REGISTRY TRIALS AND TELETRIALS

New clinical trial methodologies factsheet

VCCC Alliance
Overcoming cancer together

Clinical trials are an integral part of Australia's healthcare system. They help provide equity of access to treatments across rural, regional, and culturally diverse areas, ensuring these communities are better represented in clinical study populations.

While clinical trials are highly regulated, they have become increasingly complex, creating a barrier to both participants and those conducting trials. Travel distance, a lack of understanding of trials, disruption to home and work life restrictive eligibility criteria and the increasing complexity of trial designs can all lead to a disparity in representation and access, especially in rural and regional areas.

The emerging trial methodologies of registry trials and teletrials challenge these barriers.

Registry trials

Randomised-controlled trials (RCTs), the current gold standard in clinical trials, provide high-level scientific evidence comparing care approaches or treatment options. However, RCTs commonly have narrow eligibility criteria, limiting patient recruitment. They also have substantial per patient costs..

Clinical registries are databases that can be designed to be disease-, health services- or product-specific, and collect clinical information for a specific area of interest. They are designed to answer a variety of research questions.

When embedding a randomised controlled trial within a registry, it is known as a **registry-based randomised controlled trial, or registry trial (Reg-CT)**. Additional trial modules can be added for randomisation and specific trial data (e.g. patient reported outcomes) and data collection is achieved via the registry during routine care practices.

Reg-CTs, also known as pragmatic trials, allow for broader eligibility criteria than RCTs, providing better equity of access reflecting real-world patient populations. This innovative trial design allows for more rapid recruitment in often underrepresented areas at significantly lower cost than a conventional randomised controlled trial.

For more information, go to the VCCC Alliance page on registry trials:

Registry trials

Teletrials for cancer

Teletrials each have a primary site where the Principal Investigator is responsible for the conduct, coordination, and supervision of the clinical trial across the primary and satellite sites. This group of sites operating under the teletrial model is called a teletrial cluster. The "primary" and "satellite" sites work in collaboration and are connected by telehealth for some or all aspects of the clinical trial.

The teletrial model utilises telehealth technology to allow clinicians and the research team from a primary site to enrol, consent and treat patients on clinical trials in partnership with another centre or satellite site.

The benefits of teletrials include:

- Increased equity of access for regional and rural patients and reduced travel times
- Increased opportunities for clinical trial units to meet recruitment target (particularly for rare cancers)
- Collaboration and networking between regional and metropolitan centres
- Increased capability of clinical trial workforce.

Providing local access to clinical trials is especially important for patients in regional and remote locations. Telehealth allows research teams to use telephone or video calls to consult with participants and health professionals remotely. This allows satellite sites to take on aspects of a clinical trial they wouldn't normally have the capability or capacity for, enabling care closer to home.

Teletrials