cognizant | Australian Teletrial Program | Taking Healthcare Further

Enhancing collaboration in teletrials with intelligent technology and process alignment

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Introduction

Post-COVID-19, global clinical research has embraced new-age trials. Stakeholders including researchers, sponsors, clinical research organizations (CRO) and health authorities are moving beyond traditional clinical trial models to tackle rare diseases, enable personalized medications, speed up drug launches and boost patient access. Hybrid and decentralized clinical trials (DCT) have shifted from buzzwords to reality.

An industry survey[1] in early 2023, conducted for cancer clinical trials, indicated that almost all sponsors are incorporating at least one DCT element in their trials. The most widely adopted DCT elements were remote site monitoring, telemedicine, remote laboratory assessments, remote distribution of investigational product (IP) and local imaging assessments.

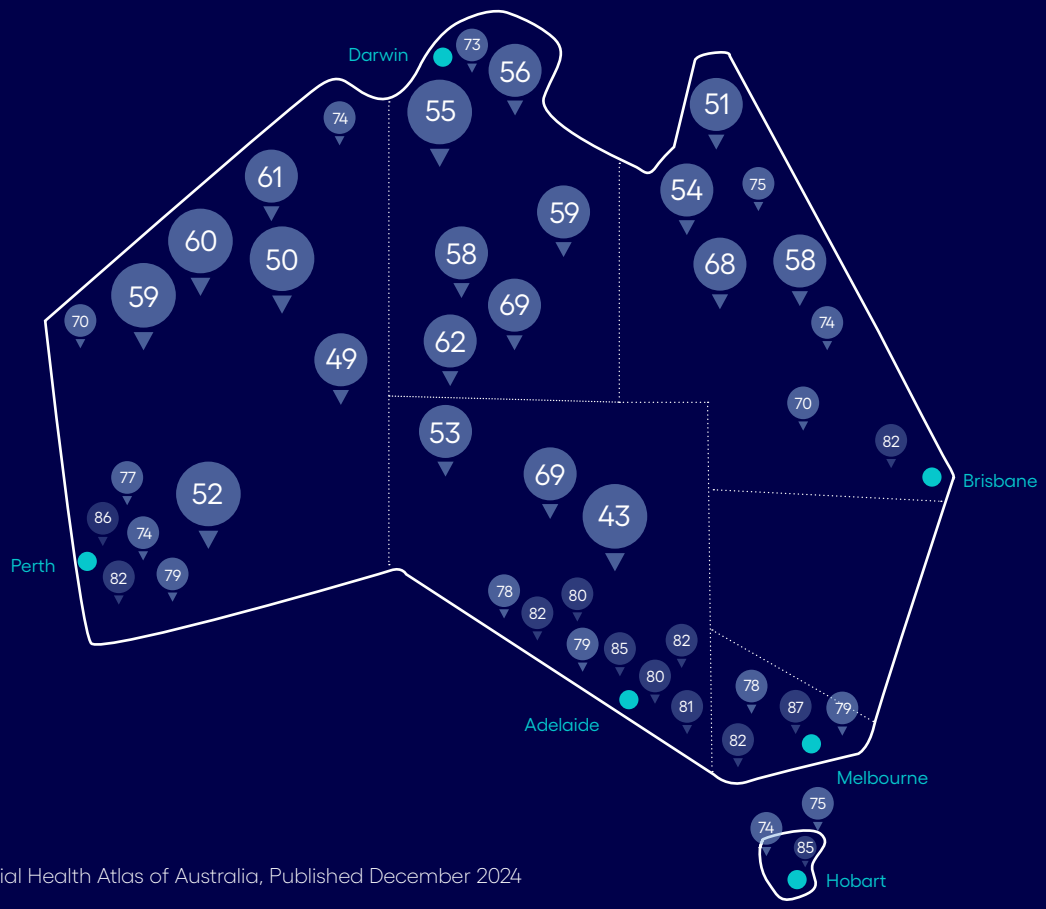
Teletrials in Australia are a similar variation of hybrid clinical trials and potentially a model which can be replicated in various other countries to make clinical trials more community-centric and patient-driven. Teletrials have already demonstrated their effectiveness in expanding trial participation and fostering collaboration by improving clinical trial access for rural, regional and remote (RRR) Australians.

Cognizant is committed to supporting initiatives like the Australian Teletrial Program (ATP) that enhance equity in clinical research and improve health outcomes for all Australians.

What is a teletrial?

On average, people living in RRR areas in Australia have shorter lives, higher levels of disease and injury, and poorer access to and use of health services. The adjacent map[3] indicates the median age (> 80 years) of death is significantly higher than the population residing in the remote and rural areas (45–70 years).

This discrepancy is being addressed by ATP by building the infrastructure needed to treat and manage more diseases and conditions locally by clinical trials. This makes the latest medical innovations—medicines, devices and preventative or different standard of care treatments—accessible to all Australians, wherever they live.



Source: Social Health Atlas of Australia, Published December 2024

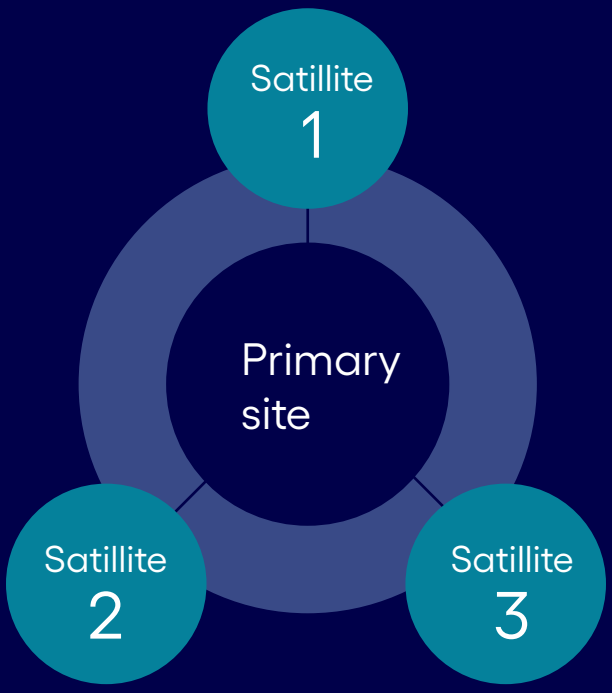
A teletrial is a new-age decentralized model of clinical trial in Australia that links RRR trial sites to a A teletrial is a new-age decentralized model of clinical trial in Australia that links RRR trial sites to a metro-based primary site, letting patients join trials closer to home. The principal investigator (PI) at the main site works with associate investigators at satellite sites. The PI oversees all sites in the cluster and must follow a supervision plan and maintain a Delegation of Authority (DOA) Log per International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice (ICH GCP) rules. Trial participants may visit both primary and satellite sites, based on the trial protocol and the supervision plan.

The major infrastructure of the program has been set up by the Regional Clinical Trial Coordinating Centre (RCCC) teams in each jurisdiction. RCCCs have been established and staff to provide state/territory-based support to the sites for teletrials. “There have been significant implementation challenges from infrastructure to research culture variability across the six participating jurisdictions,” says **Kaye Hewson, ATP Director.**

“Now that we have that infrastructure and workforce set up, we are able to harmonize existing and future policies, train and educate staff and start to see capability and capacity being built at local site levels. We already have over 1,300 participants recruited in regional, rural, or remote locations, and a teletrial pipeline that continues to grow across each jurisdiction,” she says.

Sites in a teletrial cluster use digital tools and telecommunications to operate as one team, bringing trials closer to patients. Telemedicine may be used but it isn’t mandatory. The Australian model is often perceived as a safer form of decentralized trials than home-based ones, as key DCT elements like ePRO/eCOA, eConsent, IP delivery and remote monitoring can be better managed under local medical supervision.

In addition, the primary site supports the local/RRR sites in building capacity and capability and promoting equitable health access and may lead to local sites becoming primary sites in the future. Teletrials, in general, have helped in upskilling of local staff at RRR sites by providing them with the necessary knowledge and skills to participate in clinical trials, thus leading to a more skilled and motivated local workforce. This also helps organically with the promotion of workforce recruitment and retention, which is a key focus area in the Australian clinical research landscape.



“Teletrial clusters have been established nationwide, across all medical specialties. ATP has transcended out of oncology, although it still leads with 41 teletrials to other clinical specialties, including nephrology following with 11 teletrials while the remaining trials are in mental health, public health, neurology, endocrinology, cardiology and palliative care. And that will ultimately benefit local patients and their health outcomes,” Ms. Hewson mentions.

On average, people living in rural and remote areas have shorter lives, higher levels of disease and injury, and poorer access to and use of health services. Ms. Hewson says closing the distance between patients and healthcare providers is essential.

“Currently 88% of clinical trial sites are located in city areas, forcing patients outside of metropolitan areas to travel long distances to participate at both a financial and mental burden cost. It also limits the areas clinicians who are interested in medical research are able to work. Any reduction we can make in the number of people travelling for their healthcare needs will benefit not only the patient, but the whole community and local healthcare service,” she highlights.

What is the role of the Australian Teletrial Program?

The Australian Teletrial Program is supported by funding from the Australian government under the Medical Research Future Fund infrastructures grant. The program has successfully enabled multiple pillars, as stated below, to ensure participating sites have the necessary guidance and standard operating procedures (SOPs) to conduct teletrials:

Regional Clinical Trial Coordinating Centres in each participating state and territory. The clinical trials expert workforce at these centers helps clinicians, researchers and sponsors set up and run teletrials in their local region.

Policy harmonization at a national level via guidelines, national principles to streamline research governance, standardized templates for contracting, standardized checklists for evaluation of a trial for teletrial and evaluation of a site as a satellite site, IP management SOP and supervision plans.

Impart education and training, conduct symposiums at various regions to create awareness about teletrials and best practices, and share case studies from different sites.

Provide access to free clinical trial education in each partner jurisdiction by funding Australian Clinical Trials Education Centre.

Up to September 2024, over **11,100** users have visited the ATP website, with 27,511 views and 4,868 resources downloaded. This reflects a 40% increase in six months and demonstrates a growing interest and popularity of the program and the resources provided by ATP.

Real-world case studies of teletrials

AGILE-Echo study[3] (artificial intelligence-guided echocardiography to assist cardiovascular patient management): Heart failure (HF) and valvular heart disease (VHD) are disproportionate problems in rural and remote Australia relative to the rest of the country. Echocardiography is the imaging investigation of choice, and a cornerstone of management, but access is a challenge for the remote populations, due to a lack of specialists and large geographical distances to cover. Northern Territory cardiologist Dr. Angus Baumann says this disproportionality impacts First Nations (Aboriginal Australians and Torres Strait Islanders) patients, who experience significant travel burdens, high disease rates and underrepresentation in clinical trials.

"First Nations people in central Australia have a high burden of disease, with rheumatic heart disease rates sitting at 3.5% against the national prevalence of 0.02%," he says. "The right trial, developed by the community for the community is particularly important, as we move towards a new framework that has First Nations co-design and data sovereignty at the heart of it. That allows us to deliver trials to the people who need them, in a way that they want to get actionable outcomes to improve their health," he says.

The AGILE-Echo study is now the world's first randomized controlled trial of AI testing via remote echocardiographic image acquisition and remote measurement and interpretation, which helps with early intervention to detect early stages of HF and VHD. Leveraging the teletrial model of trial conduct, this study (sponsored by Baker Heart and Diabetes Institute with chief investigator Dr. Tom Marwick) is reaching out to remote and Aboriginal communities in the Northern Territory in Australia—having Alice Springs Hospital as the primary site and cardiologist Dr. Baumann as the primary PI. The primary site is supported by satellite sites at Tenant Creek Hospital, Ti Tree Community Health Clinic and Hermannsburg Community Health Clinic, which are mainly community clinics. This is a great example where even a non-metro site (Alice Springs Hospital) can also act as a primary site for the right protocol with the right support (ATP infrastructure, regional coordinators, etc.).

Prostate cancer clinical trial at Latrobe Regional Health (LRH) with oversight provided by Alfred Health's radiation oncology team[4]. A participant in the trial confirmed he could continue to stay in the trial only because he could do it at LRH—otherwise it would have been a challenging two-and-a-half-hour trip to The Alfred for every visit. The teletrial model enables LRH to deliver trials in partnership with a major metro hospital and provide care closer to home for the local community.

General Manager of Research and Partnerships at Latrobe Regional Health Dr. Jhodie Duncan says decentralized trials are known worldwide, and teletrials are one model providing opportunities for sites to provide access to clinical trials in the geographically diverse Australian landscape. "While teletrials undoubtably benefit patients who can access care closer to home and within their own communities, they also provide an opportunity for local clinicians to develop their skills under the supervision of a primary investigator.

This builds capacity, capability and even confidence at all levels of a regional, rural or remote site, by highlighting that clinical trial delivery is possible within the local service with access for local residents, sometimes in new specialty areas that were not previously available," she says.

As per Dr. Duncan, global sponsor advocacy is key for implementation nationwide, and cautions that in the current landscape, in Victoria at least, teletrials do not mean faster startup, less workload or more significant financial gain. She says their benefits are in offering greater recruitment and diversity. In addition, working with sponsors and CROs who are willing to be adaptive and work within site capabilities continues to enhance and streamline teletrial processes. "Ultimately we all want to work together to improve access to clinical trials for those who live regionally and provide opportunities for high-quality health care closer to home," she says.

Technology and process considerations to enhance efficiency in teletrials—A point of view

1 Seamless collaboration and interoperability between sites and supporting entities

E-clinical and digital health tools have long supported collaboration between sponsors/CROs and research sites. But with modern trial models, it is now crucial to also enable smooth collaboration and information sharing between participating sites and extend support to all stakeholders.

In the case of the Australian teletrials, enabling this collaboration will help support key use cases such as:

In the case of the Australian teletrials, enabling this collaboration will help support key use cases such as:

- Exchange of documents (e.g., subcontracting document, supervision plan, monitoring visit files, etc.) and site staff information between primary site and satellite sites in each cluster.
- Sharing of dynamic patient consent between the primary and satellite sites in a near-real-time manner.
- Remote monitoring to oversee study conduct, including tracking patient safety.
- Tracking of investigational medicinal product (IMP) transfer from primary site to satellite sites, etc.
- Submissions of documents from primary/satellite site systems to RGOs and receiving acknowledgements back from RGOs—with added capability of accessing the RGO reviews across all sites that are part of the teletrial cluster.
- Real-time communication between stakeholders via chat/messenger-like tool.

Key benefits:

Better collaborative patient management, faster study startup and conduct, better tracking of actions, single document repository and reduction in duplication of process.

2 Intelligent, automated suggestions of potential sites to form a teletrial cluster

An AI-powered system can suggest potential satellite sites based on protocol details, past collaborations, therapeutic areas, study phase and regional capabilities. It can also assess patient population access to speed up site selection.

On the other hand, an intelligent system like this can also assist the RRR sites who want to take part in trials, have the patient populations and potentially a new PI, but are not quite ready to be a stand-alone or primary site. The system can recommend a primary site within the same jurisdiction, thus helping the RRR site to operate as a satellite site in a teletrial model.

Key benefits:

Faster identification and selection of cluster sites along with better collaboration from a proactive partnership.

3 Templatized checklists embedded in workflows

AI-enabled workflows between sponsors and primary sites can use prefilled ATP checklists to quickly assess teletrial suitability and satellite site eligibility. When sending feasibility surveys, these templates can auto-populate based on selected sites and past trial data, streamlining setup and decision-making.

Key benefits:

Easy evaluation of sites for teletrials using standardized templates, faster study startup.

4 Digital collaborative supervision plan

A supervision plan is the backbone of a teletrial, guiding collaboration between the primary site, satellite sites and stakeholders like RCCCs, pharmacy, pathology and imaging centers. A clear, well-documented plan is often the "secret sauce" behind a successful trial.

ATP offers educational resources and step-by-step guidance for creating supervision plans, helping new sites navigate teletrials. However, drafting these plans can be manual and time-consuming, requiring coordination across stakeholders before final submission to the RGO.

Some of the key factors driving the need for easy accessibility and update capabilities of a supervision plan are:

- The document/template has multiple sections, namely trial and site details, allocation of activities and endorsements, which need to be filled in consultation with the pertinent teams. The template can also vary based on the research site's experience with clinical trials.
- If the primary site is working with multiple satellite sites in a teletrial, it necessitates one supervision plan per satellite site which can further make the process challenging for the primary site and teletrial coordinating team.
- The supervision plan is a living document, throughout the course of a teletrial and needs to be constantly updated as capacity/capability often changes at the RRR sites which have typically higher staff turnover.

Our technology recommendations to simplify and enable a seamless collaboration are twofold:

- Enable a web-based form, built on ATP's template, which can support real-time multiuser collaboration and inputs—similar to live documents and spreadsheets used in Microsoft 365. This digital form should additionally support version history, access control (based on site personnel role), notification capabilities, and capabilities to capture multiple e-signatures to allow for endorsements from the primary site PI and associate investigators from satellite sites. Version history can help assess and monitor site capacities and capabilities at different times for different therapeutic areas.
- Auto-population of trial activities, location of activity and method of supervision, enabled via integration and machine learning:
  - Integration of the schedule of assessment from the protocol to list the trial-specific activities in the supervision plan
  - Routine trial tasks (e.g., consent, clinical care, safety) can be autofilled in supervision forms using either historical site-role data or protocol integration

Key benefits:

Faster and better-quality submission to RGO, simplified collaboration and maintenance, reduced chances of data loss during manual data input or email exchanges.

5 Consolidated online DOA Log

Teletrials require a single consolidated Delegation of Authority Log, duly signed by the primary site PI to be submitted to the sponsor. This essentially necessitates consolidating site staff, handling different responsibilities, across all satellite sites and the primary site in a single document which eventually must be signed by the primary site PI.

A potential enabler for the primary site to achieve this seamlessly can be a single platform where the entire cluster (primary site and all satellite sites) can be listed with all their respective staff with their assigned roles and dates of assignment in a single form. The system should be capable of supporting the generation of DOA documents from the online form and get it e-signed by the PI.

Key benefits:

Audit tracking, monitoring and real-time visibility of updates, no paper-based or email-based exchange of documents.

6 Transparent, collaborative budget negotiation tool

Negotiating the budget and contract is frequently identified as the longest single component of study startup. Globally, contract negotiations have been reported to exceed 100 days[5] for many multisite trials. The lengthy negotiation phase can push back every other aspect of trial activation.

Teletrials, being multisite, pose budgeting difficulties especially for RRR/satellite sites with limited experience in cost recovery. These sites often depend on the primary site to negotiate budgets, particularly across different health services or jurisdictions.

The process typically involves complex spreadsheets and multiple rounds of negotiation with sponsors, slowing down trial activation.

The key recommendations to improve the process will be an AI-driven budgeting tool that can process the study protocol and suggest a granular budget outline that references fair market rates as well as highlighting potential unbudgeted tasks. The collaborative budgeting tool should be accessible to all sites within the cluster—providing transparency, minimizing guesswork and presenting stronger cost rationale for each item.

Key benefits:

Fewer negotiation cycles, auto-generation of itemized budget reducing manual work, better collaboration.

7 Community data aggregation

Regional sites must capture local patient/community data in a secure, electronically shareable format accessible to other research sites (e.g., metropolitan sites), using anonymized or pseudonymized data. A data aggregation platform surfacing regional insights can help primary sites proactively select satellite sites, accelerating teletrial initiation.

To enable this, standardizing electronic medical record (EMR)/electronic health record (EHR) systems across sites within a state/province or establishing interoperability via application program interface (APIs) is essential. A unified "One EMR" approach would benefit patients across regions.

The standardization of EMR/EHR might not be easy, especially with many regional sites running their institutions or clinics without any formal platform.

However, with initiatives like National One Stop Shop[6] (managed by Australian Government Department of Health, Disability and Ageing), it might be worthwhile to drive an initiative to bring all regional sites on the same level of technology adoption for efficient collaboration.

Key benefits:

Better patient tracking, faster data exchange, better collaboration.

Conclusion

The Australian Teletrial Program has established a strong foundation for equitable, community-focused research by connecting metropolitan and remote healthcare. To scale teletrials and improve outcomes, integrating smart technologies and streamlined processes is essential. Innovations like AI-driven site selection, digital supervision plans, collaborative budgeting tools and interoperable data systems can make teletrials more efficient, inclusive and scalable. Embracing these tools will strengthen Australia's teletrial ecosystem and offer a global model for decentralized clinical trials.

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