## **ATP-VIC Supplementary Information**

## **ATP Teletrial Support Program (TSP)**

#### **OFFICIAL**

#### Introduction

The <u>Australian Teletrial Program</u> (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 MM2-7 location from 01 October 2021 to the end of the ATP program.

There are two categories of funding under the TSP:

# Primary Site Teletrial Cluster Management Grant\*

Funding of <u>up to</u> \$10,000 (GST exclusive) for a teletrial protocol.

Enable Principal Investigators to reinvest 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 <u>another</u> Satellite Site

\*Eligibility criteria applies

# 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 MM2-7) is enrolled at Satellite Site

### 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 teletrial. Participants whose home postcode is from an area classified as <a href="MM2-7">MM2-7</a> will be eligible for payment. Payments are available at the Primary Site and at the Satellite Site (Refer to <a href="Appendix A">Appendix A</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 for first year participant payments. Satellite Sites with eligible second year payments will be paid directly by ATP-VIC RCCC.

#### Research agreements

Schedule 2 of the <u>Medicines Australia Clinical Trial Research Agreement</u> (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 per year with a maximum of 2 payments (\$1400 total) per participant.

#### 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\*\*.

#### **Teletrial Cluster Management Payment**

Satellite Site Teletrial Per Participant Payment

A teletrial is defined by the Commonwealth's <u>National Standard Operating Procedures for Clinical</u> Trials, including Teletrials, in Australia

Teletrial sites must meet the following criteria to be eligible for the payment

The Primary Site must fulfill the following criteria:

- 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 postmarketing 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\*\*\*.
- Note: A Satellite Site located in NSW or ACT and reporting to a Primary Site in Victoria, is not eligible to receive 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.

The Satellite Site must fulfill the following criteria:

- 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\*.
- 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.

\*\*\*MM 2-7 categories are classified and use the <u>Health Workforce Locator</u> tool to find any MM category for a postcode of a patient.

<sup>\*\*</sup> Refer to Teletrial Support Program Guidelines policy document

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

#### **Funding Process:**

- The Primary Site contacts the ATP-VIC RCCC at <u>rccc@safercare.vic.gov.au</u> and ATP-VIC RCCC provides a <u>teletrial registration form</u>
- The ATP-VIC RCCC will facilitate entry of data into ATP database (REDCap)
- All teletrials conducted in Victoria will be considered for TSP payment.
- Eligibility requires the home postcode of Satellite Site participants and this information must be provided (note: postcode details are required to determine the MMM category only and not used for reporting. Only MMM categories are used for reporting).
- The ATP-VIC RCCC will assess eligibility for payments.
- The ATP-VIC RCCC will facilitate payments to the Primary Site via MAPS.
- The Primary Site will facilitate payments to the Satellite Site(s) for eligible first year participants.
- The ATP-VIC RCCC will facilitate payments to Satellite Sites via MAPS for eligible second year participants.

#### Payment of funding for interstate teletrials

- Scenario 1: A teletrial where a Victorin health service is the Primary Site and Satellite Sites are located in other jurisdictions ATP-VIC RCCC will pay only 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 only 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.

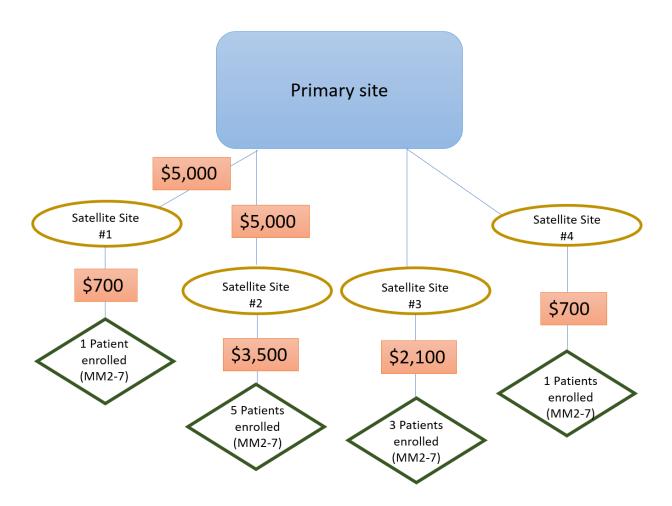
#### How to register a trial

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.
- All other teletrials can be registered into the ATP database by contacting ATP-VIC RCCC at <u>rccc@safercare.vic.gov.au</u>. Primary Site will receive a Teletrial Registration Form from ATP-VIC RCCC (Refer to <u>Appendix C</u>).

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



### Appendix B - Teletrial Support Program Flow Chart

ATP-VIC RCCC completes the **Trial and Primary Site Registration** Form in ATP database in collaboration with Primary Site. Auto generated email sent to Primary Site to complete Primary Site Start Up form. Submission of Primary Site Start Up form opens the survey queue to the Primary Site and allows completion of the following forms: Satellite Site Registration form **Primary Site Participant Registration:** (Primary Site may request that the ATP-VIC RCCC completes this form) Primary site participants who consent to their information collected Primary site participants who Submission of Satellite Site Registration form will transfer to a Satellite Site opens the Survey Queue to the Satellite Site, and **Primary Site Participant End of Study** allows completion of the following forms: form Primary Site End of Study form. **Satellite Site Start Up** form **Satellite Site Participant Registration** form **Teletrial Support Program eligibility** Satellite Site Participant End of Study form determined by Satellite Site Satellite Site End of Study form Participant Registration details.

**ATP-VIC RCCC** receives notifications when forms are submitted by Sites and requested to complete the Office Use Only sections of the forms.

The RCCC determines the MM category of Satellite Site participants and enters this on the form.

If the participant lives in an MM2-MM7 location, an alert is sent separately to the RCCC for the Primary Site and the ATP-VIC RCCC for the Satellite Site informing them of the eligibility for TSP payments.

Reminders and alerts for sites and ATP-VIC 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 ATP-VIC RCCC 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) <rcc@safercare.vic.gov.au>. Authorised and published by the Victorian Government, 1 Treasury Place, Melbourne.

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