



ATP-VIC Supplementary Information

ATP Teletrial Support Program (TSP) Addendum

OFFICIAL

Introduction

The Australian Teletrial Program (ATP) aims to improve access and participation in clinical trials for Australians living in rural, regional and remote (RRR) communities. The Teletrial Support Program (TSP) provides funding to sites conducting teletrials where eligibility criteria are met to support cluster formation and site development. Information about the TSP program in Victoria can be found [here](#).

This document is an addendum to the **ATP-VIC Supplementary Information**

Registry-Based Studies Expansion

Eligible non-interventional registry-based studies, conducted using the teletrial methodology in Victoria, **may** qualify under certain circumstances for a **Start-Up Support Package**. This **Victorian only** initiative is intended to support workforce development, build research infrastructure, promote collaboration and networking between sites and foster the creation of interconnected clusters, ensuring they are well-prepared for future teletrials. This expansion is only for registry-based studies and **does not** extend to observational studies.

Registry-Based Studies -Startup Support Package - Eligibility Criteria

An eligible **registry-based study** must:

- be a registry-based study as defined by [International Scientific Guideline- European Medicines Agency on registry-based studies](#), adopted by the Therapeutic Goods Administration - *an investigation of a research question using the data collection infrastructure or patient population of one or several patient registries*
- be conducted in accordance with the teletrial methodology (i.e. have a Primary Site with linked Satellite Sites operating as a cluster under an approved Supervision Plan)
- have both Primary and Satellite site/s located in Victoria.
- have Satellite Sites located in MM2-7 category
- 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
- open to recruitment on or after October 2021 and before 06 October 2026.
- be recorded in ATP REDCap database.
- Demonstrate capacity and capability building at satellite sites (Refer to [Registry-Based Studies- Assessment](#))

Registry-Based Studies- Assessment

Both Primary Site and Satellite Site investigators or delegates should complete the **Registry Based Studies- Assessment Form** (Refer to [Appendix B](#)) and provide justification for each of the below items:

1. How participation in the registry-based study will **expand research** into therapeutic area/s with limited or no prior research/clinical trial activities at the site.
2. How participation in the registry-based study will provide ongoing **training and mentorship** to support **new** investigators and **new** clinical trial site staff in conducting research/clinical trial activities at the Satellite Site.
 - a. Please include how essential research skills at the site will be developed including:
 - i. informed consent
 - ii. data collection and/or management
 - iii. research coordination
 - iv. regulatory and ethics compliance.
3. How the registry-based study will **strengthen relationships** between the Primary Site, Satellite Site/s and the Sponsor to foster collaboration and create opportunities for future teletrial participation.
4. If participation in the registry-based study will see the Satellite Site adopting new and emerging **health technologies** to enhance research/clinical trial capabilities locally.

Registry-Based Studies- Startup Support Package- Funding

This initiative provides financial support to Primary and Satellite Sites engaged in **registry-based studies conducted under the teletrial methodology in Victoria**. The funding is structured to cover initial costs related to trial setup and to facilitate participant recruitment. Once the allocated funding amount is exhausted no further funding will be available.

Primary Sites (working in a cluster with up to three Satellite Sites per protocol)

Funding of \$2,500 (GST exclusive) is available to a Primary Site per protocol for each new Satellite Site up to a maximum of three where the below criteria are met:

- \$1,500 payment upon completing **startup activities and study initiation** (demonstrate **Startup Activities and Site Initiation** by providing an email from the Research Governance Office (RGO) to RCCC-VIC (rccc@safercare.vic.gov.au) confirming site authorisation and study commencement) at one Satellite Site.
- \$1,000 payment when the minimum recruitment target (as defined on the [Clinical Trial Research Agreement](#) (CTRA)) is achieved at the Satellite Site.

The above payments are available when the Primary Site adds a **second** and **third** eligible Satellite Site for the same protocol. Maximum payment available to the Primary Site for a cluster of three Satellite Sites is: \$7,500

Satellite Sites (up to three Satellite Sites working with a Primary Site in a Cluster per protocol)

Funding of \$5,000 (GST exclusive) per protocol for each Satellite Site is available where the below criteria are met:

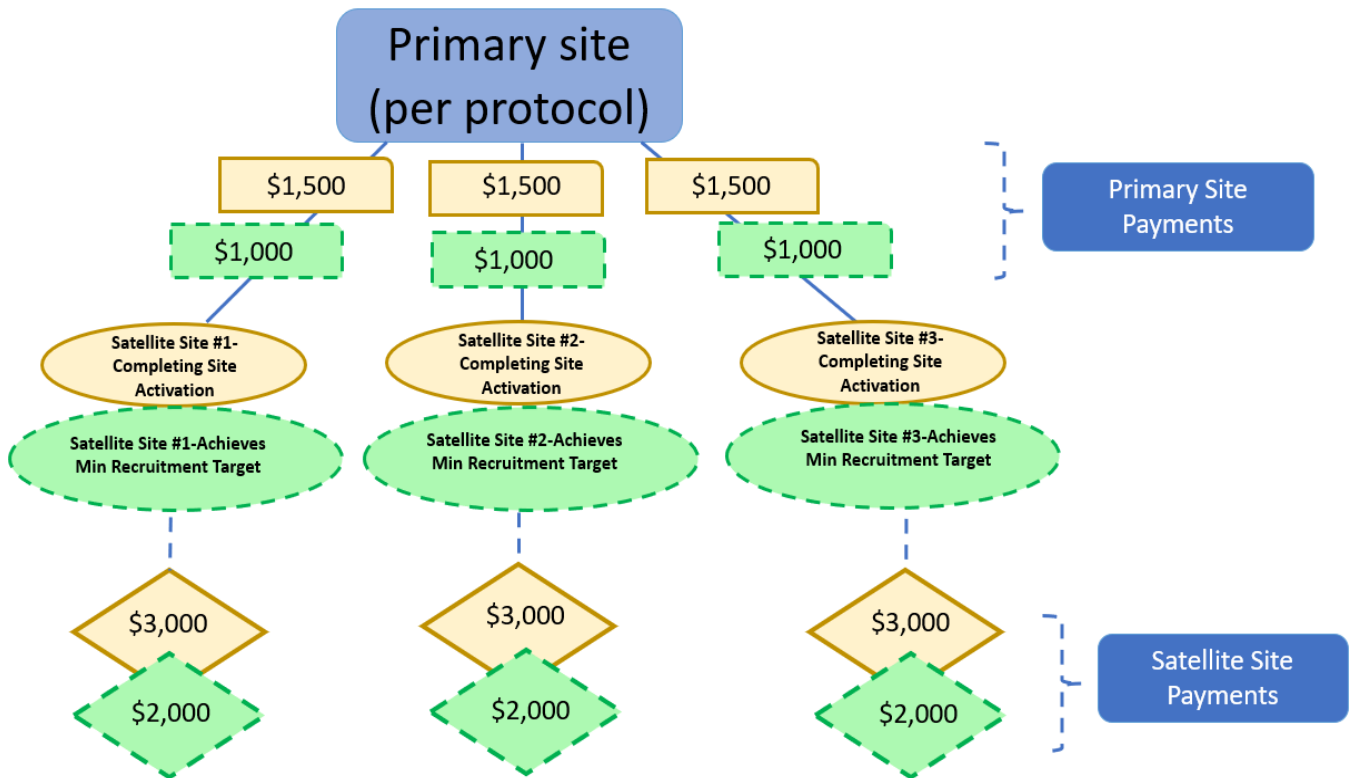
- \$3,000 payment upon completing **startup activities and study activation** (demonstrate **Startup Activities and Site Initiation** by providing an email from the Research Governance Office (RGO) to RCCC-VIC (rccc@safercare.vic.gov.au) confirming site authorisation and study commencement) at the Satellite Site.
- \$2,000 payment when minimum recruitment target (as defined on the CTRA) is achieved at the Satellite Site.

Maximum payment available per Satellite Site is \$5,000 and per cluster \$15,000 per protocol.

Note: Where minimum recruitment targets are not achieved at the Satellite Site, Primary Site and Satellite Site is not eligible for the related payment of \$1000 and \$2000 respectively.

The total amount available under this expansion program for a cluster of one Primary Site and up to three Satellite Site(s) is \$22,500.

Registry-Based Studies Startup Support Package - Primary Site and Satellite Site Payment Structure



Eligibility assessment and payment to Victorian Health Services

Funding Process:

- The Primary Site contacts the ATP-VIC RCCC at rccc@safercare.vic.gov.au and RCCC-VIC provides a [teletrial registration form](#) (alternatively, refer to [Appendix A](#) to access registration form)
- The ATP-VIC RCCC will facilitate entry of data into ATP database (REDCap information)
- The ATP-VIC RCCC will assess the eligibility for payment to the Primary Site and Satellite Site ([Refer to Registry-Based Studies Startup Support Package-Eligibility Criteria](#))

Primary Payment

- Upon eligibility confirmation, ATP-VIC RCCC will request an invoice from the Primary Site
- ATP-VIC RCCC will facilitate **Primary Site Payment** to the Primary Site via MAPS

Satellite Site Payment

- Upon eligibility confirmation, ATP-VIC RCCC will request an invoice from the Satellite Site
- ATP-VIC RCCC will facilitate **Satellite Site Payment** to the Satellite Site via MAPS

Appendix A- 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

Appendix B – Registry-Based Studies- Assessment Form

This **Registry Based Studies-Assessment 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@safecare.vic.gov.au

* This form has been adapted from the ATP-VIC Supplementary Information Australian Teletrial Program

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 \(RCCC-VIC\)](mailto:rccc@safecare.vic.gov.au) <rccc@safecare.vic.gov.au>.

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