

ATP-VIC Supplementary Information

ATP Teletrial Support Program (TSP)

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Introduction

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

The initiative aims to improve access to and participation in clinical trials for rural, regional and remote Australians. The ATP implements a scaled-up version of the Australian Teletrial Model to facilitate and expand clinical trial activity across Australia, enabling residents to access trials with reduced travel and closer to home.

Teletrial Support Program

The Teletrial Support Program (TSP) aims to support sites to participate in the ATP and provides funding to Principal Investigators and Associate Investigators (at satellite sites) to accelerate the expansion of clinical trials to rural, regional and remote patients.

The objectives of the TSP are to:

- Support clinical trial sites to expand their clinical trial activity by implementing teletrials across rural, regional and remote Victoria.
- 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.

Program structure

Teletrial Support Program Guidelines are applicable to all teletrials (guideline version 09 November 2023)

Payments are available for eligible sites that have recruited participants with a home postcode in an MM2 location from 01 October 2021 to the end of the ATP program.

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There are two levels of funding under the TSP:

Primary Site Teletrial Cluster Management Grant*

Funding of up to \$10,000 (GST exclusive) for a trial protocol.

Enable Principal Investigators to re-invest in clinical trials that have associated teletrial/s at eligible Satellite Site/s

Payments made as follows:
\$5,000 when an eligible participant is enrolled at one satellite site
\$5,000 when an eligible participant is enrolled at another Satellite Site

Satellite Site Per Participant Grant*

Funding of \$700 per participant/per year up to 2 years (GST exclusive)

Enable ongoing Satellite Site participation in the teletrial and support Associate Investigators

Payments made as follows:
\$700 per eligible participant (with a home postcode of MM2 and above) is enrolled at Satellite Site

**Eligibility criteria applies*

TSP eligibility process

A Satellite Site Associate Investigator conducts a teletrial under the supervision of a Principal Investigator. The Principal Investigator and the Associate Investigator have the responsibility of enrolling participants for the clinical trial. Participants whose home postcode is from an area classified as [MM2-7](#) will be eligible for payment. Payments are available at the Primary Site and at the Satellite Site (Refer to [Appendix A](#) for an example of TSP grant payment).

If an eligible participant is recruited at the Satellite Site a payment will be made to the Primary Site and the Primary Site is then responsible for providing payment to the Satellite Site.

Research agreements

Schedule 2 of the [Medicines Australia Clinical Trial Research Agreement](#) (Head Agreement) between the Sponsor and the Primary Site should include payment amounts, invoicing, and terms and conditions regarding the Satellite Site(s).

Schedule 2 of the teletrial Subcontract between the Primary Site and Satellite Site should include payment information indicating that costing per eligible participant is \$700 for the Satellite Site and is uncapped.

Eligibility criteria for funding

In addition to the criteria in the table below, an eligible teletrial must:

- be registered in the ATP database.
- not be funded or supported for the same activity by other recipients under this MRFF grant round**.

** Refer to *Teletrial Support Program Guidelines policy document*

Teletrial Cluster Management Payment	Satellite Site Teletrial Per Participant Payment
<p>A teletrial is defined by the Commonwealth's National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia Teletrial sites must meet the following criteria to be eligible for the payment</p>	
<p>The Primary Site must fulfill the following criteria:</p> <ul style="list-style-type: none"> • a Principal Investigator at a Primary Site located in Queensland, Victoria, Tasmania, South Australia, Western Australia or the Northern Territory that is registered under the ATP; • be a public or private hospital, day procedure service, public dental practice or University based clinical service provider, and accredited to the National Safety and Quality Health Service (NSQHS) Standards or be an accredited General Practice; • be undertaking Phase I, Phase II or Phase III (or equivalent for devices and biologicals), or other interventional clinical trials (excluding Phase IV post-marketing surveillance trials or registry studies); and • have Satellite Sites with at least one participant enrolled whose home postcode is located in an MM 2-7 category***. • <i>Note: A Satellite Site located in NSW or ACT and reporting to a Primary Site in Victoria, is not eligible to receiving funding through the TSP. If Satellite Site participant lives in an eligible postcode it may contribute towards the Primary Site eligibility for a TSP grant.</i> 	<p>The Satellite Site must fulfill the following criteria:</p> <ul style="list-style-type: none"> • an Associate Investigator at a Satellite Site in Queensland, Victoria, Tasmania, South Australia, Western Australia or the Northern Territory that is registered under the ATP, and also linked to a Primary Site; • be a public or private hospital, day procedure service or public dental practice accredited to the National Safety and Quality Health Service (NSQHS) Standards or be an accredited General Practice; • be delivering an eligible teletrial under the supervision of a Primary Site; and • have enrolled participant/s whose home postcode is located in an MM 2-7 category*. • <i>Note: A Primary Site in NSW or the ACT running a teletrial with Satellite Sites in Victoria is not eligible for TSP funding, but the Satellite Site may be eligible if funding criteria is met.</i>

***MM 2-7 categories are classified and use the [Health Workforce Locator](#) tool to find any MM category for a postcode of a patient.

Eligibility assessment and payment of funding to Victorian Health Services (VIC Only)

Funding Process:

- The Primary Site contacts the ATP-VIC RCCC at rccc@safercare.vic.gov.au and RCCC-VIC provides a [teletrial registration form](#)
- The ATP-VIC RCCC will facilitate entry of data into ATP database (REDCap information)
- The ATP-VIC RCCC will then assess the eligibility for payment to the Primary Site
- All teletrials conducted in Victoria will be considered for TSP payment.
- Eligibility requires the home postcode of Satellite Site participants; therefore, this information must be provided (note: postcode details are required to determine the MMM category of the Satellite Site participant. Postcode information will not be reported. Only MMM categories will be used for reporting purposes).
- Primary Site will facilitate payments to the Satellite Site(s).

Payment of funding for interstate teletrials

- Scenario 1: A teletrial where a Victorian health service is the Primary Site and Satellite Sites are located in other jurisdictions ATP-VIC RCCC will pay the **Primary Site** payment to the Victorian health service.
- Scenario 2: A teletrial where another jurisdiction is the Primary Site and a Victorian health service is a Satellite Site, ATP-VIC RCCC will pay the **Satellite Site** payment to the Victorian health service.

Use of funding

TSP payments are to support the conduct of teletrials in Victoria. TSP funds cannot be used for purposes other than the support of clinical trial activity.

Data in the ATP database is used for reporting purposes and to track TSP payments for eligible activity.

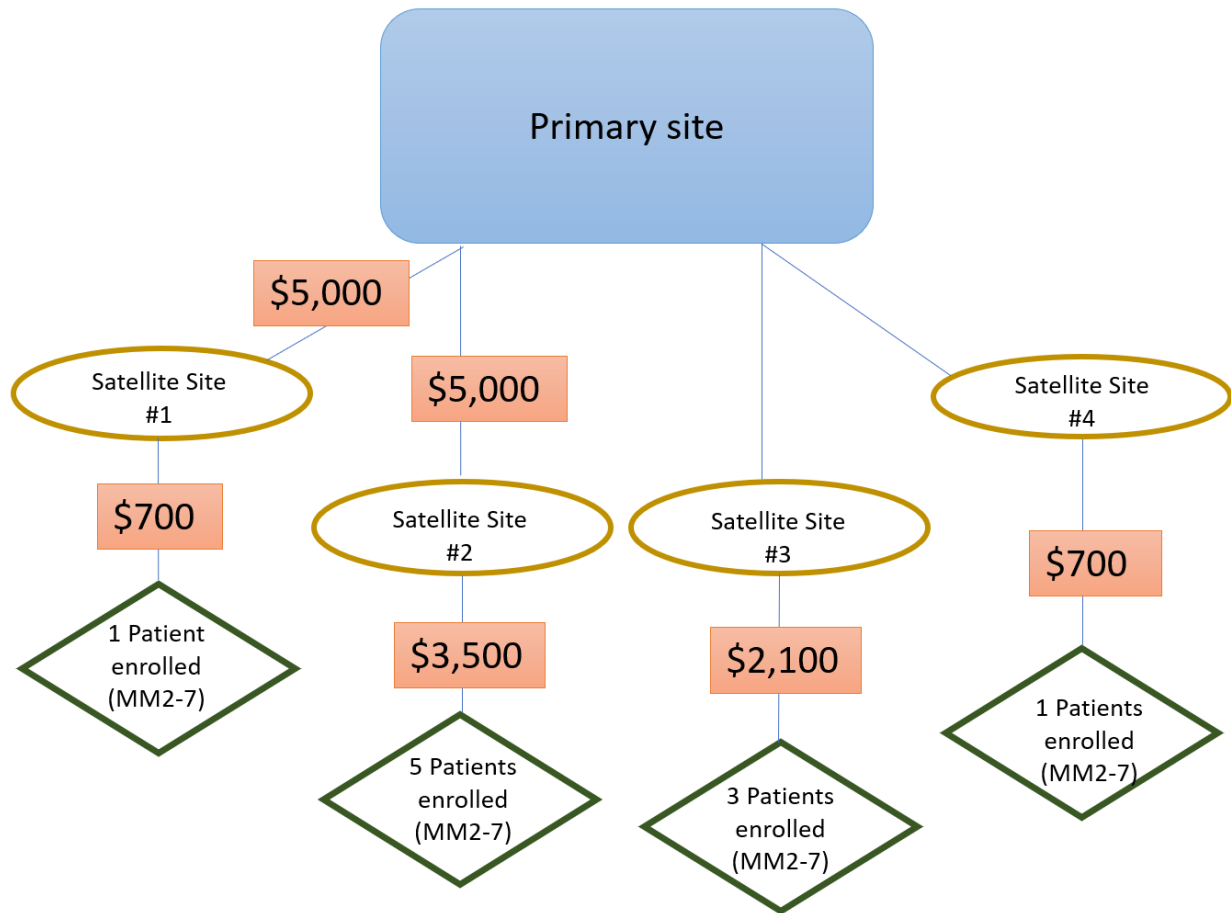
How to register a trial

How to register a teletrial under the ATP teletrial model.

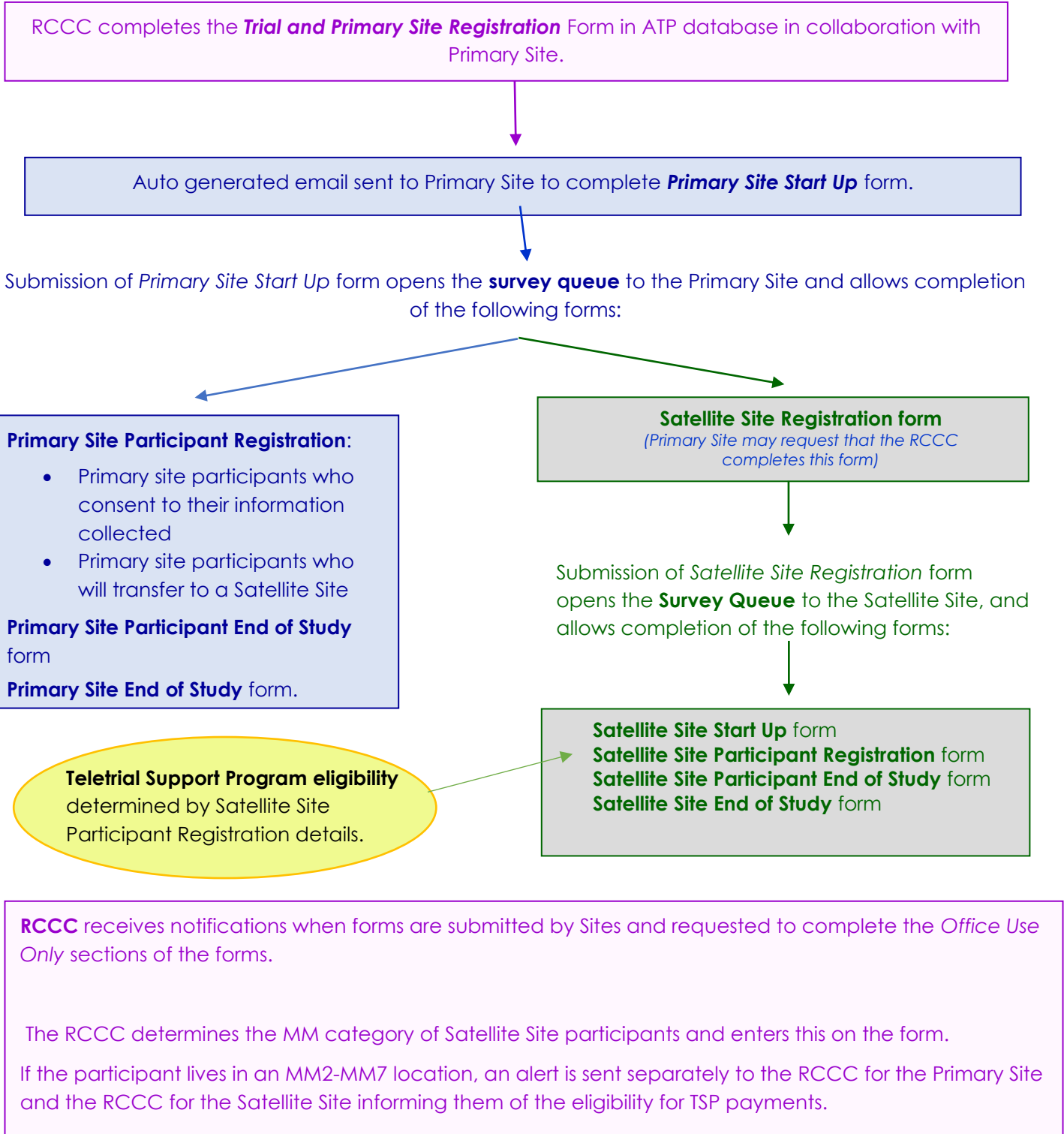
There are two pathways:

1. Victorian regional hubs with user access to the ATP database can register a teletrial by following the workflow outlined in [Appendix B](#)
*For further REDCap guidance on registering a teletrial, please refer to page 4 of the **REDCap TSP Process Summary** document.*
2. All other teletrials can be registered into the ATP database by contacting RCCC-VIC at rccc@safercare.vic.gov.au. Primary Site will receive a Teletrial Registration Form from RCCC-VIC (Refer to [Appendix C](#)).

Appendix A – Example of Primary Site and Satellite Site TSP grant payment



Appendix B – Teletrial Support Program Flow Chart



Reminders and alerts for sites and RCCCs are generated at different times during the recording of teletrial activity in the ATP database, depending on the activity that is due, and dates entered by sites. For example, if a participant's involvement is for longer than 12 months, the date of consent is requested. An alert for the Satellite Site and the Satellite Site's RCCC is generated 56 weeks after the consent date – informing them that the site may be due for a Year 2 TSP payment.

Appendix C – Teletrial Registration Form

This **Teletrial Registration Form** is to be completed as a separate WORD document and can be found under the Teletrials Support Program section in the Clinical Trials and Research [Teletrials tile](#).

Please email the completed form to RCCC-VIC at rccc@safercare.vic.gov.au

This ATP-VIC Supplementary Information document has been developed according to the ATP *Teletrial Support Program Guidelines* (November 2023).

To receive this document in another format, phone 0499 810 778, using the National Relay Service 13 36 77 if required, or [email Regional Clinical trial Coordinating Centre \(RCCC-VIC\)](#) <rccc@safercare.vic.gov.au>.

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