Australian Teletrial Program

Teletrial Support Program Guidelines

27 May 2024



Introduction

The Australian Teletrial Program (ATP) is funded by the Commonwealth Government's Medical Research Future Fund – National Critical Infrastructure Initiative – 2019 Rural, Regional, and Remote Clinical Trial Enabling Infrastructure grant.

The ATP aims to improve access to, and participation in, clinical trials for Australians living in rural, regional, and remote (RRR) areas by implementing a scaled-up version of the Australasian Teletrial Model (ATM) to facilitate and expand clinical trial activity across Australia. The ATM links Primary clinical trial sites with Satellite Sites to form a Teletrial cluster, thus enabling Australians living in RRR locations to access trials closer to home, resulting in less time separated from family and reduced travel to access health care.

Teletrial Support Program

The Teletrial Support Program (TSP) provides funding support to sites conducting Teletrials, if eligibility criteria are met, to support cluster management and site development for clinical trials. The funding program seeks to:

- support experienced clinical trial sites in expanding clinical trial activity to rural, regional, and remote sites through implementing Teletrials
- support clinicians in rural, regional, and remote areas to offer clinical trial participation locally through Teletrials
- enable patients in rural, regional, and remote areas access to potential new treatments closer to home.

Structure

Two levels of funding are available under the TSP:

Primary Site Teletrial Cluster Management grant*: funding of up to \$10,000 (GST exclusive) per protocol to enable eligible primary sites to re-invest in Teletrials and clinical trials support.

Payments will be made as follows:

- \$5,000 when an eligible participant is enrolled at one satellite site 0
- \$5,000 when an eligible participant is enrolled at another satellite site. \cap
- Satellite Site Per Participant grant*: funding of \$700 per participant per year for up to 2 years (GST exclusive) to enable ongoing Satellite Site participation in the Teletrial model.

*Eligibility criteria applies.











Australian Teletrial Program



Eligibility Criteria

An eligible Teletrial must:

- be a clinical trial as defined by WHO a research study that <u>prospectively</u> assigns human participants or groups of humans to one or more <u>health-related interventions</u> to evaluate the effects on health outcomes
- be conducted in accordance with the ATM as defined by the <u>National Standard</u> <u>Operating Procedures for Clinical Trials, including Teletrials, in Australia</u> (i.e. have a Primary Site with linked Satellite Sites operating under a Supervision Plan)
- have a Primary <u>or</u> Satellite site located in the Northern Territory, Queensland, South Australia, Tasmania, Victoria or Western Australia
- have Satellite Sites with at least one participant enrolled whose home postcode is classed as an <u>MM2 – MM7 category</u>**
- have ethics and governance approval
- be aligned with the purpose, aims, and scope of the Commonwealth Standard Grant Agreement MRFRR000005
- not be funded or supported for the same activity by other recipients under this MRFF grant round (see definition on page 3).

**MM2 – MM7 categories are classified at: <u>https://www.health.gov.au/health-topics/health-workforce/health-workforce-classifications/modified-monash-model</u> using the Health Workforce Locator tool at <u>https://www.health.gov.au/resources/apps-and-tools/health-workforce-locator</u>

Ineligibility criteria for Teletrial Support Program funding

- Clinical trials that are not conducted under the Australian Teletrial Model (ATM) (e.g., multi-site trials without Satellite Sites)
- Trial activities conducted by an entity funded under this same MRFF grant
- Phase IV post-marketing surveillance trials
- Registry studies
- Observational or retrospective research studies

How to Register for Teletrial Support Program Funding

Eligibility for funding will be recommended by each relevant RCCC based on these guidelines and information provided in the ATP database. TSP grants will be paid to eligible sites following processes negotiated with their respective jurisdictional RCCCs.

Contact your RCCC to confirm eligibility:

<u>ATP-NT@nt.gov.au</u>
<u>QRCCC@health.qld.gov.au</u>
ATP-SA@sa.gov.au
<u>ATP-TAS@health.tas.gov.au</u>
<u>rccc@health.vic.gov.au</u>
WARCCC@health.wa.gov.au

Teletrial Support Program Guidelines ver 27 May 2024









Australian Teletrial Program



Conditions of Funding

- TSP grants are to support the conduct of Teletrials at the primary site or satellite site that is, to assist primary sites in the management of a Teletrial cluster or to facilitate review of trial participants at Satellite Sites. TSP funds cannot be used for other purposes (e.g., conference attendance) not relating to conducting clinical trials or Teletrials.
- A TSP applicant operating as a beneficiary of another grant awarded under the same MRFF grant round (that is Medical Research Future Fund National Critical Infrastructure Initiative 2019 Rural, Regional and Remote Clinical Trial Enabling Infrastructure Grant) must demonstrate that any claim for payments has not already been funded.

For example: the TSP cluster management fee payable to a Primary Site conducting a Teletrial cannot be paid if that Primary Site's activities are supported by the same MRFF grant awarded to a different recipient (see notes below).

- Each grant recipient is subject to the conditions of the original grant opportunity guidelines, including eligible and ineligible expenditure.
- Funded sites/entities must
 - register Teletrial details in the ATP database (via their local RCCC) and agree to the ongoing entry of information into the ATP database as required, for the purposes of evaluation of the Australian Teletrial Model, Commonwealth reporting, and tracking TSP payments
 - if/when requested, demonstrate that they have not received funding from the MRFF for similar activity (that is, increasing access to clinical trials for people in regional, rural, or remote locations).

Notes:

- All Primary Sites including those in metropolitan areas of **partner jurisdictions** are eligible for TSP consideration:
 - A Satellite Site located in NSW or the ACT and reporting to a Primary Site in an ATP jurisdiction may contribute to the eligibility of the Primary Site to receive funding.
 - A Primary Site in NSW or the ACT running a Teletrial with Satellite Sites in an ATP jurisdiction is not eligible for TSP funding, but the Satellite Site may be eligible if funding criteria is met.
- The same costs must not be funded multiple times.
- Clinical trial or Teletrial activity included in any grant recipient's reporting cannot also be included in the reporting of any other grant recipient.

Effective Dates

These guidelines are effective from 09 November 2023 until 04 October 2026, unless revised earlier. These guidelines apply to all Teletrials that have commenced or will commence between 01 April 2023 and 04 October 2026.

Retrospective payments are available for eligible sites that have recruited participants with a home postcode in an MM2 location from 01 October 2021.

Further Information

For further information and support for Teletrials in Victoria, please contact <u>RCCC-VIC</u> <u>rccc@safercare.vic.gov.au</u>

Teletrial Support Program Guidelines ver 27 May 2024











