

29 Aug 2024 | Interviews

Pharma Warming Up To Benefits Of Australia's Teletrials Initiative

by **Vibha Sharma**

The Australian teletrials program has surpassed expectations at its mid-way point and is being used by drug and device sponsors looking to enhance trial participant recruitment and retention by enabling access to rural, regional and remote areas.

An Australian initiative that uses digital telecommunications to improve access to clinical trials in rural, regional and remote areas and deliver a more diverse pool of study participants for drug and medical device studies in a range of therapeutic areas is making headway.

The government-funded Australian Teletrials Program (ATP) has conducted over 45 studies at its halfway mark, surpassing expectations, according to program director Kaye Hewson. Nearly 30% of the studies were from commercial sponsors and this number is growing steadily, Hewson said in an interview with the *Pink Sheet*.

The ATP was set up in 2021 to bring clinical trials closer to the homes of patients in the Northern Territory, Queensland, South Australia, Tasmania, Victoria and Western Australia. While it does not cover New South Wales and the Australian Capital Territory, “we still work with them closely on our

Key Takeaways

- The Australian Teletrials Program (ATP) is making good progress in setting up infrastructure needed to enable studies that make use of digital telecommunications to connect regional and rural clinical trial site clusters.
- Teletrials are a subset of decentralized clinical trials and involve developing trial sites closer to the patient's home, which can improve access and availability of health services closer to where people live.

harmonization activities” to ensure coherence on research governance of teletrials, said Hewson. (See map below)

The program was awarded an AUD 75.2m (\$50.6 m) grant under the Medical Research Future Fund, covering a five-year period (2021-2026) to build the necessary infrastructure for conducting teletrials, some of which has now been set up.

The ATP at its launch in November 2022 stated it aimed to recruit in total 5,000 clinical trial participants from rural, regional and remote areas, 2,400 clinical trial sites, 90 general practice clinical trial sites, 208 trials and 5,000 people trained to facilitate these services. Momentum is still building, and collaboration across the country is key said Hewson.

Relatively New Model

Teletrials are a relatively new model for conducting clinical trials that involve networked collaboration between clinical trial sites using telehealth.

They connect “satellite” trial sites in rural, regional and remote areas to “primary sites” in metropolitan/urban areas via digital telecommunications to form a cluster. Any number of satellite sites can be added to a teletrial cluster with the agreement of the sponsor and the primary site.

The model allows patients to take part in clinical trials and investigations closer to their homes, which can improve retention rates. “Having clinical trials just concentrated in metropolitan areas disadvantages patients who can't travel, won't travel, or aren't even aware of their ability to access clinical trials,” Hewson noted.

The model also aims to increase trial participant diversity and generalizability of study outcomes.

- As teletrials can enhance trial participant recruitment and retention by enabling access to rural, regional and remote areas, the program has drawn the interest of several companies, including Eli Lilly, Novo Nordisk and Sanofi.
- The ATP covers a five year period (2021-2026) and is supported by a infrastructure-enabling grant of AUD 75.2m (\$50.6 m).
- At its midway, the ATP has been able to set up coordinating centers in each participating jurisdiction allowing for over 45 teletrials to be conducted, 30% of which are from commercial sponsors.
- Eli Lilly Australia expects the investment made in setting up the teletrials infrastructure to deliver returns in terms of quicker patient enrolment and greater diversity and inclusion in trials.

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Teletrials are a type or subset of decentralized clinical trials (DCTs). Other DCTs involve some or all trial-related activities being conducted in or near a patient's home, but they use digital health technologies such as glucose monitors to capture health care information directly from individuals and do not use a networked system. By developing trial sites closer to the patient's home, teletrials provide a "safety mechanism" and quality within the banner of DCTs which improves access and availability of health services closer to where people live, Hewson explained.

ATP Progress

The ATP is based on a pilot that the Clinical Oncology Society of Australia ran across three states from 2017 to 2020. The pilot convinced the federal, state and territory governments, clinicians and other supporting partners that teletrials could "revolutionize access to clinical trials in regional, rural and remote areas of Australia," Hewson said.

In 2021, the program was expanded with support from the AUD 75.2m federal grant to enhance access to clinical trials of novel drugs, technologies and models of care. Its roll-out is being led by Queensland Health, which has formed a national office to guide the ATP.

Since its launch, the ATP has "completely transcended out of oncology to other clinical specialties" and "we've proven it can work in mental health, neurology, cardiology, diabetes, and elderly care, just to name a few," Hewson said.

Over 45 trials have been completed to date and Hewson anticipates many more. "We know that there's a pipeline of teletrials coming" she said, adding that the ATP teams in the participating jurisdictions were reviewing them methodically, with each at varying stages of progress. "In terms of numbers... it will just get more and more," she declared.



KAYE HEWSON IS THE DIRECTOR OF THE AUSTRALIAN TELETRIALS PROGRAM

Coordinating Centers: A 'Bonus' For Commercial Sponsors

The ATP has set up a Regional Clinical Trial Coordinating Center (RCCC) in each participating state and territory to act as a "conduit" for the sponsor interested in running teletrials.

The staff at RCCCs are familiar with the capabilities of their respective local sites and can help set up and run studies, Hewson explained. Their involvement in a study's set up and execution is a "bonus" for sponsors looking for assistance and advice on setting up teletrials.

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CITELINE REGULATORY

Sites executing teletrials have been on a steep learning curve with respect to aspects such as how to collect pathology specimens and how to deliver investigational medicinal products to patients, Hewson observed.

While around 30% of the trials in the ATP have so far been sponsored by commercial entities and 70% by clinician researcher collaborators, Hewson aims to even this ratio, because “obviously that investment is important for our sites” and it also helps build trust, relationship and experience with companies.

The ATP RCCCs can offer a lot of logistical support, she said, adding that these centers offered commercial sponsors “a trusted workforce” with which to work and visit the trial sites, if needed.

Diversity & Wider Patient Pool

As for how other ways that teletrials can benefit commercial sponsors, Hewson said: “The diversity of the population that are available is certainly a plus.” She noted that most big pharma companies, such as Roche and Eli Lilly, have diversity and equity in their mission statements “so this fits the bill very nicely for them, but we don't pretend it's easier.”

The ATP also allows sponsors to access a larger pool of patients via satellite sites in rural, regional and remote parts of Australia. “We've actually got examples in Victoria where a satellite site” was able to recruit more patients “than the metropolitan site,” she noted.



THE ATP COVERS THE NORTHERN TERRITORY, QUEENSLAND, SOUTH AUSTRALIA, TASMANIA, VICTORIA AND WESTERN AUSTRALIA

Based on experience of working with commercial sponsors, including Novo Nordisk and Sanofi, Hewson said a key learning has been never to overpromise and underdeliver. Whether a drug company is looking for one patient or 10, they want clarity on what is actually possible. “If we can only give five [patients],” sponsors want to be informed of this in advance so they can incorporate this figure into their trial design, she explained.

The ATP also has a commercial sponsors advisory group in place to actively consult, communicate and collaborate with major pharmaceutical and medical device sponsors and continuously refine its processes. So far, the ATP has helped deliver tangible benefits for commercial trials, especially in the field of oncology, according to Hewson.

The program has also earned the backing of some industry experts in the process, such as Tyron

Johnson, who is senior clinical research lead for oncology at Eli Lilly Australia & New Zealand. Johnson is a “strong supporter because he knows for those rare cancers, we would deliver on the patients and provide the experience” needed to run teletrials, said Hewson.

“Eli Lilly Australia has welcomed and embraced the concept of teletrials since it was first proposed in 2018,” said Johnson, who is also the chair of the ATP’s commercial sponsors advisory group. Over the last few years, he said, the ATP had “done an excellent job building the infrastructure necessary to formalise a Teletrial model that is robust and sustainable across most of the Australian continent.”

“Looking to the immediate future, Eli Lilly is anticipating a return-on-investment which means consistent faster patient enrolment and increased diversity and inclusion into their trials, all of which contribute to better science, faster approval times and an equitable and fair healthcare system for all,” Johnson told the *Pink Sheet*.

Another success story relates to an ongoing diabetes trial by a commercial sponsor at a remote health service that has recruited its first patient. “That patient was really excited to have the opportunity” to participate in the trial closer to home, otherwise they would have had to travel three hours to the nearest town or six hours to Brisbane.

Efficiency Is Key

Working with commercial sponsors has delivered another learning for the ATP, specifically the length of time it takes to set up a teletrial and get it running. For this, “one of the things we developed nationally is a ‘supervision plan’,” explained Hewson.

This is an overarching document that specifies the delegated and shared responsibilities for activities at primary and satellite sites and gives confidence to the sponsors about what is going to happen, who they are working with, and the capabilities of the staff at these sites.

“We’ve also learnt, and are acting on the fact that” delays can happen “because of a lack of communication between the research governance offices,” said Hewson. This is being addressed through “active education” within those offices and the ATP has also joined hands with the Australian Clinical Trials Alliance to offer education on ethics and research governance.

“We really understand that our landscape has to be efficient to attract those commercial sponsors,” Hewson acknowledged.

The Australian teletrials model has already attracted interest from other countries. In Canada, it inspired the recent launch of the Canadian Remote Access Framework for Clinical Trials (CRAFT), which helps enable clinical trial participation for patients who live far from the health care site where the trial is primarily offered.

In the US, it has drawn interest from Texas and other states because of their similar geographical spread.