedule of assessments) can be performed via telehealth (meaning that the patient can receive care closer to home) then the trial can be conducted as a teletrial.

[A checklist to assist in evaluating the suitability of a clinical trial](https://australianteletrialprogram.com.au/clinical-teams/) to be conducted under the Australian Teletrial Model is available in the Australian Teletrial Program (ATP) toolkit.

**Is there help available to sites when considering setting up or joining a Teletrial?**

**Yes.**

Each partner jurisdiction in the ATP has a Regional Clinical Trial Coordinating Centre (RCCC), staffed by experienced clinical trialists, whose role is to work with Primary and Satellite Sites in establishing a teletrial, providing assistance in obtaining necessary approvals from trial Sponsors and Human Research Ethics Committees (HREC), and completing regulatory requirements, including site authorisation.

The RCCC also provides clinical trial related education, learning opportunities, onsite training, and support to all teletrial sites and coordinators.

In some situations, the RCCC staff may travel to assist Satellite Sites with training, assessing site capabilities and patient visits, or may organise for teletrial coordinators to travel to experienced clinical trial centres to receive on site education and experience in conducting clinical trials.

[Contact details for jurisdictional RCCCs](https://australianteletrialprogram.com.au/clinical-teams/) are on the ATP website.

Additionally, an Australian Teletrial Toolkit has been developed. This toolkit contains the following documents:

* Guidance for Sponsors and Sites in Establishing a Teletrial,
* Checklist for:
	+ Evaluating if a Trial is suitable to be a Teletrial
	+ Evaluating is a site is suitable to be a Satellite Site
* Workflow checklists for the Primary Site, Satellite Site and RCCC
* Teletrial Subcontract
* Stand-alone Teletrial Participant Information Sheet and Consent form (PICF)
* Guidance for insertion of Teletrial specific wording in the NHMRC PICF templates.

**Does the entire trial protocol have to be delivered at a specific site?**

**No.**

Not all trial activity is required to be delivered at a specific site.

Each site conducts the trial activity that they are capable of and for which they are resourced, as outlined in the agreed Supervision Plan. Some teletrials may require participants to be reviewed at the Primary Site for particular visits.

**Can an existing trial be converted to a Teletrial or does a trial have to be set up as a Teletrial from the beginning?**

**Yes** – a trial that is already open and running can convert to a teletrial if it is deemed suitable to be conducted under the model, and if the Sponsor agrees to running the trial as a teletrial. The RCCC in each partner jurisdiction can provide assistance with this.

**How many Satellite Sites can be included in a Teletrial cluster?**

Any number of Satellite Sites can be added to a teletrial cluster with the agreement of the Sponsor and the primary site.

However, as the Principal Investigator is to provide oversight to all sites within the cluster, it is recommended that a cluster should not be larger than the Primary Site and five Satellite Sites.

An exception to this might when a trial is targeting a rare disease and will have low recruitment numbers. In this case larger clusters may be manageable. Smaller clusters may be appropriate when trials are complex and have higher expected recruitment.

This decision will be determined when the trial is evaluated for its suitability to be a Teletrial.

**How do you know if a site is suitable to be Satellite Site?**

Before being accepted into a cluster, a potential Satellite Site must be evaluated as to its suitability to conduct a trial as a teletrial.

This includes an assessment of available resources and equipment at the site, including available health care practitioners. [A Satellite Site Evaluation form is available in the ATP Toolkit](https://australianteletrialprogram.com.au/clinical-teams/) and is completed in collaboration with either the Primary Site or the supporting RCCC. The trial Sponsor must agree to the inclusion of the site into the cluster.

**I have a patient who is currently travelling for a clinical trial. Could this be converted to a Teletrial?**

If the trial is assessed as being suitable to be conducted as a teletrial, and there is agreement from the Sponsor to run the trial as a teletrial, and agreement between the clinicians at both the Primary Site and the potential Satellite Site to conduct the trial as a teletrial, then Yes – the trial may be conducted as a teletrial once all regulatory processes have been completed.

**We have been asked to be involved in a Teletrial. What are our first steps?**

Contact your local RCCC for assistance. They will help with all aspects in setting up a teletrial, including assistance with regulatory requirements, education, logistics support and completion of start-up activities.

**How do we prepare for the National Clinical Trial Governance Framework (NCTGF)?**

Contact your jurisdictional RCCC who will assist with education and support as to what is required for the NCTGF.

**Do we need a contract to be part of a Teletrial?**

**Yes.**

When conducting a teletrial, the Primary Site signs a contract with the Sponsor of the trial. Each Satellite Site in the cluster signs a Teletrial Subcontract with the Primary Site.

The study budget, site costs and method for distribution of due funds are agreed between the Primary Site and Satellite Site and detailed in the subcontract. Generally, Satellite Sites will be reimbursed for the activities that they complete.

**How is the trial conducted? Who is responsible for what?**

The Supervision Plan details the tasks and responsibilities to be undertaken by the Satellite Site. Each Satellite Site has their own supervision plan for each individual Teletrial, based on the site’s clinical trials/teletrials experience. The Primary Site completes the Supervision Plan in collaboration with the Satellite Site and RCCC.

**What about Training and Delegation Logs?**

Training and Delegation Logs are the responsibility of the Principal Investigator at the Primary Site. The management of these documents is determined on a trial by trial basis, according to Sponsor preferences.

These details are established at the outset when the trial is first being considered as a teletrial.

**How are clinical notes and source data about participants at a Satellite Site monitored?**

The process depends on whether or not sites within the cluster use an electronic medical record that can be accessed at the Primary Site, or whether hard copy clinical notes at a Satellite Site must be photocopied, de-identified and coded, then scanned and emailed to the Primary Site.

Sponsor auditors and monitors may travel to Satellite Sites if so desired. The process for source data verification is discussed with the Sponsor prior to each Satellite Site joining the cluster.

**How are Site Investigator Files managed during the trial and at trial completion?**

Each Satellite Site has its own Site Investigator Files for the duration of the teletrial. At completion of the trial, the Site Investigator Files are couriered to the Primary Site for archiving in accordance with the Sponsor’s instructions.

**Who to contact if you require assistance or information regarding teletrials?**

Each partner jurisdiction in the ATP has a Regional Clinical Trials Coordinating Centre (RCCC) with experienced clinical trialists who will provide assistance and advice in setting up a Teletrial.

Contact details for each RCCC are on the ATP website, or as below:

E: Australian\_Teletrial\_Program@health.qld.gov.au

W: australianteletrialprogram.com.au