



ATP-VIC Supplementary Information

ATP Teletrial Support Program (TSP) including the ATP-VIC Startup Package Initiative

OFFICIAL

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 (ATM) 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 Primary Sites and Satellite Sites to build capacity and capability and 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.

Teletrial Support Program- Program Areas

To fulfil the objectives of the TSP, two program areas have been identified, [TSP- Program 1- Startup Package Initiative](#) and [TSP Program 2- Recruitment Boosting Support](#). Both programs support Primary and Satellite Sites to achieve the objectives of the ATP including expanding the reach of clinical trials to rural regional and remote patients in Victoria and closing the gap in health outcomes for all Victorians.

Program Eligibility

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

To be considered for either *TSP Program 1- Startup Package Initiative* or *TSP Program 2- Recruitment Boosting Tool* the following eligibility criteria must be fulfilled:

- be a clinical trial* as defined by WHO - a research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes
- be conducted in accordance with the Australian Teletrial Model (ATM) as defined by the National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia (i.e. have a Primary Site with linked Satellite Sites operating under a Supervision Plan.
- have a Primary or Satellite site located in Victoria, Northern Territory, Queensland, South Australia, Tasmania or Western Australia
- have Satellite Sites with at least one participant enrolled whose home postcode is classed as an MM2 – MM7 category**
- be registered in the ATP REDCap database (refer to [How to register a trial](#) and [Appendix D](#))
- have ethics and governance approval as required for a teletrial
- be aligned with the purpose, aims, and scope of the Commonwealth Standard Grant Agreement MRFRR000005

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.

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.

Satellite Sites within Victoria that recruit participants with a postcode that is associated with a different state, TSP payment will be made to the Victorian Satellite Site contingent on the postcode falling within the MM2-7 category.

* Registry Studies may be eligible to receive funding (eligibility criteria apply)-**Refer to document: ATP-VIC Supplementary Information-Addendum**

**[MM2-7 categories are classified](#). Use the [Health Workforce Locator](#) tool to find any MM category for a postcode of a participant.

Program structure

TSP Program 1- Startup Package Initiative

To support Satellite Sites in Victoria (located in MM2-7) to establish teletrials, the startup package initiative aims to provide financial support early in the teletrial lifecycle to help reduce the administrative burden and associated costs for sites.

Payments are available to eligible Satellite Sites upon fulfilling the eligibility criteria ([refer to Startup package eligibility criteria](#)) from 11-March 2025 until allocated funds for this initiative are expended or until 04 October 2026 whichever comes first.

Startup package funding

Two levels of funding will be provided to all Satellite Sites per protocol when each milestone outlined below is achieved during the establishment of a teletrial.



Startup package eligibility criteria (VIC Satellite Sites only)

Site Specific Assessment (SSA) Submission

The Satellite Site must fulfil the following criteria:

- Be located in an MM2-7 category
- Demonstrate teletrial **SSA Submission** by providing evidence of the submission (screenshot of submission page) including the ERM Project ID or Submission Number via email to Regional Clinical Trial Coordinating Centre Victoria (RCCC-VIC) (rccc@safercare.vi.gov.au).

Site Activation by Sponsor

The Satellite Site must fulfil the following criteria:

- Be located in an MM2-7 category
- Demonstrate **Site Activation** by providing an email to RCCC-VIC (rccc@safercare.vic.gov.au) with Letter of Activation by Sponsor.

Startup package payment process (VIC Satellite Sites only)

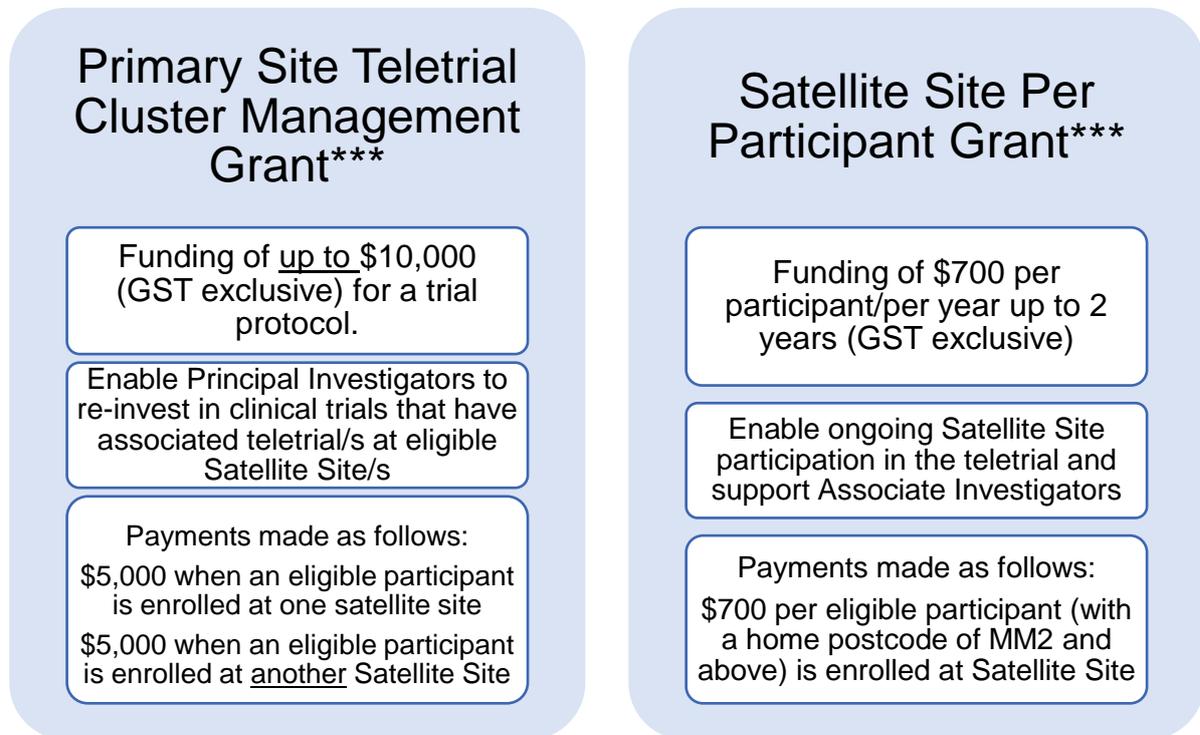
([Appendix A](#))

1. Upon eligibility confirmation, ATP-VIC RCCC will request an invoice from the Satellite Site.
2. ATP-VIC RCCC will facilitate payment to the Satellite Site via MAPS
3. Confirmation of payment and MAPS identifier will be communicated from RCCC-VIC via email to the Satellite Site upon completion of MAPS processing.

TSP Program 2- Recruitment Boosting Support

Payments are available for eligible Primary and Satellite Sites that have recruited participants with a home postcode in an MM2 to MM7 location from 01 October 2021 to the 04 October 2026 (Refer to [Appendix B](#) for an example of TSP grant payment).

There are two levels of funding under the TSP:



***Eligibility criteria applies

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](#) (alternatively, refer to [Appendix D](#) to access registration form)
- The ATP-VIC RCCC will facilitate entry of data into ATP REDCap database
- The ATP-VIC RCCC will then assess the eligibility for payment to the Primary Site and Satellite 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 MM category of the Satellite Site participant. Postcode information will not be reported. Only MM categories will be used for reporting purposes)

- **Primary Site Cluster Payment**

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

- **Satellite Site Per Participant Payment**

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

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.

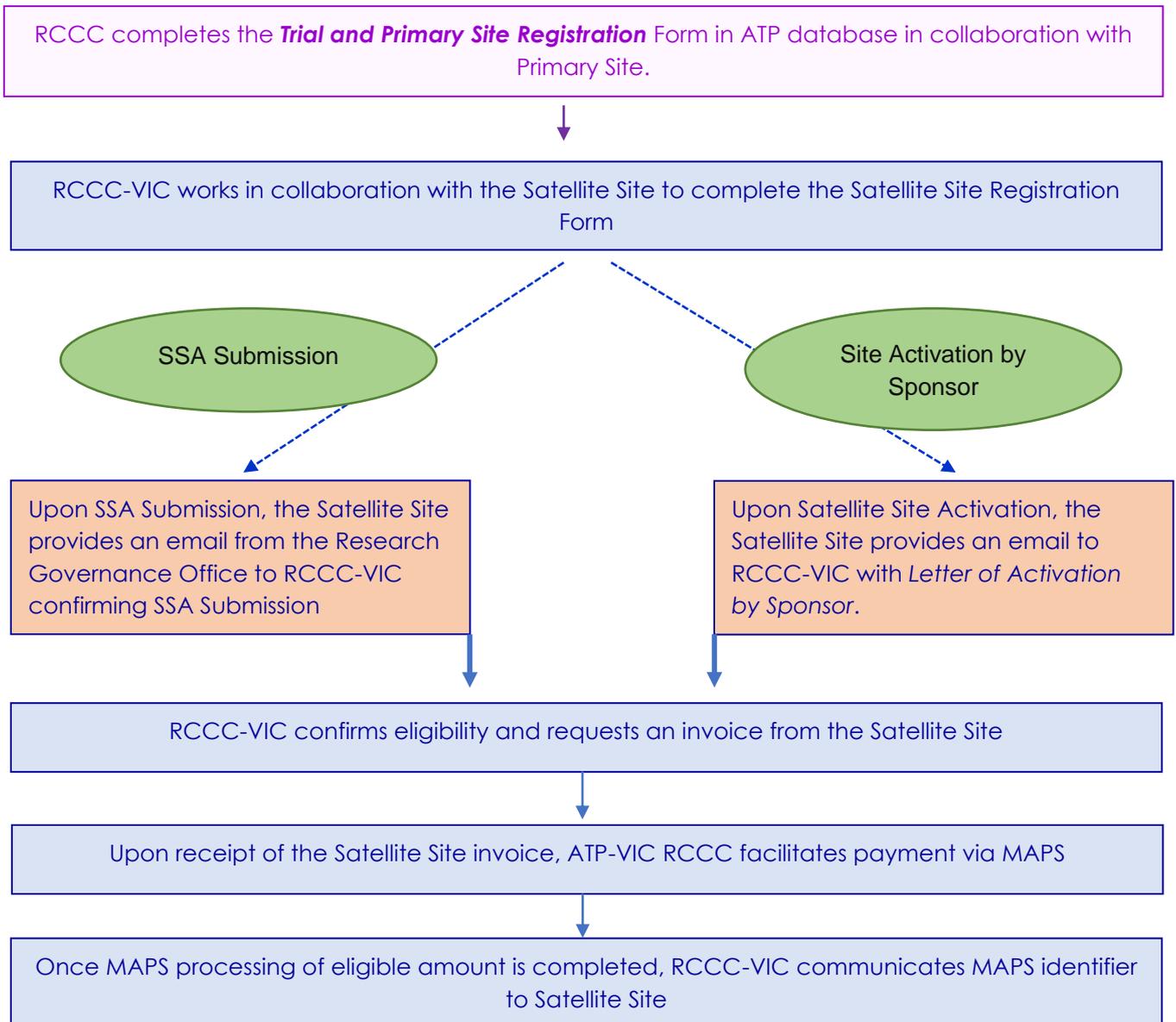
How to register a trial

How to register a teletrial under the ATP teletrial model.

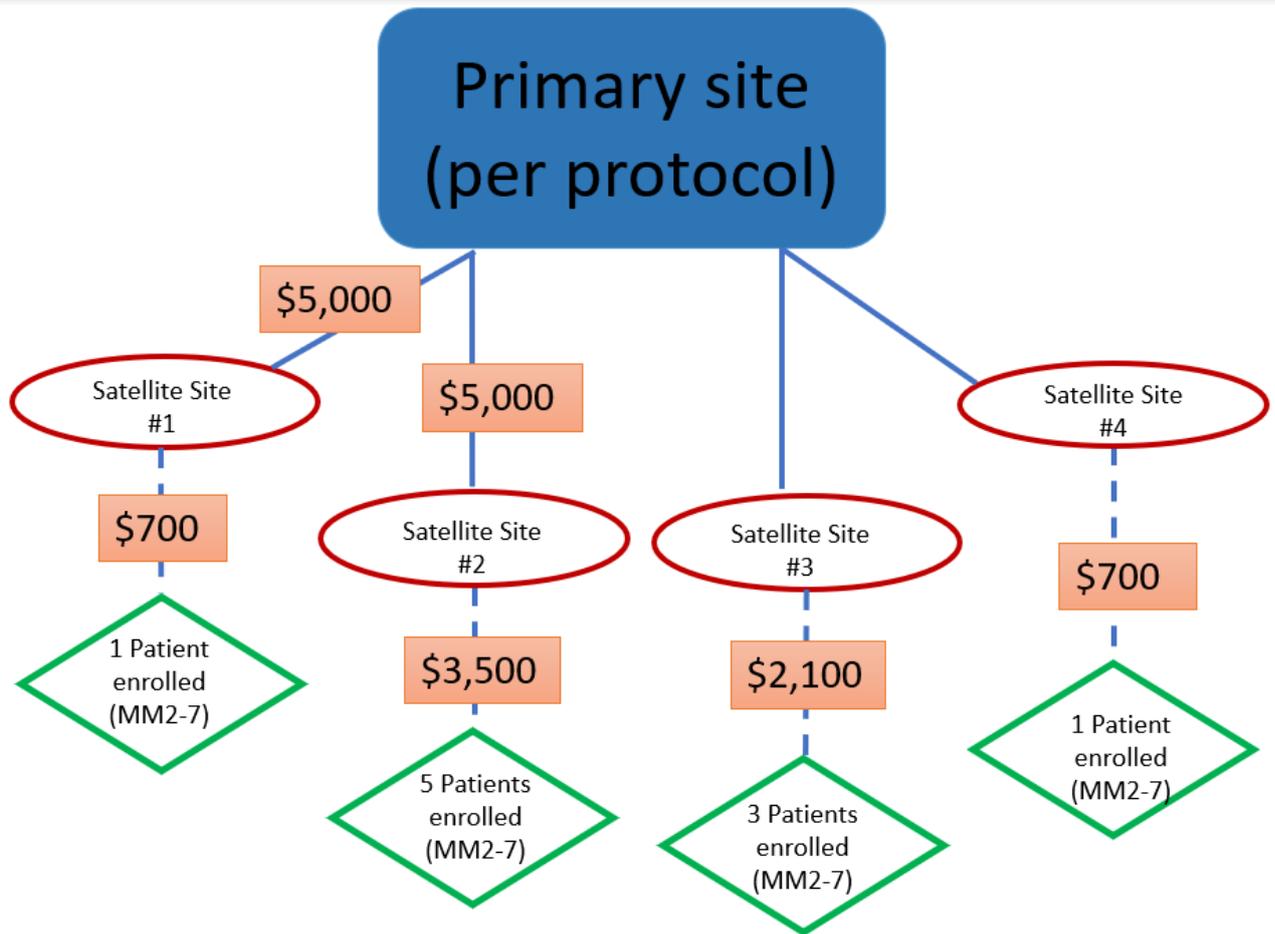
There are two pathways:

1. Victorian regional hubs with user access to the ATP database can register a teletrial by following the workflow outlined in [Appendix C](#).
*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 D](#)).

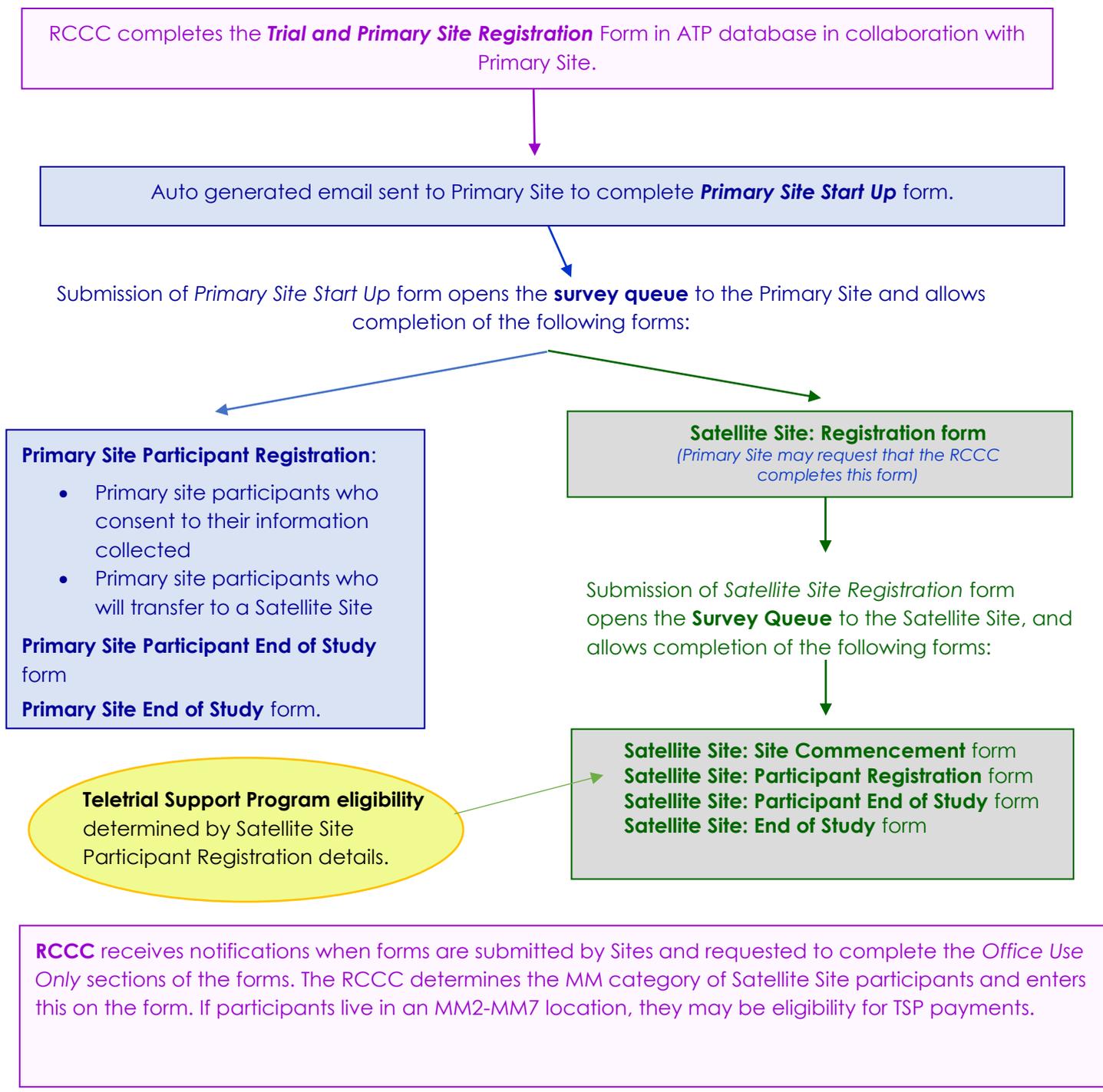
Appendix A- Program 1-Startup Package Initiative Flow Chart



Appendix B – Example of Primary Site and Satellite Site TSP grant payment (Program 2 Payments)



Appendix C – Program 2-Teletrial Support Program Flow Chart-REDCap Registration



Appendix D – 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

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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