## Frequently Asked Questions

**FAQ:** Why should I consider adopting Teletrial methodology to deliver my clinical trial?

**A:** Teletrial Methodology addresses health equity by taking healthcare further into rural regional and remote Australia. Acknowledging there are some additional requirements when comparing traditional clinical trial delivery to teletrial methodology, these additional steps allow for multiple sites to be activated within a cluster, across large geographical areas. Regional Clinical Trial Coordinating Centres are established in participating jurisdictions to support you in adopting the teletrial methodology to deliver your clinical trial and increase access and diversity to your clinical trial.

**FAQ:** How do I ensure compliance with regulatory requirements in teletrials?

**A:** Teletrials provide additional methodology in delivering clinical trials across multiple and often geographically remote locations. In addition to the usual clinical trial regulatory requirements, the ongoing use of a supervision plan and sub-contract provide governance compliance and oversight for the life of the trial.

**FAQ:** How do I ensure compliance with ethics requirements in teletrials?

**A:** Teletrials provide additional methodology in delivering clinical trials across multiple and often geographically remote locations. In addition to the usual clinical trial ethical review requirements, Human Research Ethics Committees (HRECs) may require information be provided, often within the study protocol, on how the trial will be ethically and safely delivered using teletrial methodology. HRECs may also require evidence of the qualifications of the Satellite Site Associate Investigator to ensure the appropriate personnel are leading the trial at their site. There are helpful guidance checklists available for use and your reviewing HREC and local Regional Clinical Trial Coordinating Centre will be able to assist with submission specific advice.

**FAQ:** Should I specify that I am using Teletrial methodology in my trial protocol?

**A:** Yes! As with traditional clinical trial submission requirements, your protocol should outline how your trial will be delivered to ensure robust results.

**FAQ:** What will happen to my trial when the program ends?

**A:** The Australian Teletrial Program currently has grant funding to October 2026, to build infrastructure and capacity to take healthcare further into rural, regional and remote Australia. Please speak to your local Regional Clinical Trial Coordinating Centre to discover their plans for local infrastructure and capacity building.

**FAQ:** Is a Teletrial another name for Telehealth?

**A:** No! Teletrials are a methodology of delivering Decentralised Clinical Trials (DCT’s) where ‘Tele’ refers to the site-to-site telecommunication required to run the trial within a cluster!

**FAQ:** How long will I need to allow for RGO and HREC review of my study?

**A:** the timeline for HREC and RGO review of submissions depends heavily on the quality of your submission, please take the time to review your submission documents for consistency, clarity, adherence to regulatory requirements and the appropriate level of detail to describe your trial! Please speak to your local Regional Clinical Trial Coordinating Centre for trial and jurisdiction specific advice.

**FAQ:** Is there a fee for service when engaging with my local Regional Clinical Trial Coordinating Centre?

**A:** No, engaging with your local Regional Clinical Trial Coordinating Centre will not incur a fee for service to assist in adopting teletrial methodology for your trial!

**FAQ:** What are the contractual arrangements required for my Teletrial?

**A:** As seen in traditional clinical trials, there is a Clinical Trials Research Agreement or agreed alternate contract prepared and executed between the Primary Site and the study sponsor (or their delegate). This is referred to as a head agreement when adopting Teletrial methodology to deliver your clinical trial. In addition to the head agreement, a sub-contract is prepared and executed between the Primary Site and Satellite Site to facilitate the delivery of service across multiple sites. Please speak to your local Regional Clinical Trial Coordinating Centre for trial and jurisdiction specific advice.

**FAQ:** Can there be a Principal Investigator at a Satellite Site?

**A:** No, an Associate Investigator leads the conduct of the trial at a Satellite Site under the supervision and support of the Primary Site’s Principal Investigator.

**FAQ:** Does the primary site of my cluster need to be in a metropolitan area?

**A:** No! Sites can be selected to perform the role of primary site based on experience, capacity and ability to deliver the requirements of the protocol. Please speak to your local Regional Clinical Trial Coordinating Centre for trial and jurisdiction specific advice.

**FAQ:** What aspects of my clinical trial can be delivered using teletrial methodology?

**A:** The adaptable and agile nature of teletrial methodology allows for great flexibility in determining how your clinical trial can take healthcare further into rural regional and remote Australia. Please speak to your local Regional Clinical Trial Coordinating Centre for trial and jurisdiction specific advice.

**FAQ:** Can my satellite site grow capacity to become a primary site?

**A:** Yes! A key component of the program is capacity building and upskilling sites to take healthcare further. Your local Regional Clinical Trial Coordinating Centre will be able to provide support and guidance on growing your sites capacity.

**FAQ:** Does everyone working on my teletrial need to have Good Clinical Practice training?

**A:** Your reviewing HREC and Research Governance Office will be best placed to advise you of training requirements for submission, however it is highly recommended that you complete your Good Clinical Practice training!

**FAQ:** Can our site be included as a Satellite Site if we can’t perform all protocol related activity?

**A:** Yes, you can use your supervision plan to assess your sites capabilities and allocate activities accordingly! Please speak to your local Regional Clinical Trial Coordinating Centre for trial and jurisdiction specific advice.

**FAQ:** what support is available to my Primary Site in leading a cluster?

**A:** Your local Regional Clinical Trial Coordinating Centre is the main supporting infrastructure embedded to aid in the successful delivery of your Teletrial. Please speak to your local Regional Clinical Trial Coordinating Centre for trial and jurisdiction specific advice.

**FAQ:** Are all the items on the ATP website checklists required for HREC approval?

**Answer:**No. Although there is a sample checklist available on the Australian Teletrial Program website, this is a national guidance, not a nationally harmonised document. Each participating state or territory Regional Clinical Trial Coordinating Centre can support the HREC with the relevant submission requirements.

**FAQ Consumer:** Does this mean I won’t have to travel for my treatment?

**A:** Teletrial Methodology addresses health equity by taking healthcare further into rural regional and remote Australia. Please speak to your treating doctor as this will be dependent on the treatment you are receiving.

**FAQ Consumer:** How can we participate in a teletrial when we don’t have good internet connection at home?

**A:** Teletrials are a way of delivering Decentralised Clinical Trials where Tele = the site-to-site telecommunication required to run the trial. This is different to other types of Decentralised Clinical Trials, where some or all clinical trial activities might take place in your home. This means you will likely attend a health facility for your trial treatment.

**FAQ Sponsor:** Should I count my satellite sites as separate sites when selecting Australian sites for feasibility?

**A:** No. A Satellite site is considered an extension of the Primary Sites under the supervision of the Principal Investigator. This means the Primary site is counted and any participating Satellite sites are considered as part of a wider pool of recruitment opportunities available to the Principal Investigator.

**FAQ: Supervision Plan:** What is the most efficient way to complete a supervision plan?

**A:** A supervision plan provides a safe and accountable record of what trial and protocol related activity can be allocated to a Satellite Site and the type of supervision for these allocated activities. The earlier you start communicating with respective sites and supporting departments on their requirements, the better! We recommend joint meetings between parties to get things started and keep things moving smoothly!

**FAQ: Northern Territory specific:** Why does my protocol need to undergo additional Human Research Ethics Committees (HREC) review to establish sites within the Northern Territory, doesn’t National Mutual Acceptance (NMA) mean this is not required?

**A:** There are a few instances where research can be exempted from NMA, which does mean local HREC review is required to ensure appropriate consideration of ethical and cultural requirements within the area. Please speak to your local Regional Clinical Trial Coordinating Centre for trial and jurisdiction specific advice.